

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

BAUSCH HEALTH IRELAND
LIMITED, et al.,

Plaintiff,
v.

PADAGIS ISRAEL
PHARMACEUTICALS LTD, et al.,

Defendant.

CIVIL ACTION NUMBER:

2:20-cv-05426

BENCH TRIAL (VOLUME I)

Pages 1 - 268

Frank Lautenberg Post Office & U.S. Courthouse
2 Federal Square
Newark, New Jersey 07102
Tuesday, October 4, 2022
Commencing at 9:23 a.m.

B E F O R E:

**THE HONORABLE STANLEY R. CHESLER,
UNITED STATES DISTRICT JUDGE**

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Proceedings recorded by stenographically;
transcript produced by computer-aided transcription.

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1 (PROCEEDINGS held in open court before **The Honorable**
2 **STANLEY R. CHESLER**, United States District Judge, at
3 9:23 a.m.)

4 THE COURT: Be seated, everybody. Good morning.

5 So, first of all, our rules with masks are your masks
6 are on unless you're talking.

7 Since I do want to hear you and since everybody else
8 wants to hear you, if you're actually talking, take your mask
9 off, make sure you talk into the mic. Okay?

10 I will try to do that also. Ms. Trivino tells me
11 when I'm not talking into the mic.

12 THE COURTROOM DEPUTY: This is *Bausch Health Ireland*
13 *Limited, et al., v. Padagis Israel Pharmaceuticals LTD, et*
14 *al.*, 20-5426.

15 Please enter appearances for the record.

16 MR. DENI: Your Honor, good morning.

17 This is William Deni from the Gibbons firm. And,
18 remotely, it's Jonathon Brugh Lower, also from the Gibbons
19 firm.

20 THE COURT: Good morning.

21 MR. STEINDLER: Good morning, Your Honor.

22 Thomas Steindler, McDermott Will & Emery, for the
23 plaintiffs.

24 I have with me April Weisbruch, my colleague, and my
25 colleague Chris Bruno, also from my firm.

1 At counsel table we have Thomas Savitsky, who is
2 in-house counsel -- one of the in-house counsels for Bausch.
3 I also have able assistance in the courtroom from Lisa Marth,
4 Emily Berry and Josh Splansky.

5 Good morning.

6 THE COURT: Good morning to all of you.

7 MS. CONFOY: Good morning, Your Honor.

8 THE COURT: Good morning.

9 MS. CONFOY: Karen Confoy from Fox Rothschild for the
10 defendants.

11 MS. PITZEL CRUZ: Good morning, Your Honor.

12 I'm Carol Pitzel Cruz of Knobbe Martens for the
13 defendants.

14 THE COURT REPORTER: I'm sorry. I can't hear you at
15 all.

16 MS. PITZEL CRUZ: Okay. I'll just start over.

17 THE COURT REPORTER: Thank you.

18 MS. PITZEL CRUZ: Hi. I am Carol Pitzel Cruz from
19 Knobbe Martens, and I'm represent the Padagis defendants.

20 And with me I have my colleagues Bill Zimmerman,
21 Andrea Cheek and, remotely, also Brian Barnes.

22 We also have our in-house counsel Landon Clark with
23 us and our paralegal, Claire Stoneman.

24 Thank you.

25 THE COURT: Good morning.

1 All right. Now, there were issues about what would
2 be sealed?

3 MR. ZIMMERMAN: Your Honor, Bill Zimmerman of Knobbe
4 Martens.

5 Plaintiffs had requested that one slide of the
6 opening that the defendants will present which contains
7 information about sales be redacted.

8 Our proposal is that we give Your Honor the
9 unredacted version and we refer to it but put a redacted
10 version on the screen so that the public can't see it.

11 THE COURT: And what year are those sales figures
12 from?

13 MR. ZIMMERMAN: I will leave that to the plaintiff.

14 MR. STEINDLER: They are actual sales figures. They
15 are Bausch's confidential internal sales figures that are not
16 public. They are the one thing that we've got confidentiality
17 issues with respect to.

18 And Mr. Zimmerman and I had proposed and worked this
19 out and proposed this as a solution so that you can see them
20 but the public need not see them, and we don't have to worry
21 about sealing issues today.

22 THE COURT: Okay. We will do it that way.

23 I caution you that if this gets up to the Circuit,
24 the Circuit has become very antsy about sealed submissions.

25 MR. STEINDLER: Understood, Your Honor. This is

1 nobody's first rodeo here. We get that.

2 It's the one thing -- these are the only things that
3 we're concerned about on the Bausch side of confidentiality.
4 As far as I know, there are no other confidential issues that
5 are likely to arise.

6 MR. ZIMMERMAN: And so, Your Honor, if it's
7 acceptable, we will hand up the unredacted version for you.

8 THE COURT: Fine.

9 And you have a designated timekeeper?

10 MR. STEINDLER: We both do, I believe.

11 THE COURT: Very good. Make sure you keep track of
12 the time.

13 MR. STEINDLER: We will do that, sir.

14 THE COURT: Okay.

15 And good morning.

16 THE COURT REPORTER: Good morning, Judge. Nice to
17 see you.

18 THE COURT: Good to see you.

19 All right.

20 THE COURTROOM DEPUTY: Start of the trial is 9:28.

21 MR. STEINDLER: I'm going to ask my colleague April
22 Weisbruch to present Bausch's opening statement.

23 THE COURT: Very good.

24 THE COURTROOM DEPUTY: Please state your name for the
25 record and spell your first and last name.

1 MS. WEISBRUCH: April Weisbruch.

2 THE COURTROOM DEPUTY: Thank you.

3 OPENING STATEMENT BY MS. WEISBRUCH:

4 And I'll just wait for my slides to come up.

5 Good morning, Your Honor, may it please the Court.

6 I'm April Weisbruch for the Bausch companies. This
7 is a Hatch-Waxman case about two remarkable discoveries made
8 by Bausch scientists and the real-world impact those
9 discoveries have made on the lives of patients suffering from
10 psoriasis.

11 Bausch's innovation led to two topical psoriasis
12 products, Bryhali® and Duobrii®. Defendants are seeking to
13 make generic versions of both.

14 Defendants have stipulated to infringement of all
15 asserted claims, so the only issue in this trial is validity.

16 Bausch's products are used to treat psoriasis. And
17 as the Court can see from these pictures, psoriasis is a nasty
18 disease.

19 It has painful symptoms. It is stubborn, and it
20 comes back over and over and over again. Psoriasis has
21 devastating effects on every aspect of a patient's well-being.

22 Because this disease is so persistent, when
23 dermatologists prescribe topical medications for their
24 patients, they have to bring out the big guns. And in topical
25 treatments, the big guns are called superpotent

1 corticosteroids. These are the standard of care for treating
2 psoriasis.

3 And dermatologists treating this nasty disease don't
4 want to use less potent drugs. They want to use more potent
5 drugs. They want to use the most potent weapons available to
6 them.

7 But these potent weapons also have to be safe.
8 Before Bausch's breakthroughs, all commercially available
9 superpotent corticosteroids contained concentrations of
10 0.05 percent or more.

11 One of those superpotent corticosteroids is called
12 halobetasol propionate. Sometimes just halobetasol, sometimes
13 "HP," for short.

14 The gold standard halobetasol treatment was a
15 0.05 percent concentration product called Ultravate®.

16 The evidence in this case will show there was a
17 safety problem with superpotent corticosteroids. The problem
18 was, these heavy-hitting drugs couldn't be used for more than
19 two weeks at a time.

20 And why not?

21 These topical products caused serious systemic side
22 effects, so much so that the FDA limits their use to two weeks
23 at a time.

24 We will hear from both sides' experts in this case
25 that this two-week limitation was a major problem for

1 psoriasis patients because for them, two weeks, it just
2 doesn't cut it. And this problem, it's existed for decades.

3 Ultravate® was approved in 1990. And for more than
4 20 years, psoriasis patients had to weigh the need to treat
5 their inflamed, scaly psoriatic skin using superpotent
6 corticosteroids against the risk of those serious systemic
7 side effects.

8 But Bausch solved the problem. Bausch developed a
9 unique formulation vehicle. And to do so, they bucked
10 conventional wisdom.

11 Conventional wisdom said that steroids should be
12 formulated to penetrate all the way through the skin layers
13 and go into the blood stream. And conventional wisdom said
14 that if you lowered the concentration, you would also decrease
15 the efficacy of the drug.

16 And when Bausch bucked this conventional wisdom, they
17 discovered a unique formulation vehicle that works by
18 delivering drug into the skin, not through the skin and into
19 the blood stream.

20 The magic of the vehicle that Bausch discovered is
21 that it allows for 80 percent less active ingredient when
22 compared to the previous commercially available products like
23 Ultravate®, but it is just as efficacious as those
24 higher-concentration products.

25 And Bausch's innovation had a real-world benefit to

1 psoriasis patients.

2 The Court will hear testimony that with this low
3 concentration of active ingredient formulated in this unique
4 vehicle, dermatologists can now prescribe a superpotent
5 halobetasol formulation to their patients for more than two
6 weeks.

7 But that benefit might never have been realized.
8 When Bausch told some of the best dermatologists in the world
9 that they were attempting to make a low-concentration
10 superpotent corticosteroid, those experts said Bausch was
11 crazy. Many skeptics said, This is never going to work.

12 In fact, when Bausch first discovered the results,
13 they reran the tests because the data seemed too good to be
14 true. And when they ran the test the second time, they knew
15 for sure they had proven the skeptics wrong.

16 There are two patents in this case that describe and
17 claim a low-dose corticosteroid in this unique formulation
18 vehicle. We call them the Bryhali patents.

19 Now, to understand what happened next, we need to
20 talk about another topical treatment for psoriasis called a
21 retinoid. Tazarotene, sometimes called "Taz" for short, is a
22 particular retinoid that this Court will hear a lot about in
23 this case.

24 Tazarotene was approved to treat psoriasis in the
25 1990s in a commercial product called Tazorac®. But the

1 evidence in this case will show tazarotene is an irritating
2 ingredient, and so it was not commonly prescribed to patients
3 with inflamed psoriatic skin.

4 So as part of the same development project that led
5 to the Bryhali patents, the scientists at Bausch were also
6 developing a combination product for treating psoriasis.

7 And what did they do? The testimony will show that
8 the Bausch scientists took their unique formulation vehicle
9 and they made it even better.

10 The result was a combination product that contained a
11 low concentration of halobetasol and a low concentration of
12 tazarotene, lower than what was commercially available before.

13 The evidence will show that combination products are
14 not only rare for psoriasis treatment but notoriously
15 difficult to formulate. So the invention of this new
16 combination product was achievement enough.

17 So lightning had already struck once. Bausch had
18 discovered the unique formulation vehicle that allows for
19 80 percent less active ingredient but maintains efficacy. But
20 now it struck a second time. The combination product was
21 tested in a Phase 2 clinical study which yielded astonishing
22 results.

23 The combination product, also called Duobrii®,
24 outperformed the combination of halobetasol and tazarotene in
25 terms of both efficacy and side effects.

1 This blew past the FDA requirement for combination
2 products, which required only that the combination outperform
3 each individual ingredient. And the Court will hear testimony
4 from one of the inventors of the Duobrii patents later today
5 in which he'll recall the genuine surprise and excitement he
6 felt when he received those initial results from the Phase 2
7 clinical study.

8 There are two patents that describe and claim a
9 combination product using the low-dose corticosteroid and the
10 low dose of tazarotene in the unique formulation vehicle, as
11 well as their synergistic efficacy and synergistic reduction
12 of adverse events. We call them the Duobrii patents.

13 So to just sum this up briefly for the Court, there
14 are really only three points that need to be made about this
15 slide.

16 First, Bausch's products. Bryhali® contains a low
17 dose of superpotent corticosteroid, specifically halobetasol,
18 at 0.01 percent concentration by weight in the unique
19 formulation vehicle that Bausch developed.

20 Duobrii® also contains 0.01 percent halobetasol but
21 also includes tazarotene in the amount of 0.045 percent.

22 The second point I'd like to make about the slide is
23 the relationship between the products and the patents at
24 issue.

25 The Bryhali patents cover both Bryhali® and Duobrii®.

1 The Duobrii patents cover just Duobrii®. And Padagis's
2 generic versions of each product follow the same breakdown.

3 Third, Padagis has stipulated in this case that
4 Bausch's Bryhali® and Duobrii® products are embodiments of the
5 asserted claims of their respective patents.

6 Bausch is asserting 10 claims, five from the Bryhali
7 patents and five from the Duobrii patents.

8 As I mentioned earlier and as the Court well knows
9 from the stipulation that was submitted and entered last week,
10 Padagis has stipulated to infringement of all asserted claims
11 on both products.

12 So, again, this trial is only about validity, and
13 Padagis is required to prove that each of these claims is
14 invalid.

15 Your Honor is going to hear Padagis argue that the
16 asserted claims in the case would have been obvious over the
17 prior art. And, as we all know, on this issue Padagis bears
18 the highest burden of proof in civil law, that is, one of
19 clear and convincing evidence.

20 Padagis's burden is made all the more difficult by
21 the fact that many of it's asserted prior art references --
22 I'll start that sentence again.

23 THE COURT REPORTER: Sure.

24 MS. WEISBRUCH: Padagis's burden is made all the more
25 difficult by the fact that many of its asserted prior art

1 references were considered by the U.S. Patent and Trademark
2 Office during examination. And the evidence will show that
3 all of Padagis's arguments about the art amount to little more
4 than a rehash of what the examiner said before ultimately
5 deciding to allow the claims.

6 And what's more, this prior art that Padagis relies
7 on to make out its case for invalidity is old.

8 For example, Padagis's core reference with respect to
9 the Bryhali patents is dated from 1980, 30 years before the
10 invention of the Bryhali patents.

11 And Padagis will tell the Court that references like
12 this one render the asserted claims obvious because the
13 problem with superpotent corticosteroids was known. But for
14 decades Padagis's references were out there. And for all that
15 time, nobody solved the problem. Until Bausch did.

16 As the evidence will show in this case, the
17 formulation of a drug makes all the difference in how that
18 drug is delivered to the skin. But topical development is
19 more art than science.

20 The Court will hear evidence about all the different
21 types of interactions a topical formulator must take into
22 account when designing a new formulation and the extensive
23 testing required as part of this process due to
24 unpredictability in the field. And the fruits of Bausch's own
25 development and extensive testing did yield truly unexpected

1 results.

2 The Court will hear the experts talk about how truly
3 unexpected it was to be able to drop the concentration of an
4 active ingredient by 80 percent but remain just as efficacious
5 as the higher-concentration drug.

6 And in the case of Duobrii®, the combination product,
7 Bausch's experts will talk about the clinical data from the
8 Phase 2 study and how it unexpectedly showed both the
9 synergistic efficacy and a synergistic reduction in adverse
10 events.

11 And the Court will hear the word "synergy" can have
12 different meanings depending on the context. But the types of
13 synergies that Duobrii® demonstrated in the Phase 2 clinical
14 study, that is, benefits over the combined individual
15 therapies, are exceptionally rare and valuable.

16 Finally, the obviousness case that Padagis will put
17 on this week is all about hindsight or, to use the federal
18 circuit's own colorful language, the insidious attraction of
19 the siren hindsight.

20 So every time Padagis's experts cherry-pick a
21 disclosure from the art, that is, when they look at a broad
22 disclosure but pluck from it a particular species that also
23 happens to appear in the asserted claim, you have to ask
24 yourself: Is this hindsight?

25 And every time Padagis's experts read only a few

1 sentences from a reference without considering the other
2 contradictory portions of the same reference, you have to ask
3 yourself: Is this hindsight?

4 And every time Padagis's experts even say the words
5 "formulation optimization," you have to ask yourself: Is this
6 hindsight?

7 In every instance, the answer will be yes.

8 So now, separately, defendants will say that the term
9 "liquid oil component" is indefinite.

10 The Court's construction of this term puts that issue
11 to rest. It is perfectly clear and would be understood by any
12 person of skill in the art.

13 And with that, I would like to give the Court a
14 preview of our batting order this week.

15 The Court will hear from four Bausch witnesses, one
16 inventor and three expert witnesses.

17 The Court will hear from one of the inventors on the
18 Duobrii patents, Dr. Pillai. Dr. Pillai will describe the
19 development project that led to Bryhali® and Duobrii®.

20 Bausch's dermatology expert and vice president of the
21 American Academy of Dermatology, Dr. Stein Gold, will discuss
22 the real-world treatment of psoriasis including treatment
23 using both retinoids and superpotent corticosteroids. She
24 will also address some of Padagis's invalidity arguments.

25 Dr. Stein Gold will testify twice, first today by

1 Zoom on background of the invention. She will appear live
2 later in the week to discuss her opinions relating to
3 validity.

4 Bausch's formulation expert, Dr. Lane, will discuss
5 the field of formulation science, including the challenges
6 formulators face in the field of topical formulations. She
7 will also address some of Padagis's invalidity arguments.

8 And, finally, Dr. Sheridan will testify on commercial
9 success. Dr. Sheridan will also be testifying remotely.

10 We are confident that after hearing the evidence, the
11 Court will conclude that Padagis fails to meet its burden to
12 show that the patents are invalid.

13 Thank you very much, Your Honor.

14 THE COURT: Thank you.

15 OPENING STATEMENT BY MS. PITZEL CRUZ:

16 MS. PITZEL CRUZ: Good morning, Your Honor.

17 My name's Carol Pitzel Cruz.

18 THE COURT REPORTER: Pull the microphone closer
19 before we start. I don't want to keep interrupting you.
20 Thank you so much.

21 MS. PITZEL CRUZ: I'm Carol Pitzel Cruz on behalf of
22 the Padagis defendants.

23 And Bausch has described the alleged inventions of
24 the patents in-suit as shattering expectations and winning the
25 lottery ticket of drug delivery.

1 But this case is not about a new drug. It's not
2 about treating a new disease. It's not even about treating a
3 previously -- a new disease with a previously known drug or
4 using new excipients.

5 Instead, the evidence will show that Bausch simply
6 used conventional methods of drug formulation to lower the
7 concentration of a well-known corticosteroid in response to a
8 widely recognized issue with that corticosteroid.

9 The evidence will also show that Bausch then added
10 tazarotene, another well-known drug used to treat psoriasis,
11 to that same exact low-dose halobetasol formulation.

12 None of Bausch's routine drug development is worthy
13 of patent protection given the breadth of the prior art.

14 If we could turn to the next slide, please.

15 The asserted claims of the '307 and '502 patents,
16 which counsel referred to as the Bryhali® patents, we'll also
17 refer to them as the halobetasol patents, recite many similar
18 claim limitations, all of which would have been obvious.

19 Every asserted claim recites a composition that
20 includes halobetasol at a certain concentration which ranges
21 from 0.05 percent to 0.01 percent or less.

22 Among the other claim limitations, there is a
23 recitation of "a liquid oil component that includes a known
24 compound referred to as diethyl sebacate."

25 Next slide, please.

1 Next slide. Thanks.

2 Bausch doesn't claim to have invented halobetasol.
3 It's undisputed that halobetasol was a well-known steroid used
4 to treat psoriasis for many years.

5 In fact, as counsel had mentioned, halobetasol was
6 commercially available and FDA approved as the Ultravate®
7 product that was -- included a concentration of 0.05 percent
8 halobetasol.

9 The parties also agree that Ultravate® and other
10 corticosteroids were known to have serious systemic side
11 effects such as HPA axis suppression, and if too much of the
12 steroid was absorbed into the bloodstream, a patient could
13 suffer from this serious side effect.

14 Because of this the FDA limited the use of Ultravate®
15 to a period -- because of this serious side effect, the FDA
16 limited the use of Ultravate® to a period of no longer than
17 two consecutive weeks.

18 Next slide, please.

19 The parties agree that psoriasis is a chronic
20 condition and that for most patients treatment longer than two
21 weeks is required. Thus, there was a need for effective
22 topical treatments with a lower risk of that severe side
23 effect of HPA axis suppression and that could be given for
24 longer than two weeks.

25 As the evidence will demonstrate, one obvious

1 solution to this widely recognized problem would have been to
2 lower the dose of halobetasol.

3 One of skill in the art would have expected that
4 lower concentrations would allow for a lower risk of systemic
5 side effects which, in turn, would allow for a longer
6 treatment period.

7 Next slide, please.

8 In fact, the prior art reference, one of which you'll
9 hear about, the Blum reference, disclosed that 0.02 percent
10 halobetasol was effective in treating psoriasis.

11 The prior art also disclosed that one of skill in the
12 art could reduce the dose of a particular topical formulation
13 through the use of an appropriate formulation or vehicle.

14 The art included multiple references that disclosed
15 the use of a class of compounds referred to as dicarboxylic
16 acid esters such as the claimed diethyl sebacate that I
17 mentioned.

18 And those were known in the art in multiple
19 references to dissolve corticosteroids in order to improve the
20 release of the steroid into the skin and reduce the HP
21 concentration in the formulation.

22 Next slide, please.

23 As defendant's experts will explain, the 1986 article
24 by Blum, which is shown on the -- a portion of which is shown
25 on the slide, compared the efficacies of halobetasol at

1 0.02 percent and 0.05 percent and also included a reference
2 product that was approved, Dermovate, to treat psoriasis.

3 As the evidence will show, the concentration of
4 halobetasol was reduced by over half, from 0.05 to 0.02, and
5 the resulting treatment success rates differed by only
6 9 percent, 81.4 percent treatment success compared to
7 90.2 percent success.

8 This information would have provided one of skill in
9 the art a reasonable expectation of success that a lower-dose
10 halobetasol formulation would be efficacious in treating
11 psoriasis.

12 Next slide, please.

13 And, as I mentioned, the use of dicarboxylic acid
14 esters to solubilize corticosteroids and halobetasol in
15 particular was nothing new. One of skill in the art would
16 have known that halobetasol was insoluble in water and
17 required a lipophilic or oily solvent.

18 One obvious choice for such an oily solvent would
19 have been the dicarboxylic acid such as diethyl sebacate, and
20 these were commonly known in the art to dissolve
21 corticosteroids.

22 Numerous references disclose this information, and
23 throughout the trial you'll hear about three of those
24 references -- the '295 patent, the '566 patent, and the JP 228
25 patent -- all of which taught how to effectively formulate

1 corticosteroids in oil and water lotion formulations using
2 these dicarboxylic acid esters.

3 Next slide, please.

4 And just to have a preview of some of the references,
5 for example, if we look at the '295 patent, it explained that
6 dicarboxylic acid esters were useful in solubilizing
7 corticosteroids to provide the absorption needed to achieve a
8 therapeutic response for treating psoriasis.

9 Next slide, please.

10 If we look at the '566 patent, it similarly taught
11 the use of dicarboxylic acid esters and importantly --

12 THE COURT REPORTER: I'm sorry. Can you start that
13 again?

14 MS. PITZEL CRUZ: Sure.

15 THE COURT REPORTER: Thank you.

16 MS. PITZEL CRUZ: If we look at the '566 patent, it
17 similarly taught the use of dicarboxylic acid esters to
18 enhance the penetration of topical drugs, including
19 corticosteroids, into the patient's skin, enabling more
20 effective compositions.

21 Next slide, please.

22 And if we could take a look at this slide, it's
23 discussing the JP 228 reference that you will hear about.

24 This also confirms the use of dicarboxylic acid
25 esters, and the JP 228 reference disclosed that preparations

1 in the -- where the corticosteroid was dissolved in the oil
2 phase with dicarboxylic acid esters such as diethyl sebacate.

3 It also disclosed that testing of these compositions
4 demonstrated high treatment efficacy due to improved steroid
5 release and absorption.

6 Next slide, please.

7 Defendant's experts will explain how a person of
8 skill in the art would have been motivated to combine these
9 teachings and how doing so would have resulted in the
10 compositions and methods claimed in the patents.

11 Thus, the defendants will demonstrate the combination
12 of Blum and the '295 patent, alone or in combination with the
13 '566 patent, the JP 228 patent, or, for one set of claims,
14 another reference called the Temovate® Label, rendered the
15 asserted claims of the halobetasol patents obvious.

16 Next slide.

17 Defendants will also explain why the claims of the
18 halobetasol patents are indefinite. As this Court previously
19 held at claim construction, the specification defines "the
20 liquid oil component" in a certain manner.

21 But subsequent disclosure in the patent is
22 inconsistent with this definition, and our experts will
23 explain why this prevents a reasonably clear understanding of
24 the term.

25 Next slide, please.

1 With respect to the indefiniteness argument, the
2 calculations in table 2 exclude a specific emulsifier,
3 sorbitan monooleate, which indisputably falls within the
4 construction of "the liquid oil component." As the evidence
5 will show, this inconsistency renders the scope of the claim
6 term unclear to one of skill in the art.

7 Bausch's expert will likely try to reconcile these
8 inconsistencies in the patent, but this is a departure from
9 her prior testimony that a person of ordinary skill in the art
10 would not be able to reconcile the definition of "the liquid
11 oil component" adopted in this case with table 2 of the
12 patent.

13 Next slide, please.

14 I'd like to move on now to the '895 and '787 patents,
15 which counsel referred to as the Duobrii® patents. And we
16 also refer to them as the combination patents.

17 The combination patents at a high level claim
18 compositions of 0.01 percent halobetasol and 0.045 percent
19 tazarotene with a dermatologically acceptable carrier that
20 includes the diethyl sebacate we spoke of well as light
21 mineral oil.

22 The claims also include synergy limitations of
23 synergistic efficacy and a synergistic reduction in a grouping
24 of adverse events.

25 Next slide, please.

1 The concept of combining tazarotene with a topical
2 corticosteroid such as halobetasol to treat psoriasis was not
3 inventive. Such combinations were explicitly described in the
4 prior art.

5 For example, the Gollnick reference that you will
6 hear about disclosed two clinical studies of such combinations
7 and found in both studies that combining tazarotene with a
8 highly potent corticosteroid significantly improved the
9 efficacy of the treatment and reduced local skin irritation.

10 Next slide, please.

11 And the use of the 0.01 percent halobetasol as part
12 of a combination with tazarotene was also non-inventive. To
13 the contrary, Bausch effectively took the exact
14 low-concentration halobetasol formulations of the halobetasol
15 patents, which share the disclosure as the prior art '824
16 Publication, and added the well-known compound tazarotene that
17 was already known to use -- used and to treat psoriasis.

18 Thus, the '824 Publication discloses every limitation
19 of the combination patent claims except for the tazarotene and
20 synergy limitations.

21 As defendant's experts will explain, a person of
22 skill in the art would have been motivated to use the '824
23 publication's low concentration halobetasol as part of a
24 combination therapy.

25 One of skill in the art would have been motivated by

1 the '824 publication's disclosure of 0.01 percent halobetasol
2 formulations with similar potency and efficacy to higher
3 concentration formulations that could be safely applied for
4 periods of longer than two weeks.

5 Next slide, please.

6 Tazarotene was also a widely-known, FDA-approved
7 treatment for psoriasis prior to the combination patents.
8 It's commercially available at concentrations of 0.01 percent
9 and 0.05 percent in the Tazorac® product. Tazarotene had a
10 tendency to cause local skin irritation, limiting its
11 usefulness. But the Tazorac® Label taught that using the 0.05
12 percent dose of tazarotene could alleviate the irritating side
13 effects of the drug when 0.1 percent, the higher
14 concentration, was used and, thus, those of skill in the art
15 would have been motivated to use an even lower concentration
16 of 0.045 percent to further reduce these irritating effects.

17 The teachings of the '824 Publication that disclosed
18 compositions that allowed for a lower drug concentration while
19 retaining efficacy and improving safety would have reinforced
20 one of skill in the art's reasonable expectation of success in
21 using 0.045 percent tazarotene while still retaining efficacy
22 and improving safety.

23 Next slide, please.

24 Bausch cannot claim novelty in either the combination
25 of halobetasol and tazarotene or the specific concentrations

1 of those ingredients recited in the claims as a prior art
2 posting from ClinicalTrials.gov disclosed the combination of
3 those ingredients, including the percentages of each.

4 As you will hear throughout this case, the study
5 record from the ClinicalTrials.gov of a Phase 2 study of
6 IDP -- what was referred to as IDP-118 lotion was disclosed in
7 January of 2014 and included reference to one of the
8 formulations being tested for treatment of psoriasis
9 containing halobetasol at 0.10 percent and tazarotene at
10 0.045 percent.

11 So, again, those exact concentrations were disclosed
12 in January of 2014.

13 If we could go to the next slide.

14 In the face of all of these part art teachings,
15 Bausch will likely argue that the claims are not obvious
16 because of these recited synergy limitations. But those
17 limitations merely reflect expected, inherent properties of
18 the claimed compositions. The expectation of synergy was
19 expressly recognized in the prior art.

20 The Gollnick reference that I mentioned stated that
21 the combination of tazarotene and topical corticosteroid would
22 likely have additive or synergistic effects.

23 Gandhi, another prior art reference, disclosing the
24 combination of halobetasol and tazarotene in a single
25 formulation disclosed that the combination of tazarotene and

1 halobetasol would provide synergistic effects.

2 If we could turn to the next slide.

3 Although Bausch will likely argue to this Court that
4 synergy was unexpected, they told a different story to the FDA
5 during the approval process for Duobrii®. For example, in a
6 2011 submission, based on the literature reference, Bausch
7 told the FDA that when tazarotene is combined with a
8 corticosteroid, irritation is reduced and a synergistic effect
9 allows for a longer duration of treatment and remission. And
10 they were citing to a 2011 publication.

11 Next slide, please.

12 Later in that same submission, Bausch, again, based
13 on the literature, told the FDA that the concept of combining
14 halobetasol and tazarotene for psoriasis was specifically
15 based on the potential for synergistic effects due to the
16 different mechanism of action for the two drugs.

17 Next slide, please.

18 And, again, in that same submission, Bausch repeated
19 that the improved efficacy that had been observed with the
20 combination of tazarotene and corticosteroids was likely due
21 to the different mechanisms of action of the two drugs, each
22 of which contributed additively or synergistically to the
23 desired therapeutic effect.

24 The evidence will show that this 2011 submission was
25 not an isolated incident but rather Bausch's FDA submissions

1 are riddled with such statements acknowledging the expectation
2 of synergy.

3 Next slide, please.

4 Bausch has argued in its briefing that this
5 combination product formulation had all the makings of a
6 failure, but these supposed makings of a failure ignore the
7 knowledge of one of skill in the art and the explicit
8 disclosures of that art. The recitation of expected and
9 inherent synergistic effects do not save the validity of those
10 claims.

11 Thus, as defendants will demonstrate, the combination
12 of the '824 Publication and Gollnick in further combination
13 with the tazarotene label, the ClinicalTrials.gov IDP-118
14 study or Gandhi render all of the claims of the combination
15 patents obvious.

16 And, Your Honor, with respect to commercial success,
17 Bausch will be unable to demonstrate commercial success in
18 order to save the asserted patents. Bausch does not even
19 contend that its Bryhali® product has been a success.

20 With respect to Bausch's Duobrii® product, for at
21 least the reasons described in the slide that you have, Your
22 Honor, the evidence will show that Duobrii® lacks commercial
23 success.

24 And who you will hear from in Padagis's case. We
25 have three different experts that will provide testimony. The

1 first is Dr. Robert Stern. He is a Harvard Medical School
2 professor of dermatology and a board-certified dermatologist
3 with over 45 years of clinical experience treating patients
4 with psoriasis.

5 You will also hear from Dr. Michniak-Kohn, an expert
6 in the field of pharmaceutical science, particularly in the
7 area of developing and evaluating dermatological formulations.
8 Dr. Michniak-Kohn is a tenured full professor in pharmaceuticals
9 at the Ernest Mario School of Pharmacy at Rutgers. She is
10 also the founder and director of the Center for Dermal
11 Research at Rutgers.

12 Dr. Mickey Ferri is an economist at Insight Economics
13 and has expertise in applied business economics and will
14 address the lack of commercial success argument.

15 And with that, Your Honor, thank you.

16 THE COURT: Thank you.

17 THE COURTROOM DEPUTY: Two minutes, Judge, to switch
18 over.

19 Mr. Walker, let us know when you're ready.

20 MR. BRUNO: Good morning, Your Honor, Christopher
21 Bruno on behalf of the Bausch plaintiffs. I see we're getting
22 our remote feed set up right now, so it may just be a moment.

23 In the meantime, however, Bausch would like to move
24 some exhibits in which I understand are not be objected to by
25 the defendants, and I'll recite those exhibit numbers.

1 JTX-1, JTX-2, JTX-3, JTX-4, JTX-5, JTX-6, JTX-7,
2 JTX-8, JTX-12, JTX-12-9, JTX-12-10, JTX-19, JTX-20, JTX-21,
3 PTX-37, PTX-67, PTX-243, PTX-301, PTX-341, PTX-358, PTX-395.

4 THE COURT: They are all evidence.

5 THE COURTROOM DEPUTY: Can I have a copy of that
6 list?

7 (Exhibit Number JTX-1 is received in evidence.)

8 (Exhibit Number JTX-2 is received in evidence.)

9 (Exhibit Number JTX-3 is received in evidence.)

10 (Exhibit Number JTX-4 is received in evidence.)

11 (Exhibit Number JTX-5 is received in evidence.)

12 (Exhibit Number JTX-6 is received in evidence.)

13 (Exhibit Number JTX-7 is received in evidence.)

14 (Exhibit Number JTX-8 is received in evidence.)

15 (Exhibit Number JTX-12 is received in evidence.)

16 (Exhibit Number JTX-12-9 is received in evidence.)

17 (Exhibit Number JTX-12-10 is received in evidence.)

18 (Exhibit Number JTX-19 is received in evidence.)

19 (Exhibit Number JTX-20 is received in evidence.)

20 (Exhibit Number JTX-21 is received in evidence.)

21 (Exhibit Number PTX-37 is received in evidence.)

22 (Exhibit Number PTX-67 is received in evidence.)

23 (Exhibit Number PTX-243 is received in evidence.)

24 (Exhibit Number PTX-301 is received in evidence.)

25 (Exhibit Number PTX-341 is received in evidence.)

1 (Exhibit Number PTX-358 is received in evidence.)

2 (Exhibit Number PTX-395 is received in evidence.)

3 MR. BRUNO: I'm sorry, I didn't hear you.

4 THE COURTROOM DEPUTY: If I do not have that list can
5 I get the list for the court reporter?

6 MR. BRUNO: Of course.

7 Dr. Stein Gold, can you hear me?

8 DR. STEIN GOLD: I can.

9 MR. BRUNO: Excellent. Good morning.

10 DR. STEIN GOLD: Good morning.

11 THE COURTROOM DEPUTY: I have to swear her.

12 DR. LINDA STEIN GOLD, PLAINTIFF'S WITNESS,
13 having been duly sworn, testifies as follows:

14 THE COURTROOM DEPUTY: Please state your name for the
15 record.

16 THE WITNESS: Linda Stein Gold.

17 THE COURTROOM DEPUTY: Thank you.

18 DIRECT EXAMINATION

19 BY MR. BRUNO:

20 Q. Good morning. Please introduce yourself to the Court.

21 A. My name is Dr. Linda Stein Gold.

22 Q. How many times have you testified at trial?

23 A. This is my first time.

24 Q. Let's start by telling everyone little bit about who you
25 are. What's your current job?

1 A. I am the director of dermatology clinical research at
2 Henry Ford Health. I'm also a division head of dermatology,
3 and I'm the elected vice president of the American Academy of
4 Dermatology.

5 Q. What is the American Academy of Dermatology?

6 A. It is considered to be the premier association for
7 board-certified dermatologists in the United States. We have
8 international members as well.

9 Q. Where did you go to school?

10 A. I went to the Wharton School at the University of
11 Pennsylvania. I then went to medical school at the University
12 of Pennsylvania where I did my internship, and then I
13 completed my dermatology residency at Henry Ford Hospital in
14 Detroit, Michigan.

15 Q. And where do you practice now?

16 A. I still practice at Henry Ford Hospital.

17 Q. And how long have you been practicing at Henry Ford
18 Hospital?

19 A. For over 25 years.

20 Q. Today, about how often do you see patients?

21 A. I'm a full-time staff there, so I am a medical
22 dermatologist. I see, basically, medical patients three days
23 a week and clinical research patients at least one day a week.

24 Q. About how many patients would you estimate you've treated
25 for psoriasis over the years?

1 A. Too many to count. Hundreds to thousands.

2 Q. Now, you mentioned that you've been the director of the
3 dermatology clinical research. What kinds of research have
4 you been involved in over the years?

5 A. So I do all of general dermatology, but I have a special
6 interest in psoriasis, especially topical therapy of
7 psoriasis. So I've done most of those new medications for
8 topical therapy, but I also do systemic therapies and biologic
9 therapies.

10 Q. What kinds of companies do you work with when you conduct
11 this research?

12 A. I work with all different companies. We work with very
13 small, startup companies, we work with large pharmaceutical
14 companies, we work with generic companies. Really everybody.

15 Q. About how many publications have you authored over the
16 years?

17 A. I'm going to guess about 200. I publish maybe 20 times
18 or so a year.

19 Q. How many of those publications relate to the treatment of
20 psoriasis?

21 A. Approximately 50.

22 Q. About how many conferences have you spoken at?

23 A. Again, too many to count. I speak both nationally and
24 internationally. I speak, on average, at least once a month.
25 I also co-chair four national meetings a year.

1 Q. As part of your clinical research, have you assisted
2 specifically in drug development?

3 A. I have.

4 Q. And what roles have you served when assisting in drug
5 development?

6 A. So I really help in all areas. I help often to identify
7 unmet needs, where do we need new medications to help our
8 patients. I help with protocol development. I help with
9 analysis of the data. I then help with, often, writing up the
10 publications.

11 Q. Have you served as a principal investigator in clinical
12 trials?

13 A. I have.

14 Q. Can you estimate how many clinical trials?

15 A. No. But after about the first five years of practice,
16 I've been the principal investigator on every trial that I've
17 done.

18 Q. How many of these clinical trials do you think related to
19 psoriasis?

20 A. I don't know, but I know that we do maybe four or five
21 psoriasis trials every year.

22 Q. I know we haven't touched on all of your professional
23 credentials. Have you summarized your credentials in a CV?

24 A. I have.

25 MR. BRUNO: And if we can pull up PTX-341.

1 BY MR. BRUNO:

2 Q. Is this your CV?

3 A. It is.

4 Q. And is this CV up to date?

5 A. It was up to date as of the date on the -- January 2022.
6 Since then, I've had a number of additional clinical trials
7 and additional publications. But it's up to date as of that
8 date.

9 MR. BRUNO: Your Honor, at this time, we would like
10 to offer Dr. Linda Stein Gold as an expert in dermatology,
11 including dermatological clinical studies, psoriasis and the
12 topical treatment of skin diseases including psoriasis.

13 THE COURT: Any objections or any requests for voir
14 dire?

15 MR. ZIMMERMAN: No objections, Your Honor.

16 THE COURT: All right. The witness is so deemed an
17 expert.

18 BY MR. BRUNO:

19 Q. Dr. Stein Gold, can you explain to all of us what
20 psoriasis is?

21 A. Yes. Psoriasis is really a devastating inflammatory skin
22 disease. It can affect almost anybody. It usually affects
23 adults, but it also can affect children. It causes red, thick
24 skin. It's physically devastating. It can be painful, it can
25 be itchy. It's emotionally devastating.

1 These patients suffer from depression, from anxiety.
2 You can imagine, for instance, this patient with lesions on
3 their hands, when they walk into a room and they want to shake
4 somebody's hand, people are going to jump back. You walk into
5 a room and instead of people judging you by your smile, they
6 judge you by your skin.

7 Q. What causes psoriasis?

8 A. So we are getting better at understanding the cause of
9 psoriasis. We understand that this is a defect of the immune
10 system. And with each year, we get better and better in
11 understanding it, but we don't have the exact answer yet.

12 Q. Is there a cure for psoriasis?

13 A. Unfortunately, no, we don't have a cure, but we're
14 actually getting better and better at treating it.

15 Q. Approximately how many people in the United States are
16 afflicted with psoriasis?

17 A. It affects about seven to eight million people.

18 Q. Now, can you explain the difference between healthy skin
19 and psoriatic skin?

20 A. Sure. So normally when we look at the skin, we see the
21 upper layers of skin called the epidermis. In psoriasis,
22 there are signals that tell that skin to replicate very
23 rapidly.

24 So normally, we start with the lower level of skin
25 and as the skin progresses, those cells kind of venture up to

1 the upper layer and then they slough off. And at each layer,
2 the cell becomes differentiated, or schooled, to perform a
3 different function, to help protect us as the outer layer and
4 the barrier to the outside environment.

5 Now, in psoriasis, this is rapidly changed. So
6 normally it takes about a month for a cell to venture from the
7 basal layer, the bottom layer, all the way up to the top layer
8 and then fall off.

9 In psoriasis, there are signals that tell the skin to
10 replicate very, very fast. So those cells go from the bottom
11 layer to the top layer maybe in, like, days instead of a
12 month. And so in that process, those cells don't get schooled
13 appropriately, so they lack appropriate differentiation. And
14 they don't slough off the way they're supposed to, so we end
15 up with really thick plaques, they're red, they're inflamed,
16 and they have a lot of thick scale on top of them. And they
17 actually can be painful and itchy.

18 Q. What kinds of treatments are available for psoriasis?

19 A. So treatment really depends on the amount of psoriasis
20 that you have and where your psoriasis is located. If you
21 have localized disease, we usually treat you with a topical
22 agent. If you have really wide-spread disease, often we'll
23 use a systemic medication. But even patients who are on
24 systemic medications still are often treated with topical
25 therapies as well.

1 So pretty much every psoriasis patient has topical
2 therapy.

3 Q. What types of topical therapies are available for
4 psoriasis?

5 A. So for topical therapies, we really have three main
6 categories. We have topical corticosteroids, which are really
7 the mainstay of therapy, and then we have some nonsteroidal
8 options, including vitamin A analogs, which are retinoids like
9 tazarotene, and then we have vitamin D analogs.

10 These are not steroids, so they are benefits to that
11 but they tend to be quite irritating.

12 Q. What is a corticosteroid?

13 A. So a corticosteroid is, especially a topical
14 corticosteroid, is a topical medication that we actually apply
15 directly on the skin. And it has really good
16 anti-inflammatory properties, and it helps to calm down the
17 signs and symptoms of psoriasis.

18 Q. Are there any problems with topical corticosteroids?

19 A. There are. You know, as we use stronger medications,
20 especially superpotent topical steroids, they have some side
21 effects that we certainly worry about. We worry about
22 thinning of the skin and stretch marks, but we also worry
23 about the fact that when we put the medication on the skin, it
24 actually gets absorbed into the system and that systemic
25 absorption can lead to some hormonal abnormalities.

1 Q. Are all potencies of corticosteroids used for treating
2 psoriasis?

3 A. Well, you saw the pictures of psoriasis. Our goal is to
4 try to get these patients out of their pain and discomfort.
5 We generally want to use the most potent medication possible
6 to get them under control, and that generally means using
7 superpotent steroids.

8 We tend to go to that Class 1 or that high-potency
9 steroid. We come in hard. We want to get them under control
10 fast, we want to decrease the redness, the scaling, the
11 itching, the burning. We try to get them under control, and
12 then we pull back as the disease calms down.

13 Q. So what is the standard of care in the treatment of
14 psoriasis?

15 A. Standard of care, and really gold standard, is using
16 superpotent topical corticosteroids.

17 Q. How is the potency of a corticosteroid determined?

18 A. So the way we figure out how strong a steroid is with
19 something that we call a vasoconstrictor assay. When you put
20 a steroid on a skin, one of the things that it does is it
21 actually squeezes closed the blood vessels. And when you
22 squeeze close the blood vessel, you push the blood out and you
23 cause the skin to blanch or turn white.

24 And we figured out that if you can put a steroid on
25 the skin and see how white the skin becomes, that actually is

1 a really good determination of how potent that particular drug
2 is.

3 Q. What factors generally affect the potency of a drug?

4 A. So when I talk about a topical therapy, I describe it as
5 really a marriage, and it's a marriage of the active
6 ingredient and the vehicle. And each of these components
7 plays a very important role in the potency, the efficacy, the
8 tolerability and the patient acceptability. So each one of
9 the factors, the active drug is important, but the vehicle is
10 also very important.

11 Q. Which superpotent corticosteroid active ingredient do you
12 understand to be at issue in this case?

13 A. Halobetasol.

14 Q. And what is halobetasol?

15 A. So halobetasol is a Class 1, or a superpotent, topical
16 corticosteroid that is very commonly used for the treatment of
17 psoriasis.

18 Q. When was halobetasol first commercialized?

19 A. It was first commercialized in 1990.

20 Q. And what brand name was halobetasol first commercialized
21 under?

22 A. It went by the name called Ultravate®.

23 Q. What was the doses of halobetasol in Ultravate®?

24 A. So what's interesting is it came pretty much as a fixed
25 dose, 0.05 percent, and that was true whether it was the cream

1 or the ointment.

2 Q. When was halobetasol first invented?

3 A. It was invented in 1978.

4 Q. Now earlier you also mentioned retinoids. What are
5 retinoids?

6 A. So retinoids are another topical medication that actually
7 have been used. There's a lot of retinoids. There are only,
8 actually, two that have been used to treat psoriasis, one
9 topical and one oral, and they actually work in a different
10 way, different from the topical corticosteroids.

11 So earlier I mentioned that when the cells go so fast
12 between the basal layer and the top layer that they don't get
13 schooled appropriately, they're going too fast to kind of
14 learn their lessons, what the retinoids do is they actually
15 calm that down and they allow for appropriate differentiation
16 of the cells, and they also have some anti-inflammatory
17 properties.

18 Q. And what retinoids, specifically, again, do you
19 understand is important in this case?

20 A. Tazarotene.

21 Q. Under what brand name was tazarotene first
22 commercialized?

23 A. Tazorac®.

24 Q. Now, are you familiar with the drug called Bryhali®?

25 A. I am.

1 Q. What is Bryhali®?

2 A. So Bryhali® is a superpotent topical corticosteroid that
3 has the active ingredient of halobetasol, but the
4 concentration is 0.01 percent and it comes as a lotion
5 formulation. And I understand Bryhali® can be used for up to
6 eight weeks.

7 Q. And, again, what are the benefits of Bryhali®?

8 A. So the benefits are, this is a drug that before Bryhali®,
9 halobetasol had a very strict limitation on its use. People
10 tend to like halobetasol as a topical corticosteroid, but no
11 matter which form you used, it had a two-week limitation.

12 What was unique about Bryhali® is it has a lotion
13 formulation, which is cosmetically elegant, but it also has a
14 duration of treatment that's eight weeks. So that means as
15 opposed to two weeks where you're treating, you know, one of
16 those psoriasis patients, you're just trying to get them
17 feeling better and then oh, you've got to stop.

18 With Bryhali®, it allows you to use this medication
19 for a full eight weeks. So that's four times longer than what
20 we'd seen before.

21 Q. Are you also familiar with a drug called Duobrii®?

22 A. I am.

23 Q. How are you familiar with Duobrii®?

24 A. Well, I'm familiar with it for two ways. First of all, I
25 did participate in the Phase 3 clinical trials and in the

1 long-term studies, but I have also used it as a medical
2 dermatologist in practice.

3 Q. Do you speak about Bryhali® at conferences -- I'm sorry.
4 Let me re-ask the question.

5 Do you speak about Duobrii® at conferences?

6 A. Yes.

7 Q. And what is Duobrii®?

8 A. So Duobrii® is actually a fixed concentration. With this
9 particular drug, you have halobetasol in the very low
10 concentration, the 0.01 percent, and you also have tazarotene
11 but also in a lower concentration. You have it in the
12 0.045 percent.

13 So it's a fixed combination, which means every time
14 the person squeezes that tube and puts on the medicine, they
15 get both drugs. So they get the benefit of both drugs every
16 single time.

17 What's unique is even though this has this
18 superpotent steroid, there's not a cap on how long you can use
19 this fixed combination.

20 Q. Before Duobrii®, was tazarotene used alone in the
21 treatment of psoriasis?

22 A. So that's really an interesting question because I've
23 already talked about the fact that topical retinoids,
24 especially tazarotene, makes a lot of sense for psoriasis
25 because it does that really important thing, which is cause

1 the differentiation of the cells to normalize. Steroids don't
2 do that, but the topical retinoid does do that. So it made
3 sense to use the topical retinoid.

4 But the problem was tazarotene was very, very
5 irritating. So even though it was FDA approved -- and to be
6 honest, I did the tazarotene topical studies for psoriasis, as
7 well, so I know what it was like when we looked at tazarotene
8 as monotherapy. It was very difficult to keep those patients
9 in the clinical trial because the irritation was quite, quite
10 great.

11 So it was rare for a dermatologist to use tazarotene,
12 especially as monotherapy for psoriasis.

13 Q. Now, are you aware that there are four patents at issue
14 in this case divided into two sets?

15 A. I am.

16 Q. Is one set referred to as the Bryhali® patents?

17 A. Yes.

18 Q. And is it your understanding that the Bryhali® patents
19 cover Bryhali® and Duobrii®?

20 A. Yes.

21 Q. Is the other set of patents referred to as the Duobrii®
22 patents?

23 A. Yes.

24 Q. And is it your understanding that the Duobrii® patents
25 cover Duobrii®?

1 A. Yes.

2 Q. Did you author opinions on the validity of the Bryhali®
3 and Duobrii® patents in this case?

4 A. I did.

5 Q. Do you expect to testify about your validity opinions
6 later in this trial?

7 A. I will.

8 Q. Thank you.

9 MR. BRUNO: I have no questions at this time.

10 THE COURT: Cross.

11 MR. ZIMMERMAN: Yes, Your Honor.

12 CROSS-EXAMINATION

13 BY MR. ZIMMERMAN:

14 Q. Good morning, Dr. Stein Gold.

15 A. Good morning.

16 Q. My name is Bill Zimmerman, and I represent the Padagis
17 defendants. I just have a couple of questions for you today.

18 If you could look at DX-009.

19 Do you have that document in front you?

20 A. Yes.

21 Q. Do you recognize this as the prescribing information for
22 Ultravate® Cream?

23 A. I do.

24 Q. And Ultravate® Cream contains halobetasol propionate at a
25 concentration of 0.05 percent, correct?

1 A. Yes.

2 Q. And it's been commercially available since at least 1995?

3 A. I would have to double-check, but okay.

4 Q. I believe you said it was launched in 1990, correct?

5 A. Right.

6 Q. Okay. So it's been publicly available since at least

7 1990?

8 A. Right.

9 Q. Okay. Now, if you look at the description heading on the
10 first page, you see that it's described as a topical
11 anti-inflammatory and antipruritic agent.

12 Do you see that?

13 A. Yes.

14 Q. And do you agree with that characterization?

15 A. I do.

16 Q. And Ultravate® is FDA approved for topical dermatologic
17 uses, correct?

18 A. Yes.

19 Q. And do you agree that it was known to use Ultravate®
20 Cream to treat psoriasis prior to 2010?

21 THE COURT REPORTER: Can you repeat the question?

22 BY MR. ZIMMERMAN:

23 Q. Do you agree that Ultravate® Cream was known to be useful
24 in treating psoriasis prior to 2010?

25 A. Yes.

1 Q. And Ultravate® contains halobetasol propionate, correct?

2 A. It does, yes.

3 Q. And in your deposition, you refer to that as a
4 tried-and-true molecule, right?

5 A. Yes.

6 Q. Now, the FDA limited the use of Ultravate® to no more
7 than two consecutive weeks, right?

8 A. Yes.

9 Q. And that limitation is because you can have HPA axis
10 suppression with Ultravate®, correct?

11 A. Yes.

12 Q. And that was a known limitation on Ultravate® in the
13 '90s, correct?

14 A. Yes.

15 Q. Now, two weeks of treatment, in your clinical experience,
16 is generally not long enough to treat most patients'
17 psoriasis, is it?

18 A. No.

19 Q. I'd like to shift gears, Dr. Stein Gold, and look at
20 DX-10.

21 Do you recognize this document as the prescribing
22 information for Tazorac® Cream?

23 A. I do.

24 Q. And the label indicates that Tazorac® Cream was marketed
25 in concentrations of 0.05 percent and 0.01 percent tazarotene,

1 correct?

2 A. Yes.

3 Q. Okay. And if you look at the highlights of prescribing
4 information, do you see that the U.S. approval date for
5 Tazorac® was 1997?

6 A. Yes.

7 Q. And under that same section, it also indicates that
8 tazarotene at a concentration of 0.05 percent was specifically
9 approved as a topical treatment for psoriasis, right?

10 A. Yes.

11 Q. And if you look at the lower portion of the page, DX-10
12 is dated 2013, correct?

13 A. Yes.

14 Q. So prior to June of 2015, tazarotene was FDA approved for
15 topically treating psoriasis at a concentration of
16 0.05 percent, wasn't it?

17 A. Yes.

18 Q. And you agree that 0.05 percent tazarotene would be
19 expected to be efficacious in treating psoriasis, right?

20 A. Yes.

21 Q. Now, I think you mentioned it in your direct, but can we
22 agree that tazarotene was known to have irritant effects prior
23 to 2015?

24 Can we agree that tazarotene was known to have
25 irritant effects prior to 2015?

1 A. It was.

2 Q. Now, the Duobrii® product is a combination of halobetasol
3 propionate and tazarotene, both of which were previously
4 approved drugs by the FDA, right?

5 A. Yes.

6 Q. And based on your experience in treating psoriasis, you
7 would agree that combination topical therapy is the standard
8 of care for most patients, right?

9 A. So combination in various different ways, including using
10 two different drugs at different times. But using more than
11 one medication that works by different mechanisms of action
12 was the standard of care.

13 Q. Okay. And that was the standard in 2015 as well,
14 correct?

15 A. Yes.

16 Q. Okay. If we could go back to your demonstrative
17 PDX-2-11, you indicate that Bryhali® had an equal potency to
18 Ultravate®.

19 Now, you're not contending that all of the
20 compositions encompassed by the '502 and '307 patents have
21 equal potency to Ultravate®, are you?

22 MR. BRUNO: Objection, beyond the scope.

23 THE COURT: What was the objection?

24 MR. BRUNO: Beyond the scope.

25 THE COURT: Overruled.

1 BY MR. ZIMMERMAN:

2 Q. Do you need me to repeat the question, please,
3 Dr. Stein Gold?

4 A. Please.

5 Q. So you said on your slide 2-11 that Bryhali® has an equal
6 potency to Ultravate®.

7 And I'm asking you, you're not contending that all of
8 the compositions encompassed by the '307 and '502 patents,
9 what plaintiffs refer to as the Bryhali® patents, have equal
10 potency to the Ultravate®, are you?

11 A. I'm saying that the Bryhali® itself has an equal potency
12 to the Ultravate®, that particular drug.

13 Q. And I'm asking, do you have an opinion as to whether the
14 rest of the compositions within the asserted claims are equal
15 potency to Ultravate®?

16 A. So maybe I need a clarification, because in the Bryhali®
17 patents, they mention that you can -- you know, basically the
18 Bryhali® patent is a recipe for adding different topical
19 corticosteroids at low concentrations.

20 So halobetasol is one of those superpotent
21 corticosteroids that should have and does have equal potency
22 to the Ultravate® -- so just that the -- when we put
23 halobetasol in that recipe of the patent, the halobetasol has
24 equal potency to the Ultravate®.

25 BY MR. ZIMMERMAN:

1 Q. And my question to you, Dr. Stein Gold, have you reviewed
2 the patents, the '502 and the '307 patents?

3 A. Yes. Right.

4 Q. You'll see that there were claims that you could have
5 concentrations of halobetasol less than 0.01 percent, correct?

6 A. Yes.

7 Q. You're not saying that those compositions that have less
8 than 0.01 percent halobetasol are equivalent to Ultravate®
9 with respect to potency, are you?

10 A. No, I'm just saying that this particular one, the
11 0.01 percent in this particular vehicle, has equal potency to
12 the Ultravate®.

13 Q. Okay. If we could go to your next slide, PDX-2-12.

14 You wrote that Duobrii® has superior efficacy and
15 tolerability.

16 Superior compared to what?

17 A. Superior compared to the individual ingredients and
18 superior tolerability compared to potentially tazarotene or
19 using the two as individual ingredients.

20 Q. Okay. And you're saying that with respect to the
21 specific compositions of Duobrii® only, correct?

22 A. Yes.

23 Q. Not any other composition disclosed in the '895 or the
24 '787 patent?

25 A. I'm speaking specifically here about Duobrii®.

1 Q. And have you seen anything to say that a composition,
2 other than Duobrii®, covered by those two patents experiences
3 what you call "superior efficacy and tolerability"?

4 MR. BRUNO: Objection, outside the scope.

5 THE COURT: Overruled.

6 THE WITNESS: Can you say it one more time, please?

7 BY MR. ZIMMERMAN:

8 Q. Yes.

9 Have you seen any data indicating that a composition,
10 other than the Duobrii®, covered by the '895 and '787 patents
11 elicits the superior efficacy and tolerability you're
12 discussing?

13 A. No.

14 Q. Now, I have one final question for you, Dr. Stein Gold,
15 Bryhali® and Duobrii®, they both contain the same vehicle,
16 that is the inactive ingredients in the same amounts, correct?

17 A. You'd have to double-check with the formulator, but I
18 believe that that's true.

19 MR. ZIMMERMAN: I have no further questions at this
20 time, Your Honor.

21 THE COURT: Thank you.

22 Any redirect?

23 MR. BRUNO: No redirect, Your Honor.

24 THE COURT: Thank you very much. You're excused.

25 MR. BRUNO: Your Honor, at this time we request a

1 break to get set up and take a customary 15-minute break
2 anyway.

3 THE COURT: Okay.

4 THE COURTROOM DEPUTY: All rise.

5 (Recess taken from 10:41 a.m. to 10:56 a.m.)

6 THE COURTROOM DEPUTY: All rise.

7 THE COURT: Be seated.

8 Let's proceed.

9 MR. BRUNO: Counsel next calls Dr. Radhakrishnan
10 Pillai to the stand.

11 THE COURT: Good morning, Doctor.

12 DR. RADHAKRISHNAN PILLAI, PLAINTIFF'S WITNESS,
13 having been duly sworn, testifies as follows:

14 DIRECT EXAMINATION

15 THE COURTROOM DEPUTY: Please state your full name
16 for the record.

17 THE WITNESS: Radhakrishnan Pillai.

18 THE COURTROOM DEPUTY: Please spell your first name
19 slowly and your last name.

20 THE WITNESS: Radhakrishnan Pillai,
21 R-A-D-H-A-K-R-I-S-H-N-A-N.

22 MR. BRUNO: And spell Pillai as well.

23 THE WITNESS: And the last name is Pillai, P as
24 Peter, I-L-L-A-I.

25 THE COURTROOM DEPUTY: Thank you.

1 BY MR. BRUNO:

2 Q. Good morning.

3 A. Good morning.

4 Q. Please introduce yourself to the Court.

5 A. My name is Dr. Radhakrishnan Pillai.

6 My name is Dr. Radhakrishnan Pillai. I am the vice
7 president for R&D at Bausch Health. I work at our R&D site,
8 which is based in Petaluma, California. That's it.

9 THE COURTROOM DEPUTY: Doctor, when you speak, speak
10 slowly, clearly and directly in the microphone so the court
11 reporter can understand every word.

12 THE WITNESS: Okay.

13 THE COURTROOM DEPUTY: Thank you.

14 BY MR. BRUNO:

15 Q. And what are you here to talk about today?

16 A. I'm here to talk about the formulation development for --
17 the product development, formulation development for Duobrii®
18 and Bryhali®.

19 Q. Are you an inventor on any of the patents that you
20 understand to be at issue in this case?

21 A. Yes, I am.

22 Q. Where did you go to school?

23 A. I did my bachelor's in pharmacy from University of
24 Mumbai, India. And then I did my master's in the field of
25 medicinal chemistry at Duquesne University in Pittsburgh. And

1 then I did my Ph.D. in pharmaceuticals at the University of
2 Michigan in Ann Arbor.

3 Q. Where did you work after school?

4 A. After school, I worked for a company called Healthpoint
5 Ltd.

6 Q. How long were you at Healthpoint Ltd.?

7 A. About six years.

8 Q. How did you end up working for Bausch?

9 A. So at around the end of the six-year time frame, I was
10 looking for a new opportunity and I actually applied and got a
11 job with the company called Dow Pharmaceutical Sciences, which
12 is based in Petaluma, California.

13 And then Dow Pharmaceutical Sciences eventually got
14 bought by Bausch, and that's how I started working for Bausch.

15 Q. What kind of company was Dow?

16 A. Dow Pharmaceutical Sciences was a contract development
17 company. And the main function was to develop formulations,
18 especially in the topical or the dermatological area.

19 And in addition, it was -- and in addition, they were
20 also involved in complete product development for
21 pharmaceuticals, pharmaceuticals.

22 Q. What kind of companies do you perform contract
23 development work for?

24 A. Pretty much the big companies that were involved in the
25 field of dermatology, companies like Medicis, Galderma,

1 Pfizer, Johnson & Johnson.

2 So Dow Pharmaceutical Sciences pretty much worked for
3 all of these companies.

4 Q. Why do these companies like Galderma and Pfizer come to
5 Dow?

6 A. Well, I think the biggest reason was their formulation
7 development expertise. They were -- they were really good at
8 formulation development. And that was headed up by Dr. Gordon
9 Dow, who was the founder of Dow Pharmaceutical Sciences. He
10 was very well known to be one of the best formulators for
11 topical dosage forms.

12 Q. And what is the relationship between Dow and the Bausch
13 entities in this litigation?

14 A. So Bausch bought Dow Pharmaceuticals in late 2008/early
15 2009. So Dow Pharmaceutical Sciences became a part of Bausch.

16 Q. At a high level, how are you involved in the development
17 of Bryhali®?

18 A. I was responsible for the overall management of the
19 Bryhali® project. It includes formulation development,
20 analytical development, clinical, nonclinical, clinical
21 pharmacology, all of those aspects.

22 When it came to clinical, it was more of an oversight
23 of the group as well as regulatory. But essentially, I was
24 responsible to the company for the project.

25 Q. At a high level, how are you involved in the development

1 of Duobrii®?

2 A. Exactly the same. I was responsible for the overall
3 management of the project, and my responsibility was directly
4 to the management.

5 Q. How did the development project for Bryhali® and Duobrii®
6 begin?

7 A. So the project actually began with the development for
8 Duobrii®. That was what we started with back in 2008.

9 Based on the results, some excellent results we got
10 for the Duobrii® project, we also initiated this project which
11 resulted in being Bryhali®.

12 Q. And what was the initial concept for the project?

13 A. So the initial concept or the idea came from Dr. Gordon
14 Dow. His idea was we should combine a retinoid and a
15 corticosteroid to give us a better product for the patients,
16 but as well as these two products would help each other in
17 terms of, for example, the corticosteroid would help with the
18 irritation -- would potentially help with the irritation from
19 the retinoid and the retinoid will help with the side effects
20 from the corticosteroid.

21 Q. Is Dr. Dow still at Bausch?

22 A. No, he is not.

23 Q. What was the goal of the development program?

24 A. So the goal was to combine a retinoid with a
25 corticosteroid to come up with a novel product which would be

1 better than products that existed in the market, which would
2 be extremely beneficial for the dermatology community as well
3 as the patients.

4 Q. And when you say "better," what do you mean by better?

5 A. Something where -- again, this is what we were designing,
6 something that would meet an unmet need that existed at that
7 point.

8 Q. Did you have an idea of the strength of the product you
9 were trying to achieve?

10 A. Can you repeat that question, please?

11 Q. Sure. Did you have an idea of the strength of the
12 product you were trying to achieve?

13 A. Well, when we initially conceptualized, the idea was to
14 come up with, you know, look at the products that were already
15 approved in the market, for example, Tazorac®.

16 The only retinoid approved was Tazorac®. And we
17 wanted to look at the concentrations of these. The 0.1 and
18 0.05 percent was approved.

19 And so we were targeting something close to those as
20 the concentration. And a corticosteroid, we were looking at
21 super-high potent corticosteroids. So we were looking at
22 something closer to like 0.05 percent.

23 Q. So did you want something stronger than a -- or as strong
24 as a superpotent corticosteroid?

25 A. Yes.

1 Q. Did you want something stronger or as strong as a
2 superpotent corticosteroid?

3 A. Correct. The goal was to match as much as possible the
4 strength of a superpotent corticosteroid in this combination.

5 Q. How did you refer to this development program internally
6 at Dow Pharmaceutical Sciences?

7 A. So, initially, back in 2008, this program was put under
8 what we call skunk works. And this was a term coined by our
9 founder, Dr. Dow, and this essentially represented early
10 development projects.

11 Eventually it was given -- once it was fully funded,
12 it was given a number IDP-118.

13 Q. Was IDP-118 ever commercialized?

14 A. Yes, IDP-118 currently -- the commercial product that
15 came out of that program is Duobrii®.

16 Q. Was Duobrii® the only commercial product to result from
17 the IDP-118 development project?

18 A. No. As I previously stated, Duobrii® was an initial
19 program and idea that we started with. But based on some of
20 the results, we actually were able to come up with another
21 product, another program, a project, which was IDP-122.

22 And that IDP-122 eventually became the commercial
23 product that is known as Bryhali®.

24 Q. Did you ever summarize the development history of IDP-118
25 or IDP-122 in internal documentation?

1 A. Yes, we did.

2 Q. Did you create a development report for IDP-118?

3 A. Yes. So we had the formula development, product
4 development reports for IDP-118.

5 MR. BRUNO: Let's take a look at PTX-67.

6 BY MR. BRUNO:

7 Q. Is this the development report that you created for
8 IDP-118?

9 A. Yes, it is.

10 Q. Did you also create a development report for IDP-122?

11 A. Yes, we did.

12 MR. BRUNO: Let's take a look at PTX-301.

13 BY MR. BRUNO:

14 Q. Is this the development report for IDP-122?

15 A. Yes, it is.

16 Q. What kinds of psoriasis treatments were available when
17 you started the IDP-118 development project?

18 A. Back in 2008, again, when the idea was conceived, the
19 majority of the therapies available for patients were
20 corticosteroids, and the most-used corticosteroids were the
21 superpotent corticosteroids.

22 Besides that, there were some other therapies. A
23 retinoid had been approved, which was tazarotene. A vitamin D
24 analog had been approved --

25 MR. BRUNO: -- Vitamin D.

1 THE WITNESS: Vitamin D analog, which was
2 calcipotriene. So these were the therapies that were
3 available for the dermatologists and the patients.

4 BY MR. BRUNO:

5 Q. Were there any marketed products with halobetasol in it?

6 A. Yes. There were two products with halobetasol propionate
7 in them. Both of them were under the trade name Ultravate®,
8 and one was a cream and one was an ointment.

9 Q. Did either product have light mineral oil in it?

10 A. No, none of the two products had light mineral oil in
11 them.

12 Q. Did the Ultravate® ointment have petrolatum in it?

13 A. Yes. The Ultravate® product did have the white
14 petrolatum, or petrolatum as we call it, yeah.

15 Q. And you mentioned petrolatum or white petrolatum.

16 Is there a real distinction in pharmaceuticals
17 between those two?

18 A. So when we use the petrolatum in pharmaceuticals,
19 generally, the product that is used is white petrolatum USP.
20 That's the one which is used by most pharmaceutical companies.

21 Q. What was the concentration of halobetasol in the
22 Ultravate® products?

23 A. 0.05 percent.

24 Q. How would you describe the field of psoriasis treatments
25 when you started the IDP-118 development project?

1 A. Again, as I previously stated, the products available,
2 the primary products available were corticosteroids. And the
3 main used were the super-high or the high potent
4 corticosteroids and tazarotene and calcipotriene.

5 Q. Were there a lot of corticosteroids available for
6 treatment of psoriasis at the time?

7 A. Correct. There were a bunch of corticosteroid available,
8 but, again, the most used were the super-high potent or the
9 high potent corticosteroids.

10 And these had certain limitations, as you'll see with
11 that. Essentially, they could be used for two weeks and maybe
12 in some cases up to four weeks. That's the super-high or the
13 high potent corticosteroids.

14 And then it comes to the other side, the tazarotene
15 or the calcipotriene. Both of them did not have this
16 restriction of a two- or a four-week, but they were highly
17 irritating compounds. And generally, its use was restricted
18 just because it was highly irritating.

19 Q. And you've mentioned tazarotene already. What were the
20 available concentrations of tazarotene when you were beginning
21 the IDP-118 development project?

22 A. So the available concentrations were 0.05 percent and 0.1
23 percent.

24 Q. Was tazarotene being used as a psoriasis treatment?

25 A. Yes. So tazarotene was available in the tradename called

1 Tazorac®, and it was approved -- sorry. It was approved for
2 the treatment of psoriasis, but it was not as much used
3 because of the reasons I stated, highly irritating.

4 Q. What types of vehicles were available at the time Dow set
5 out to make an improved psoriasis treatment?

6 A. Pretty much most of the vehicles that we currently see,
7 things like creams, ointments, gels, solutions. These were
8 all available.

9 Q. How many dermatological pharmaceutical ingredients were
10 available when you set out to make an improved psoriasis
11 treatment?

12 A. A lot. There is a lot of ingredients which were
13 available, which could be used. Because, again, as I said,
14 there were a lot of corticosteroid products and then, of
15 course, other products, right, products that were approved for
16 acne, for atopic. So there was a lot of ingredients that were
17 available.

18 Q. Did you envision what was going to work when you first
19 started the project?

20 A. No, absolutely not. Yeah.

21 Q. And why not?

22 A. Well, the whole concept is it's a derivative process.
23 You actually have to develop a formula, which is, in the first
24 place, stable. And then you have to prove that it actually
25 works. And this is, you know, obviously written in the law by

1 the FDA.

2 So you have to -- there's a lot of stuff that you
3 have to do to make sure that your product is actually working
4 and is meeting the requirements that you had set out.

5 Q. When did the IDP-118 development project begin to take
6 form?

7 A. So again, original was in 2008, when we started the
8 program. When this idea was conceived, we got into the skunk
9 work area and we started working on this program.

10 MR. BRUNO: Let's pull up PTX-37.

11 BY MR. BRUNO:

12 Q. Do you recognize PTX-37?

13 A. Yes. These are the minutes of a meeting that we had back
14 in 2008.

15 Q. Were you still vetting theories for the development
16 program in 2008?

17 A. Yes. We were still discussing and brainstorming about
18 this project.

19 Q. Who were the team members involved in the IDP-118
20 project?

21 A. There was several people who were involved. Some of the
22 ones, key members involved, were the ones listed on this page:
23 Arturo Angel, or Angel. Gina Martin. Of course, Gordon Dow,
24 Dr. Gordon Dow. Dr. Pramod Sarpotdar. Well, of course,
25 myself, R.K. I go by "R.K."

1 And then -- yeah. And these were the -- some of the
2 people who were involved in the formulation and managing the
3 project, yeah.

4 MR. BRUNO: Now I'd like to pull up Section 5 from
5 the IDP-118 development report, which is PTX-67.

6 BY MR. BRUNO:

7 Q. What were the different stages of the development
8 project?

9 A. Correct. So for formulation development, essentially the
10 stages that we follow were -- start off with a preformulation,
11 and then get into actual formulation or prototype development.
12 And then end with, once through all of the prototypes, select
13 the final formulation.

14 Q. After the initial conception of the project for a
15 combination product, what were the next steps in development?

16 A. So the next steps was come up with a -- to start off the
17 preformulation effort, right?

18 And preformulation, what we do during preformulation
19 is evaluate the solubility of these compounds in different
20 solvents. Evaluate the compatibility of these two compounds
21 that we are talking about in different solvents. So those
22 were the activities.

23 And, of course, we had to choose the two compounds,
24 so that was actually very frustrating.

25 Q. And did you choose the two active ingredients?

1 A. Yes. So the tazarotene was an automatic choice because
2 that was the only retinoid approved at that point.

3 And then among the corticosteroid, we decided to
4 choose one of the super-high potent corticosteroids available,
5 which was halobetasol propionate.

6 MR. BRUNO: Let's turn back to the August 2013
7 meeting minutes, which is PTX-37. And zoom in on the first
8 paragraph.

9 BY MR. BRUNO:

10 Q. What doses were you experimenting with?

11 A. So when we chose these, we decided that we will initiate
12 activities at the 0.09 percent for tazarotene and the
13 0.045 percent for halobetasol.

14 The reason behind them, and it was noted in the
15 minutes, was that the concentration of halobetasol, as I had
16 previously stated, in the Ultravate® products was
17 0.05 percent. And the concentration of Tazorac® or tazarotene
18 was either 0.1 percent or 0.05 percent.

19 And the management at that time, including Dr. Dow,
20 said that we should come up with a combination, but we should
21 not use the same concentrations that were already available in
22 the market.

23 So either we went up on the concentration or we went
24 down on the concentration. And what we -- what was decided by
25 management that we should target about 10 percent lower than

1 what was existing. So that's how we came up with that.

2 We definitely did not want to go high because that
3 means doing a lot more work for the FDA. So we decided to go
4 lower and about 10 percent lower. So that's how we came up
5 with 0.045 percent for halobetasol propionate and
6 0.09 percent, which was 10 percent lower than the highest
7 concentration of tazarotene approved.

8 Q. And by "management," are you referring to Dr. Dow?

9 A. Yeah. I mean, he was the founder and the owner. And so
10 there were a few other people, but yes, primarily him.

11 Q. Did you have any expectation when you started the idea of
12 putting halobetasol and tazarotene together that it would
13 work?

14 A. No. There was a hope and that there is a potential that
15 these should do what the idea that Gordon Dow -- Dr. Dow had,
16 you know, that, yes, that there was a -- you know, we were
17 hoping that this would actually do the job.

18 MR. BRUNO: Now let's turn to the fifth paragraph of
19 the August 2008 meeting minutes.

20 BY MR. BRUNO:

21 Q. At this point in the project, did you know what
22 formulation you wanted to develop?

23 A. No. No. I think we were pretty much open to any
24 formulation. Again, the ones I talked about, the gels,
25 lotions, creams, even a liposomal formulation. Any of these

1 formulations were open for us.

2 Q. So once the team had selected these active ingredients,
3 what was the next step in the development process?

4 A. So the next step was what I had previously stated would
5 be starting up with the preformulation efforts. So -- and the
6 first part we did on that was assessing the solubility of
7 these actives in different solvents.

8 Q. And is this work reflected in the IDP-118 development
9 report?

10 A. Yes, it is.

11 MR. BRUNO: Let's pull up table 5.2.1-1 of the
12 development report, which is PTX-67.

13 BY MR. BRUNO:

14 Q. What are we looking at on the screen in table 5.2.1-1?

15 A. So this table actually shows the solvents which were
16 evaluated to assess the solubility of halobetasol propionate
17 and then also some of the mixes of these solvents.

18 BY MR. BRUNO:

19 Q. For those of us without a chemistry degree, what's a
20 solvent?

21 A. Oh. A solvent generally is a liquid which will help
22 dissolve the active ingredient or any ingredient.

23 Q. Did you pick the specific ratios for your combinations
24 for any particular reason?

25 A. Oh. The ratios which were listed? No. There was no --

1 you know, as you can see, maybe focus on the top four, you
2 know, the DIPA IPM. So, as you can see, we did pretty much a,
3 you know, 2 is to 1, 1 is to 1, 1 is to 2.

4 So it was just a -- just a random, but just to assess
5 what are we looking at in terms of solubility.

6 Q. And why did you need to conduct solubility studies?

7 A. So with the dermatological products or topical --

8 THE COURT REPORTER: "Topical"?

9 THE WITNESS: Topical products -- well, for topical
10 products, you know, when you have the drug, it can be either
11 in a solubilized form or in a suspended form. And generally
12 it is always beneficial if the drug is in a solution.

13 So if the drug needs to be in a solution, we need to
14 assess what would be good solvents to keep the drug in
15 solution. And so that's why we ran these solubility studies.
16 And our goal was to keep it in solution.

17 BY MR. BRUNO:

18 Q. Did you know what the values on the right-hand column
19 were going to look like before you actually conducted the
20 studies?

21 A. No. We had no idea what it would turn out to be.

22 Q. Did you conduct the same type of studies for tazarotene?

23 A. Yes, we did.

24 MR. BRUNO: Let's pull up PTX-67 at table 5.2.1-2.

25 BY MR. BRUNO:

1 Q. Does this table reflect the results of your solubility
2 studies with tazarotene?

3 A. Yes, it does.

4 Q. And what do the results tell you?

5 A. Well, again, the -- just is -- the table just shows the
6 solubility for tazarotene in various solvents as well as mixes
7 of solvents.

8 Q. Did you know what the results on the right-hand column
9 were going to look like for the tazarotene solubility studies
10 before you actually conducted them?

11 A. No. No. Same answer. There's no way we could have
12 predicted these numbers.

13 Q. What was your next step after the individual solubility
14 studies were performed?

15 A. So the next step after -- you know, after we finished
16 these two sets of solubility, you know, having the individual
17 active ingredients assessed in various solvents or solvent
18 mixes, the next step was to put both of the active ingredients
19 into certain chosen solvents and solvent mixes.

20 Again, that is a -- you know, even though we knew
21 based on all the initial work how soluble halobetasol and
22 tazarotene were in some of these solvents by themselves, when
23 you mix them together, there is always a chance that the
24 solubility changes.

25 And these are things that bother you later in the

1 stage when -- you know, when you progress. So we wanted to
2 make sure that we understood this right now, whether this is
3 happening or not. And that's why we would do -- we did
4 something called simultaneous. So we would put both actives
5 into certain solvents together.

6 Q. Are the results of the simultaneous studies reflected in
7 the IDP-118 development report?

8 A. Yes, they are.

9 MR. BRUNO: Let's pull up PTX-67 at table 5.2.1-3.

10 BY MR. BRUNO:

11 Q. Does the table on the screen reflect the results of the
12 combined solubility studies?

13 A. Yes, they do.

14 Q. What was your next step after performing the combination
15 solubility studies?

16 A. So after we had finished the combination solubility
17 studies, the next step was to assess compatibility of the two
18 actives with these solvents.

19 Q. Why did you have to do that?

20 A. Well, the -- you know, the -- we were developing a
21 pharmaceutical product. And after we assessed some of the
22 solubility, we expect the drug to be in these solvents. And
23 then the drug product that comes out of it, hopefully, has a
24 long shelf life. Maybe two years, maybe three years.

25 So we needed to make sure that there is a

1 compatibility between the solvents and the drug actives.

2 MR. BRUNO: Let's pull up PTX-67 at table 5.2.2.

3 BY MR. BRUNO:

4 Q. Does this section of the IDP-118 development report
5 reflect the chemical compatibility studies that you performed?

6 A. Yes. They do reflect the chemical compatibility studies.

7 Q. And what are the solvents identified in table 5.2.2-1?

8 A. The solvents, some of the ones that are listed there:
9 diethyl sebacate, dibutyl sebacate, diisopropyl adipate, and
10 IPM, or isopropyl myristate.

11 MR. BRUNO: Now let's turn to the top of the next
12 page.

13 BY MR. BRUNO:

14 Q. Were any solvents ruled out during the compatibility
15 study?

16 A. Yes. During that compatibility study, we did see that
17 there was an incompatibility between tazarotene and dibutyl
18 sebacate. And, therefore, that pretty much ruled out for us
19 dibutyl sebacate.

20 Q. How did diethyl sebacate perform?

21 A. Diethyl sebacate was compatible with both of the actives.

22 Q. How is dibutyl sebacate related to diethyl sebacate?

23 A. So dibutyl sebacate -- I mean, both have sebacate, the
24 ester sebacate. And the only difference between them are in
25 one case it is diethyl, which is two carbons, and in the other

1 case is dibutyl, which is four carbon, two of these
2 four-carbon compounds.

3 So they are very closely related. I mean, they
4 are -- you know, when you do structure relationships, they
5 would belong to one family of compounds.

6 Q. Were these results surprising to you?

7 A. Yeah. Extremely surprising. We do -- you know, in the
8 world of when we do these developments, we do expect that some
9 of these solvents may have different solubility properties.

10 But when they are so closely related, we do not
11 expect a compatibility difference between like, for example,
12 in the case diethyl sebacate and dibutyl sebacate.

13 So this was -- this definitely was surprising for us.
14 And that's why we do these studies, so, you know.

15 Q. Had the formulation vehicle been set after you completed
16 the solubility and compatibility studies?

17 A. No. No. So that was only the first stage of
18 development.

19 Q. What was the next stage?

20 A. So the next stage was to develop the prototypes, or
21 formula development, as we call it. So we have formulation
22 development. So that's what we started right after finishing
23 these preformulation studies.

24 MR. BRUNO: Let's turn to PTX-67 at table 5.3.1-1.

25 BY MR. BRUNO:

1 Q. Does table 5.3.1-1 reflect some of the prototypes that
2 you selected at the time?

3 A. Yes, it does. It does reflect some of the prototypes
4 which were developed in this formulation development effort.

5 Q. Were these all the prototypes?

6 A. No, absolutely not. There was a whole host of
7 formulations that were put together and developed.

8 But these were the ones which were chosen for -- you
9 know, for their evaluation for multiple reasons. It could be
10 stability or some other reason.

11 Primarily, it was stability, you know. If we didn't
12 get comfortable with the stability of the actives, the APIs,
13 you know. Actives, yeah.

14 BY MR. BRUNO:

15 Q. What nomenclature did you use to differentiate prototypes
16 from one another?

17 A. So right on the first row there, you can see this number,
18 the label LB-090. So that essentially stands for "lab book,"
19 lab notebook, and the number of the lab notebook is 90 or 090.

20 And then each of those numbers following, like 39,
21 40, 41, 42, so these would be the actual identifying
22 formulations, you know, which -- you know, which is reflected
23 below.

24 Q. What did you do after you chose the prototypes?

25 A. So because one of the active ingredients we were dealing

1 with is -- was corticosteroids, we decided that we will, we
2 wanted to, obviously, develop what would be ideal strength for
3 the corticosteroid halobetasol propionate.

4 And we decided that we would do what is called a
5 vasoconstrictor assay, known as VCA assay. So that's what we
6 first decided we would do.

7 Q. What is a VCA assay?

8 A. So the VCA is vasoconstriction assay. Essentially, when
9 you put a corticosteroid product on your skin, what it does is
10 it constricts the blood vessels.

11 And when it does constrict the blood vessels, it
12 reduces the blood going to that part of the skin, which causes
13 that part to be blanched. Or they call it skin blanching or
14 skin whitening.

15 And some really good experts were -- studied this and
16 came up with the fact that that level of skin blanching can be
17 correlated to the potency of these corticosteroids.

18 So that's what the vasoconstrictor assay is involved.

19 Q. Were the prototypes similar to one another?

20 A. No. As you can see, there was differences between most
21 of the formulations here. In some cases, it is the difference
22 in the percent amount, sometimes it's just the ingredients
23 were different. And each of them were unique.

24 Q. Were there differences among the active ingredients?

25 A. Yes. So, for example, you're seeing the halobetasol

1 propionate on the top. And we evaluated multiple different
2 concentrations of this active ingredient, halobetasol
3 propionate, from 0.01 to 0.025, 0.035.

4 Q. Did you have any expectation at the time which system
5 would perform better than the others?

6 A. No, no. And that's the whole point of us conducting this
7 vasoconstrictor assay. I mean, you know, there's -- from a
8 logic, you would think that if it's lower concentration, you
9 may get less of the vasoconstriction or the skin blanching.

10 But again, that's not -- you know, we obviously got
11 the study to evaluate that.

12 MR. BRUNO: Let's turn to PTX-67 at table 5.3.1-1, as
13 we had up on the screen. And let's put that next to Figure 3
14 from the report.

15 BY MR. BRUNO:

16 Q. Now, does Figure 3 reflect the results of the VCA
17 studies?

18 A. Yes. So the Figure 3 is the plot of the results of the
19 VCA study.

20 Q. And how does Figure 3 correlate to table 5.3.1-1?

21 A. Correct. So as I had previously explained, on the top
22 row, you have those LB-090-39. So that one was the first
23 column in the graph in Figure 3 and so on.

24 So if you go to the next one, it was LB-090-40,
25 LB-090-41. So essentially, these were the prototypes in the

1 vasoconstriction assay.

2 And then last row, to the far right, was the RLD. It
3 was called RLD, which meant "reference listed drug." And that
4 was the control we used, which was Ultravate® cream 0.05
5 percent. 0.05 percent.

6 BY MR. BRUNO:

7 Q. What did you conclude from this first round of VCA
8 testing?

9 A. Well, I mean, it is evident that we got some surprising
10 results. We saw that for certain formulations that we had
11 developed, you know, that the first four of them, as you can
12 see, those numbers of vasoconstriction were similar to the
13 reference product, the Ultravate®, on the far right. And some
14 of the formulations, the next three of them, did not actually
15 match up with Ultravate®.

16 So this was definitely -- the results on the left was
17 very definitely very surprising to us, especially when you
18 look at the range. You know, even down to 0.01 percent, which
19 is about 20 percent of Ultravate® concentration, we were able
20 to see -- get the same level of skin blanching or
21 vasoconstriction.

22 Q. What was the next step of the development program?

23 A. So the next step for us was we needed to further
24 evaluate. So, as I stated, it was exciting and very
25 surprising to see the 0.01 perform the way it did, so we

1 wanted to further test this out. We wanted to do a second VCA
2 study.

3 And this is a very important step in our development.
4 Again, you know, this could help us determine what would be
5 the concentration. So we decided we would do a second
6 vasoconstriction with a second set of prototypes.

7 MR. BRUNO: Let's pull up table 5.3.2-1.

8 BY MR. BRUNO:

9 Q. This table that's up on the screen, does it reflect the
10 results of the second VCA test?

11 A. Yes, it does. So this was the results from the second
12 VCA.

13 Q. Had you settled on a specific concentration of
14 halobetasol before conducting the second VCA study?

15 A. Well, for the second VCA study, again, as you see on the
16 first row of listed halobetasol propionate, we were now
17 evaluating two concentrations.

18 So 0.01, which, again, as I had previously stated, we
19 wanted to make sure that that's actually, you know, going to
20 repeat, you know, show the same, as well as 0.025 percent. So
21 we had basically restricted down to two concentrations at this
22 point.

23 Q. Why did you have to make sure that the 0.01 was going to
24 repeat the same?

25 A. Again, so as I stated, it was extremely surprising when

1 we did our first VCA study to have seen the 0.01 percent
2 formulation be the same or similar to Ultravate®.

3 So we made several different formulations of 0.01,
4 and then we wanted to just confirm. This is one of the
5 reasons. And again, further evaluate different prototypes.

6 Q. And how did the other ingredients of the prototypes
7 become selected?

8 A. Well, some of the ingredients that we already talked
9 about. Like, we chose the dibutyl sebacate and some of these
10 ingredients were chosen based on the solubility studies.

11 And then the rest of the ingredients that we are
12 seeing would help for different facets, right? Either
13 stabilizing, microbiologically protecting the product. Those
14 would be like the -- can you highlight it for me?

15 The methylparaben and propylparaben listed on the
16 bottom of the table, those two. So those would help with
17 preserving microbiologically. And then -- and, you know. So
18 EDTA, which is the list -- oh, yeah. So I'm pointing it in
19 mine, but yeah.

20 So those would be the, you know, ones which we use to
21 help stabilize the product.

22 BY MR. BRUNO:

23 Q. How did you select the diethyl sebacate for the
24 prototypes?

25 A. So we had -- you know, from all the preformulation

1 efforts. And also the stability -- you know, the stability on
2 the formulations that we had seen, diethyl sebacate checked
3 all the boxes for us.

4 It was -- had enough solubility for the two actives,
5 was compatible with the two actives. The formulations that we
6 prepared with it were stable. And last but not the least, we
7 got pretty good results in our vasoconstriction assay.

8 So all of those, you know, pulled us towards diethyl
9 sebacate as one of the key ingredients.

10 Q. What were the results of the second set of VCA studies?

11 A. So again, as you see in the bottom row there, we were
12 able to validate that the 0.01 percent that we had first
13 tested still showed very similar vasoconstriction of the
14 validity to the control.

15 In this case, we decided to use fluocinonide cream
16 USP, which is also a high or super-high potent corticosteroid,
17 and we got pretty much the same. And so that was one of the
18 key findings from this study.

19 Q. What was your reaction to the results of the second VCA
20 study?

21 A. And so we were initially surprised with the first VCA
22 study. And then the second study was absolutely, you know,
23 confirmatory.

24 It was exciting for us because -- you know, we had
25 come up with a concentration that had never been developed

1 before for a corticosteroid, for the same corticosteroid that
2 existed in the market at 20 percent, and we were developing
3 it -- we could be potentially developing a product at
4 20 percent of that.

5 And so that was very exciting for us, so it opened up
6 a lot more doors. You know, it made the project more
7 fundable. Let's put it that way.

8 Q. What was the next step in the development project of the
9 combination product?

10 A. So even though we had these exciting results on 0.01, we
11 still -- we still did not want to give up on the
12 0.025 percent. So what we did was we did some skin
13 penetration with some of these prototypes that we had
14 developed.

15 MR. BRUNO: Let's turn now to PTX-67 at
16 Table 5.3.3-2.

17 BY MR. BRUNO:

18 Q. Does this table reflect the in vitro skin penetration
19 results?

20 A. Yes, it does.

21 Q. How much tazarotene did you use in the prototypes for the
22 in vitro skin penetration studies?

23 A. So tazarotene, which is in the first row, we pretty much
24 used the same concentration, which was the 0.09 percent at
25 that point.

1 Q. How much halobetasol did you use?

2 A. So the halobetasol, as we had gotten from our
3 vasoconstriction. So we restricted it to now two
4 concentrations, which was the 0.01 percent and then the
5 0.025 percent. So those were the two concentrations that --
6 for halobetasol.

7 Q. What did the in vitro skin permeation results reveal to
8 you?

9 A. So, overall, the skin penetration results revealed that a
10 lot of these formulations that we were testing were -- a lot
11 more of these drugs were actually going through the skin into
12 what we call the receptor phase, which reflects the blood
13 vessels, the bloodstream, the blood under the skin. So
14 that's -- that was what we saw in these -- in the skin
15 penetration study.

16 Q. What did you understand scientists were normally trying
17 to achieve when they perform a skin permeation test?

18 A. So normally, then, when scientists do these skin
19 penetration studies, they're looking to drive as much drug
20 through skin, right, through the epidermis, through the dermis
21 and looking at the receptor phase.

22 So just below the dermis, we would call that -- we
23 call what is called the receptor phase. And the higher that
24 amount, the better the formulation.

25 So that's what most scientists would do.

1 Q. What were you hoping for?

2 A. So in our case, based on the formulations, we were
3 actually looking to have as low amount of drug get into this
4 receptor phase.

5 So, you know, again, when I had previously stated
6 there were some side effects that we had seen with these
7 corticosteroids, and those were like systemic side effects
8 called HPA axis suppression, which is the reason FDA restricts
9 their use to two weeks and four weeks.

10 So we wanted to make sure that that was not going to
11 be the case for us. So we were trying to restrict the amount
12 getting into the receptor phase.

13 Q. Before you had conducted the skin permeation study, did
14 you have an expectation of how it would turn out?

15 A. No. No. We had -- we had no way to have predicted what
16 would have happened in the skin penetration studies.

17 Q. What change to the formulation, if any, did you make as a
18 result of the skin penetration studies?

19 A. So one of the change that we did was we had this
20 ingredient, propylene glycol, which was part of the
21 formulation.

22 Propylene glycol has a bad rap. Essentially, it is
23 kind of referred to as an irritating ingredient. If it is
24 used -- irritating. It irritates the skin. And irritation of
25 skin generally can allow for the skin to get inflamed and

1 could allow for more drug to go in.

2 So we decided -- one thing we decided, even though we
3 had not evaluated the irritation, we said, Let's -- you know.

4 The property of -- for propylene glycol that we had
5 included in the formulation was because it was a humectant,
6 something which would keep water. And we replaced it with
7 another humectant, sorbitol. So we decided that's a switch we
8 could do, again, in the anticipation that we wanted to lower
9 the potential irritation.

10 Q. Did you make any changes to the active ingredients?

11 A. For the halobetasol propionate, no. We stuck with the
12 two concentrations, the 0.01 and the 0.025.

13 But for the tazarotene, which was at 0.09 percent, we
14 decided -- and we know that tazarotene is -- or it was known
15 that tazarotene is a pretty irritating ingredient. And for
16 the same reason that I just talked about, we decided to just
17 cut the tazarotene by half to 0.045 percent.

18 Q. Did you optimize the 0.045 percent concentration?

19 A. No. No. We just decided to cut it to half, you know, to
20 the 0.045 and left it at that.

21 Q. Did you conduct any testing of other concentrations of
22 tazarotene, like 0.035 percent or 0.025 percent?

23 A. No, we did not.

24 Q. Do you know whether any concentration of tazarotene might
25 work better than the 0.045 percent?

1 A. I wouldn't know. You have to test it. You have to try
2 it out. I mean, maybe lower concentrations would have been
3 equally good or better. Again, I wouldn't know.

4 MR. BRUNO: Let's turn now to Table 5.3.4-1.

5 BY MR. BRUNO:

6 Q. What does Table 5.3.4-1 tell you about the lead
7 compositions?

8 A. So this was a combination of our formulation development
9 efforts. And we had two lead formulations that we had
10 developed.

11 In one case, we -- the halobetasol propionate was at
12 two different concentrations, the 0.01 for the A and 0.025 for
13 the B. And then for the tazarotene, we kept both of these at
14 0.045.

15 Q. Did Bausch ultimately settle on a concentration of
16 halobetasol?

17 A. Ultimately, we did set on a concentration for halobetasol
18 propionate. And that ended up to be 0.01 percent, the magical
19 0.01 percent for -- from the VCA study, yeah.

20 Q. Is this where drug development stopped?

21 A. No. No. So this is where we -- our formulation
22 development, you know, came to some sort of a plateau. And we
23 still had to do a whole bunch of animal, nonclinical studies
24 as well as clinical studies in order to further develop these
25 products -- this product.

1 Q. How long from the conception of the idea to the final
2 vehicle did your work take?

3 A. About three to four years it took for us to get to this
4 stage.

5 Q. Now I'd like to switch gears and talk to you more about
6 some of the clinical testing.

7 What phases of testing did you conduct as part of the
8 IDP-118 and IDP-122 development programs?

9 A. So as part of the 118, again, so as I said before, this
10 program was all IDP-118. The other program was not in -- had
11 not been even initiated, or we didn't even know that there was
12 going to be one.

13 So for IDP-118, we conducted a bunch of studies,
14 including Phase 1. These are, like, cumulative irritation,
15 sensitization, and also systemic exposure studies, which is
16 basically how much drug gets into the blood.

17 Then some Phase 2 studies, primarily safety and
18 efficacy studies. And then the pivotal Phase 3 studies. And
19 then also, we also conducted a one-year long-term safety
20 study. So...

21 MR. BRUNO: Let's turn first to IDP-122.

22 BY MR. BRUNO:

23 Q. Did Bausch ever conduct a VCA study comparing the potency
24 of Bryhali® and Ultravate®?

25 A. Yes, we did conduct a VCA study comparing the potency for

1 Bryhali® and Ultravate®.

2 Q. What did that show?

3 A. It showed us that -- confirmed what we had seen before
4 for -- we saw that vasoconstriction potency, or the potency of
5 Bryhali®, was very similar to that of Ultravate®.

6 Q. Did Bausch ever compare the efficacy of IDP-122, which
7 was later marketed as Bryhali® --

8 Did Bausch ever compare the efficacy of IDP-122,
9 later marketed as Bryhali®, to Ultravate® in a clinical
10 setting?

11 A. Yes, they did.

12 Q. Was the protocol and results of this study summarized
13 anywhere?

14 A. Yes. It was summarized in our NDA.

15 MR. BRUNO: Let's pull JTX-012-10.

16 BY MR. BRUNO:

17 Q. Is this the clinical study report that summarizes the
18 efficacy testing between Bryhali® and Ultravate®?

19 A. Yes, this was the study report that summarized that --
20 that study, yes.

21 Q. Can we refer to JTX-012-10 as the 203 study?

22 A. Yes.

23 MR. BRUNO: Let's turn to the heading 9.1. And if we
24 can blow out the two paragraphs that are underneath that
25 heading.

1 BY MR. BRUNO:

2 Q. How was the 203 study conducted?

3 A. So the 203 study was a comparison of Ultravate® cream
4 with Bryhali®. It's a safety and efficacy comparison, so we
5 enrolled about 150 subjects and split them up into four arms.
6 It was a double-blind -- again, on the top, the first sentence
7 there, "Double-Blind, randomized, parallel group study
8 design."

9 So we had Ultravate® cream, Bryhali®, which was
10 IDP-122 lotion, the vehicle cream and a vehicle lotion; again,
11 for double-blinding purposes. And we conducted this study
12 with a treatment duration of two weeks and evaluated at the
13 end of two weeks the efficacy and safety.

14 Q. Why was the study performed for only two weeks?

15 A. Because we were including Ultravate® cream in the study,
16 Ultravate® cream was restricted to only two weeks of use. So
17 when we conduct our study, we had to restrict the study to two
18 weeks, just because even though we are doing this under IND,
19 Investigational New Drug application with FDA, FDA does not
20 want us to investigate Ultravate® because that was already
21 approved. So we are not allowed to go anywhere beyond two
22 weeks if we have Ultravate® in the study.

23 MR. BRUNO: Now let's turn to the bullet that's
24 summarizing efficacy on Page BAU00262835.

25 BY MR. BRUNO:

1 Q. How did you measure efficacy in the 203 study?

2 A. Efficacy was measured as shown in that first bullet
3 point. So essentially it is the percent of subjects with
4 treatment success, and these subjects were enrolled as
5 moderate to severe. You know, when we got them into the
6 study, they had moderate to severe plaque psoriasis.

7 And then we were looking for improvement in that
8 plaque psoriasis, and moderate to severe reflects three or
9 four in the scale that we were using for the severity. And so
10 we were looking for at least a two-grade improvement from
11 baseline and also that they would be clear or almost clear,
12 which is a score of zero or one.

13 So essentially we are comparing -- and that was
14 defined as treatment success so we were comparing the
15 treatment success for Ultravate® cream versus Bryhali®.

16 Q. Does this scale have a well-recognized name?

17 A. Again, sorry. Can you repeat that?

18 Q. Does the numerical scale you were just describing have a
19 recognized name?

20 A. Yes. So this is referred to as the Investigative Global
21 Assessment scale.

22 Q. And is that abbreviated IGA?

23 A. IGA, yes. That's what we call, lovingly, IGA. Yes.

24 MR. BRUNO: Now, if we could turn to the first
25 paragraph on Page BAU00262885, with the efficacy underlined.

1 BY MR. BRUNO:

2 Q. What did the efficacy results of the 203 study
3 demonstrate?

4 A. So as it's shown in the last sentence of that paragraph,
5 in the IDP population, 30 percent of the subjects in the
6 IDP-122 and 31.58 in the Ultravate® cream had treatment
7 success, essentially reflecting that they are very similar in
8 terms of efficacy.

9 Q. What was your reaction when you learned of the results of
10 the 203 study?

11 A. Again, and I think these were just, you know, culminating
12 in all of the efforts that we had gone through, this was
13 further proof and this was, again, elation for us because, you
14 know, even though we had done all these vasoconstrictions,
15 which was a single application on skin, on healthy skin -- how
16 it would perform with psoriasis subjects was still an unknown.
17 And this was great news for us; that it actually showed
18 exactly what we had wanted or expected and we got something
19 which was similar to Ultravate®.

20 MR. BRUNO: Now I'd like to turn your attention back
21 to IDP-118.

22 BY MR. BRUNO:

23 Q. After having made the decision to proceed with a
24 0.01 percent halobetasol, 0.045 percent tazarotene product,
25 what further studies did you conduct?

1 A. So for the IDP-118 program, we -- after we had the
2 strengths decided, we decided we would do the first study
3 which would be a combination study. It's a study to address
4 the combination rule that is required by the FDA.

5 And that's the first study that we conducted.

6 Q. Around the time that you conducted these studies, did you
7 consult with dermatologists about whether they thought the
8 product would work?

9 A. Correct. We did consult with dermatologists primarily on
10 the design of the clinical study; what are the different
11 aspects, what do we evaluate. Not asking them about, you
12 know, is this product going to work, but unsolicited, we got
13 advice from them.

14 Some of them were surprised that we were actually
15 moving forward with such a concentration, especially on the
16 halobetasol is where they were concentrating. And in some
17 cases, at least in one case, we were also labelled as -- that
18 we were crazy to move forward with this kind of a low
19 concentration on halobetasol.

20 Again, their focus was halobetasol.

21 Q. Were you involved in the pivotal Phase 2 study for
22 IDP-118?

23 A. I was definitely involved in the Phase 2 -- the study
24 that I talked about, the combination rule study, yes.

25 Q. How were you involved?

1 A. I was involved with, you know, the design of the study,
2 the synopsis. I talked about we talked to several
3 dermatologists. So developing the synopsis for the study and
4 then working with the clinical operation group in managing the
5 study. Of course, they managed the study, but we oversaw all
6 aspects of the program.

7 Q. Did Bausch document the conduct and results of its Phase
8 2 studies for IDP-122?

9 A. Yes, we did.

10 MR. BRUNO: Let's pull up JTX-12-9 at BAU00249125.

11 BY MR. BRUNO:

12 Q. And is this part of the clinical report for the Phase 2
13 study?

14 A. Yes. As you can see at the top, this was the study, the
15 118-A-201, yes.

16 Q. And can we refer to this as the 201 study?

17 A. Yes, we can.

18 Q. What was the design of the 201 study?

19 A. So as shown in the second paragraph, essentially it
20 was -- we had to do the combination. We had to address the
21 combination rule from the FDA. So the design involved a
22 four-arm study.

23 The first arm is the actual combination, the IDP-118,
24 compared to its vehicle, which is the second arm, and then the
25 third and fourth arm were what we call as monads or just the

1 individual --

2 THE COURT REPORTER: Mondads?

3 THE WITNESS: Monad, M-O-N-A-D. Monads.

4 Essentially, that is the term that is for just --
5 when you are developing a combination when you have the
6 individual ingredients. So there was one arm with halobetasol
7 propionate at 0.01 percent, and then the one arm with
8 tazarotene at 0.045 percent. So those were the four arms.

9 And this was double-blinded. Again, if you look at
10 the first line of the first paragraph, "Multicenter,
11 double-blind, randomized, parallel group study."

12 BY MR. BRUNO:

13 Q. As part of the development of IDP-118, do you believe it
14 was necessary to conduct the 201 study?

15 A. Absolutely. This is, as I said before, any combination
16 product that is developed has to meet the combination rule
17 that the FDA specifies. And, essentially, you have to -- what
18 that means is you have to show the contribution of each of the
19 actives in your formulation towards the final product.

20 MR. BRUNO: Your Honor.

21 THE COURT: Yes.

22 MR. BRUNO: We'll be about another 10 to 15 minutes,
23 and I'm cognizant that we're approaching the lunchtime.
24 Should we take a break now and then come back?

25 THE COURT: That's fine. Thank you.

1 THE COURTROOM DEPUTY: All rise. You only have 15
2 minutes left?

3 MR. BRUNO: I'm sorry?

4 THE COURTROOM DEPUTY: How much longer did you say
5 you have?

6 MR. BRUNO: I would say about 10 to 15 minutes.

7 THE COURTROOM DEPUTY: We only have 10 more minutes
8 to go until lunch. Do you want to keep going?

9 THE COURT: What do you want to do?

10 MR. BRUNO: Your Honor, I think it would be our
11 preference for lunch, but we're, obviously, of course --

12 THE COURT: No, if you want to finish, we'll finish.

13 MR. BRUNO: No, no, no. It's our preference for
14 lunch, actually, Your Honor, but we're happy to, of course,
15 indulge the Court if it has a different preference.

16 THE COURT: Whatever your pleasure is.

17 MR. BRUNO: Okay. Why don't we take a lunch break
18 now for half an hour.

19 THE COURT: Fine.

20 (Lunch recess taken at 12:13 p.m.)

21 THE COURTROOM DEPUTY: All rise.

22 AFTERNOON SESSION

23 (In open court at 12:49 p.m.)

24 THE COURT: Be seated.

25 Doctor, we're going to hold you to counsel's

1 representations. You got 15 minutes.

2 MR. BRUNO: Thank you, Your Honor. May I proceed?

3 BY MR. BRUNO:

4 Q. Now, Dr. Pillai, before the break, we were talking about
5 the IDP-118 Phase 2 study.

6 Do you remember that?

7 A. The combination study, yes. Yes.

8 Q. As part of the development, did you believe it was
9 necessary to conduct the 201 study?

10 A. Yes, it was required for us from the FDA to conduct that
11 study.

12 Q. How important is it to conduct Phase 2 studies before
13 selling your product?

14 A. The Phase 2 studies, such as part of our normal
15 development process, those Phase 2 studies are followed by
16 Phase 3 studies. And in some cases like us, we had to do a
17 long-term safety study and submit for approval and hopefully
18 get approved and then we could sell the product.

19 So there was a lot more steps to meet after that.

20 Q. Was any IDP-118 sold during the conduct of the 201 study?

21 A. Absolutely not, no.

22 MR. BRUNO: Let's pull up PTX-12-9 at Table 1.

23 BY MR. BRUNO:

24 Q. How long was the study period?

25 A. As shown on this table, it was 12 weeks; eight weeks of

1 treatment and four weeks of follow up.

2 Q. Is 12 weeks unusually long for a Phase 2 study?

3 A. No.

4 Q. What kinds of confidentiality restrictions were in place
5 for the 201 study?

6 A. So in terms of confidentiality, we had confidentiality
7 agreements in place with the contract research organization to
8 help us -- who was helping us run the clinical studies, the
9 different groups, like biostatistics group, database
10 management group, medical monitor, all of these guys had
11 confidentiality, as well as the dermatologists who were the
12 investigators. They all had to be signing a confidentiality
13 agreement.

14 Q. Were records maintained during the conduct of the 201
15 study?

16 A. Yes, there were.

17 Q. What types of records were maintained during the conduct
18 of the 201 study?

19 A. So as you see on the document that is shown here, or the
20 slide that is shown here, it shows a study schedule of
21 assessment. So this actually is part of a protocol. So the
22 first part we're saying is there is a protocol in place for
23 the study.

24 And then all of those stuff that it just says there,
25 baseline, week two, week four, week six, and then there are Xs

1 against a lot of rows, so all of those are data that is
2 actually collected on the days that the patient comes in.

3 So week two would be the patient comes in for a
4 week-two visit, we call it, and then all of the information,
5 the Xs, are then collected, and they are collected for every
6 visit, and then all of them are kept at the site and,
7 obviously, passed on to the central database management.

8 Q. Does Bausch have a team that monitored the conduct of the
9 201 study?

10 A. Yes. So we had a clinical operations team which was
11 managing the conduct of the study.

12 Q. Was the 201 study posted publicly anywhere before the
13 study was completed?

14 A. The essential aspects of the design of the study was
15 posted in ClinicalTrial.gov, and this is something we have to
16 do before we start a study. This is a FDA requirement.

17 Q. What role did you play in having the 201 study posted on
18 ClinicalTrials.gov?

19 A. I just had to make sure it happened.

20 Q. Now let's talk about what you learned from the 201 study.

21 When Bausch sponsored the study, did you have any
22 expectations about its outcome?

23 A. No, absolutely not. We were running the study to --
24 essentially what we were hoping is to satisfy the combination
25 group.

1 Q. In terms of efficacy, what was the goal for the
2 performance of the IDP-118 product in the 201 study?

3 A. So first and foremost, we obviously hoped that the
4 IDP-118 was better than the vehicle, but all and above, we
5 also hoped that it would also be better than each of the
6 individual components. And, essentially, you will get some
7 contribution from both actives to give us this product that we
8 were hoping to get out of it.

9 Q. Do you recall receiving the results of the 201 study?

10 A. Yes, I did.

11 MR. BRUNO: Let's pull up PTX-243.

12 BY MR. BRUNO:

13 Q. Dr. Pillai, what is PTX-243?

14 A. This was an e-mail sent by Dr. Binu Alexander to a few of
15 us telling us -- sending us the TopLine Data from the Phase 2
16 study there, the 201 study.

17 Q. When was this e-mail received by you?

18 A. So this was received, as it says there, on the 26th of
19 November. It was just a day before Thanksgiving.

20 Q. What was attached to this e-mail?

21 A. The TopLine Data for the 201 study.

22 Q. What is TopLine Data?

23 A. So once we finish the study, all of the data is put
24 together, and then we analyze the data for the outcome. Those
25 tables and listings that we put together could be voluminous,

1 it could be a lot of pages. For us, we needed to just see
2 some of the key ones, key efficacy tables, key safety tables,
3 key demographic tables -- not all of them -- just so we know,
4 is this study successful. And you get those tables within a
5 week of closing, you know, finishing up the study and rather
6 than waiting for about six weeks to eight weeks.

7 So that's what the TopLine Data is, and these are
8 standard for most pharmaceutical companies.

9 Q. Do you review the TopLine Data?

10 A. Yes, I did, that very evening.

11 Q. What did you determine from the TopLine Data?

12 A. Again, this is -- this is going back to my memory, which
13 is this was one of the most exciting -- this is one of the
14 best projects I've been involved with. And the results from
15 this study was one of the best I've ever seen, right. And it
16 was beyond any expectations for us.

17 Q. And when you say "best," what do you mean by that?

18 A. The results for 118 was better than anything that had
19 come prior to that in terms of its efficacy, you know, the
20 treatment success. Over 50 percent treatment success. Over
21 50 percent of the patients actually got clear or almost clear.
22 And that had never been seen previously in any -- you know,
23 for any topical psoriatic clinical study.

24 Q. And why were those results so surprising to you?

25 A. Because we were hoping, as I said, that it would be

1 better, but we just didn't expect it to be this good. Again,
2 as I'm saying, about 50 percent is not an easy outcome for a
3 product that is applied directly on the skin.

4 Q. What did you later determine about the data?

5 A. Later, you know, a few weeks, maybe a few months later,
6 we did determine that it also actually was -- showed
7 synergistic behavior.

8 Q. Dr. Pillai, we can see from the e-mail that Mr. Alexander
9 was wishing you a Happy Thanksgiving. Did you have a Happy
10 Thanksgiving that year?

11 A. Absolutely. That was one of our best Thanksgivings for
12 all of us, including me.

13 MR. BRUNO: Thank you. I have no further questions.

14 THE COURT: Your witness.

15 MR. ZIMMERMAN: Your Honor, may I approach?

16 THE COURT: You may.

17 CROSS-EXAMINATION

18 BY MR. ZIMMERMAN:

19 Q. Good afternoon, Dr. Pillai.

20 A. Good afternoon.

21 Q. My name is Bill Zimmerman, and I have a few questions to
22 ask you based on your testimony here today.

23 So you spent about an hour talking about the
24 development of the formulation aspects of the Duobrii®
25 product, correct?

1 A. Duobrii® and Bryhali®, yes.

2 Q. Okay. Were you personally involved in any formulation
3 aspects of the development of Duobrii®?

4 A. Yes, I was involved in meetings with the formulations
5 group where we would brainstorm. Yeah.

6 Q. Okay. And you were involved in the things you testified
7 about earlier today, correct?

8 A. Can you be more specific? Yeah.

9 Q. The design choices for the formulation.

10 A. Yes, yes.

11 Q. Okay. Now, you were deposed in this case, correct?

12 A. Yes.

13 Q. And you gave truthful and accurate testimony, right?

14 A. Yes.

15 Q. And you were given an opportunity to correct your
16 testimony, weren't you?

17 A. To review the testimony, yes.

18 Q. Okay. If you could go in your binder, the second
19 binder --

20 A. Yes.

21 Q. -- the last -- towards the end --

22 A. Oh, the second binder?

23 Q. -- there's a copy of your deposition transcript, and I
24 can bring it up on the screen for you, if you prefer.

25 A. Yes. Okay. So second binder.

1 Q. Okay. If you look at lines -- Page 23, Line 21 of your
2 deposition.

3 A. So which one is this? The DX what? Oh, it's a
4 deposition.

5 Q. Yes.

6 A. All right. Yes.

7 MR. BRUNO: Your Honor, I would like to note the
8 objection to the deposition testimony here.

9 BY MR. ZIMMERMAN:

10 Q. So, Dr. Pillai, you were asked: Were you involved in any
11 formulation aspects of developing the Duobrii® product?

12 And you responded: No, I was not.

13 You were asked that question and you gave that
14 answer, correct?

15 A. Yes.

16 Q. Okay. And now you're giving testimony that you were
17 involved in the formulation development such that you can
18 spend an hour talking about it, correct?

19 A. Yes, I was -- okay, yes.

20 Q. So your deposition testimony is not consistent with your
21 testimony here today, is it?

22 A. Correct.

23 Q. Okay. Thank you.

24 A. Can I --

25 Q. Thank you.

1 Now, the --

2 MR. BRUNO: Objection, Your Honor, the witness should
3 be allowed to complete his answer.

4 MR. ZIMMERMAN: He answered the question, Your Honor.

5 MR. BRUNO: He was cut off by Mr. Zimmerman, Your
6 Honor.

7 MR. ZIMMERMAN: If he can explain on redirect, that's
8 fine.

9 BY MR. ZIMMERMAN:

10 Q. Okay. Now, Dr. Pillai, you looked at a number of
11 documents that Bausch submitted to the FDA during the course
12 of your testimony today, correct?

13 A. Yes.

14 Q. Okay. And Bausch submitted true and accurate information
15 to the FDA in its submissions related to Duobrii® and
16 Bryhali®, right?

17 A. Yes.

18 Q. I'd like you to look at JTX-009-3. And it's in your
19 first binder, and we will put it on the screen as well.

20 A. JTX what?

21 Q. JTX-009-3.

22 A. All right.

23 Q. And I'll represent to you that this is part of the
24 Duobrii® IND submission from October of 2011. We excerpted it
25 so you didn't have the massive volume.

1 Is that okay?

2 A. Sure.

3 Q. Okay. If you look at the page that ends in 2788, you'll
4 see there's a Section 2.5, the Clinical Overview.

5 A. Yes.

6 Q. This section generally describes the clinical studies
7 that were planned for IDP-118, the combination product, and
8 some background on why Bausch was pursuing this product,
9 right?

10 A. Can you point out exactly where it says about combination
11 studies?

12 Q. No, no. It talks about the clinical studies that were
13 planned for IDP-118, the combination product.

14 A. Oh, oh, oh.

15 Q. Right?

16 A. Oh, yes, yes. It just talks in general about -- it's an
17 overview in the IND, yes.

18 Q. Okay. And it provides background on why Bausch was
19 pursuing this product, right?

20 A. Yes.

21 Q. Okay. If we look at Page 2788, you'll see that there's a
22 sentence that reads: Although topical corticosteroids are
23 very effective, long-term safety remains a concern,
24 particularly with respect to the more potent ones.

25 Do you see that sentence?

1 A. Yes.

2 Q. And you agree with that sentence, right?

3 A. Yes.

4 Q. Okay. And at this time in 2011, Ultravate® was available
5 at 0.05 percent halobetasol, correct?

6 A. Yes.

7 Q. And that product was approved to treat psoriasis?

8 A. Yes.

9 Q. Okay. But Ultravate® had adverse offense -- I'm sorry,
10 let me rephrase.

11 Ultravate® had side effects like HPA axis
12 suppression, right?

13 A. Correct.

14 Q. And the use of Ultravate® was limited by FDA to two
15 consecutive weeks because of those side effects, right?

16 A. Yes.

17 Q. You'll agree that by the date of this document, 2011,
18 that the two-week limitation on Ultravate® was a recognized
19 limitation on its effectiveness and use, right?

20 A. That was the package insert that FDA had approved for
21 Ultravate®.

22 Q. And for clinicians, that two-week limitation posed a
23 problem, didn't it?

24 A. For some it did.

25 Q. Now, if you look further down the page, 2788 of JTX-9-3,

1 it states that: Tazarotene applied topically has been proven
2 to be effective in the treatment of psoriasis at 0.05 percent
3 and 0.01 percent concentrations and is available in gel and
4 cream forms.

5 Do you see that?

6 A. Yes.

7 Q. That was an accurate statement in 2011, wasn't it?

8 A. Yes.

9 Q. So by at least November of 2011, tazarotene was known to
10 be effective for treating psoriasis at a concentration of
11 0.05 percent, right?

12 A. Can you repeat that?

13 Q. Okay. By November of 2011, tazarotene was known to be
14 effective for treating psoriasis at a concentration of
15 0.05 percent.

16 A. Was approved to be used for the treatment of plaque
17 psoriasis, yes.

18 Q. Okay. And it was approved by the FDA, right?

19 A. It was approved by the FDA.

20 Q. And you'll see later on in the paragraph, it refers to
21 the tazarotene is a corticosteroid-sparing drug with a
22 limitation based on local irritation.

23 That was a correct statement at the time, wasn't it?

24 A. Yes.

25 Q. And so the irritation of tazarotene limited its use with

1 patients, correct?

2 A. That was the understanding, yes.

3 Q. Now, if you look further down the page, Bausch told the
4 FDA, applying a topical corticosteroid in conjunction with
5 tazarotene alleviates the irritation and also treats the
6 psoriasis, citing to a 1998 Lebwohl article.

7 Do you see that?

8 A. Yes, that's the Lebwohl article citation, yes.

9 Q. And you agree with that statement, correct?

10 A. That's what Lebwohl had stated, and we were just making
11 that statement in the IND.

12 Q. And so --

13 A. It's like a paper. You give the background and this is
14 what Lebwohl had stated.

15 Q. And so you represented in your filing to FDA that
16 applying the topical corticosteroid in conjunction with
17 tazarotene alleviates the irritation and also treats
18 psoriasis, right?

19 A. Yes. So our idea, as we had also wanted, was allow
20 combined tazarotene with a corticosteroid.

21 Q. And when you say your idea, it was actually Lebwohl's
22 idea, wasn't it?

23 He had proposed that beforehand. This was not a new
24 idea, was it?

25 A. So there's a big difference. It's clear what Lebwohl is

1 saying if you were to use the two products. What we were
2 talking about is putting it in a combination product.

3 It's a big difference because Lebwohl is making it --
4 Dr. Lebwohl, sorry, is making a general statement of the use
5 with no regiment, no direction.

6 Q. You'll agree with me that it was known prior to 2011 that
7 combining a corticosteroid and tazarotene would alleviate
8 irritation from tazarotene, right?

9 A. Yes, the general concept was known.

10 Q. And if you look further down the page, 2788, it indicates
11 halobetasol propionate and tazarotene were appropriate to be
12 combined because they have a different mechanism of action.

13 Do you see that?

14 A. Yes.

15 Q. Okay. And you'll agree that halobetasol propionate and
16 tazarotene have different mechanisms of action, right?

17 A. Yes.

18 Q. And that was known prior to 2011, wasn't it?

19 A. Yes.

20 Q. And then if we go down that same paragraph on Page 2788
21 of JTX-009-3, you'll see that it states, tazarotene, quote, in
22 combination with a corticosteroid, the irritation is reduced
23 and a synergistic effect allows for longer duration of
24 treatment and remission.

25 It cites to an article from Menter in 2011, correct?

1 A. Correct.

2 Q. So Bausch told the FDA in 2011 that tazarotene in
3 combination with a corticosteroid was known to reduce
4 irritation and provide a synergistic effect that allowed for a
5 longer duration of treatment and remission of psoriasis,
6 didn't they?

7 A. So the context in which -- if you read the sentence
8 again, tazarotene is a corticosteroid-sparing drug with
9 limitation on local irritation; however, in combination with a
10 corticosteroid, the irritation is reduced and the synergistic
11 effect allows for a longer duration.

12 So what is being talked about is, because of the
13 reduction in irritation, you can get a longer treatment
14 duration, potentially.

15 That is what is being talked about. Not it's
16 symbiotic or complementary. Synergistic is a word that was
17 used by Dr. Menter, but that is what we understood what was
18 being said.

19 Q. And you told the FDA -- you didn't say they were
20 complementary. You didn't say they were additive. You said
21 they were synergistic?

22 A. We didn't say it. It was talked by Dr. Menter. We
23 cannot change what he said.

24 Q. And you chose to put Dr. Menter's synergistic finding in
25 your filing to the FDA, right?

1 A. I don't think it was a finding. It was a statement made
2 by Dr. Menter.

3 Q. And did you believe the statement to be true?

4 A. The statement that adding a corticosteroid to tazarotene
5 will reduce the -- potentially reduce the irritation, yes, we
6 truly believed that that could happen.

7 Q. Did Bausch believe that combining tazarotene and a
8 corticosteroid created a synergistic effect at the time they
9 made that statement to FDA?

10 A. No, Bausch did not believe -- and I would say that nobody
11 -- nobody in the world, even most experts, could not have
12 predicted this.

13 Q. So your representations -- I want to make sure I
14 understand your testimony.

15 A. Correct.

16 Q. You're saying that you put in your FDA filing that
17 tazarotene and a corticosteroid would have a synergistic
18 effect, even though Bausch did not believe that to be true at
19 the time?

20 A. Correct, sir. It was the reference. If you just keep
21 going back, it was Menter who stated that.

22 Q. And so we can agree that prior to Bausch doing anything
23 with IDP-118, Menter had proposed that combining tazarotene
24 and a corticosteroid would give you a synergistic effect,
25 right?

1 A. Again, again, this is where we differ, and what you're
2 saying, this synergistic was, in this context, we believed was
3 being used as something like symbiotic, as you can see, allows
4 for a longer duration.

5 It's not saying it will do better. It just allows
6 for a longer duration of treatment and remission.

7 Q. And none of that explanation about this after-the-fact
8 definition of synergy appears in your FDA documents, does it?

9 A. None of what?

10 Q. Your statement that synergy is some kind of symbiotic
11 relationship, none of that appears in your FDA document, does
12 it?

13 A. Because at that time we were quoting. There was no
14 expectation of anything. So this is what you're quoting.
15 This is the IND, which you initially file, and you are quoting
16 from the background information and you're not going to try to
17 go around and say, Menter was wrong or this is what he was
18 meaning, because why?

19 I'm not clear. Because it's clear from him, he's
20 pretty much -- I know it's a "he" because I know Dr. Menter,
21 and this is what he was saying.

22 Q. Okay. If you look at that same paragraph, it indicates
23 that: Clinical studies have shown that the combination of
24 tazarotene with corticosteroids resulted in greater and more
25 rapid improvement in psoriasis than with either the

1 corticosteroid or tazarotene alone prior to 2011, correct?

2 A. That's what it says, yes.

3 Q. Okay. So that's saying the combination of the
4 corticosteroid and tazarotene gives you a better result than
5 either one of the monads, right?

6 A. Correct. That's what I also stated. That's what we
7 thought it would do for our combination.

8 Q. And you'll agree that both active ingredients in IDP-118,
9 the halobetasol and tazarotene, had already been shown to be
10 effective by themselves in treating plaque psoriasis by 2011,
11 right?

12 A. Yes, both had been individually approved for the
13 treatment of plaque psoriasis, yes.

14 Q. If you look at Page 2789, you'll see that it states the
15 concept of combining a retinoid, tazarotene, with a high
16 potency corticosteroid, halobetasol propionate, for the
17 treatment of plaque psoriasis is based on the known efficacies
18 and safety of each of these active components as exemplified
19 by the approved listed drugs, tazarotene cream 0.05 percent
20 and 0.01 percent tazarotene and Ultravate® cream, 0.05 percent
21 halobetasol propionate.

22 Do you see that?

23 A. Yes, I do see that.

24 Q. And so the concept of combining them was based, in part,
25 on the fact that they were both FDA-approved active

1 ingredients, right?

2 A. Yes.

3 Q. And it was known prior to 2011 that combining tazarotene
4 and halobetasol would help reduce the irritation of the
5 tazarotene, right?

6 A. Not combining halobetasol. Combining a corticosteroid.

7 Q. And Ultravate® is a corticosteroid, right?

8 A. Correct. But all corticosteroids are not the same,
9 but...

10 So, yes, the concept was that combining tazarotene
11 with a high potent or superpotent corticosteroid would
12 potentially reduce the irritation.

13 Q. It was known prior to 2011 that combining tazarotene and
14 a corticosteroid reduced the irritation of the tazarotene,
15 right?

16 A. Yeah, not combining. Applying both of these products
17 together. There was never a combination, ever, ever, in
18 existence when we submitted this IND, right?

19 This is an Investigational New Drug, so the FDA does
20 not allow you to just, you know, put two products together.

21 So this combination was novel.

22 Q. Okay.

23 A. But what was written was that if you -- some people,
24 Lebwohl, maybe, said that when you used the two products
25 together there was a reduction in irritation.

1 Q. And when you used the two products together, halobetasol
2 and Tazorac®, the tazarotene would counteract the skin effects
3 of the halobetasol, correct?

4 A. That was not very clear. You know, by mechanisms, that's
5 what we proposed that it could, but that was not documented or
6 clear.

7 Q. So you knew that corticosteroids had an effect on the
8 skin prior to 2011, right?

9 A. Yes.

10 Q. Okay. And you'll agree that it was known that applying
11 tazarotene and a corticosteroid together would reduce the
12 irritation from the corticosteroid, right?

13 That was in the literature, wasn't it?

14 A. There is no irritation from the corticosteroid. That is
15 corticosteroids don't really -- are not known to irritate.

16 Q. Dr. Pillai, if you could look at Pages 57 and 58 of your
17 deposition.

18 A. My deposition, okay.

19 Q. I'll focus specifically you were asked: And can you
20 provide that understanding? At Line 15.

21 Feel free to look at the deposition for context.

22 A. Correct.

23 Q. And you go on to say: So, with my understanding -- and
24 again, this is me -- tazarotene was known to be an irritating
25 drug and by the general concept would be to combine the

1 Ultravate®, sorry, the halobetasol to help reduce the
2 irritation from tazarotene.

3 A. Yes.

4 Q. And then you go on: And then the second one would be
5 halobetasol being high potent. Super-high potent
6 corticosteroid would cause an effect on the skin, which
7 tazarotene can potentially can counteract.

8 A. Yes.

9 Q. So can we agree that applying tazarotene in combination
10 with Ultravate® reduces the skin irritation caused by the
11 corticosteroid?

12 A. Again, I think when you talk about irritation -- when we
13 talk about irritation, let me just clarify, for example,
14 tazarotene, it irritates the skin. Steroid, corticosteroid,
15 does not irritate the skin. So it causes an adverse event,
16 but that's not irritation.

17 Q. Okay. So that's where our disconnect is.

18 A. Okay. So I just want to make sure. Because when you use
19 the same term, then it's almost -- I don't want -- I just
20 wanted to make sure that you're saying --

21 Q. Let me see if I can rephrase.

22 A. Yes.

23 Q. In 2011, it was known that for -- applying a
24 corticosteroid caused a side effect to the skin. And if you
25 did it in combination with tazarotene, that side effect was

1 reduced?

2 A. No, it was not known. This was our hypothesis. It was
3 not known that tazarotene would actually -- it is the concept.
4 This is our concept, that the tazarotene would help with the
5 skin atrophy adverse events from the corticosteroid. And the
6 corticosteroid will help with the irritation aspect.

7 Q. We'll come back to that in a moment, then.

8 If we could go to Page 2791 of JTX-009-3, you'll see
9 that it states: IDP-118 lotion will contain a lower
10 concentration of halobetasol propionate, i.e., 0.01 percent or
11 0.025 percent, than the listed drug, Ultravate® cream
12 0.05 percent, to potentially support longer treatment duration
13 than the recommended two-week duration for Ultravate®.

14 Do you see that?

15 A. Yes.

16 Q. So Bausch expected that by lowering the concentration of
17 halobetasol propionate compared to Ultravate®, it would be
18 able to extend the duration of treatment, right?

19 A. Again, keyword is "potential." So, yeah. So we were
20 hoping, that's what we were going to study and evaluate in the
21 clinical study to understand if lowering the concentration can
22 extend the duration.

23 You're not saying it will.

24 Q. But before you had any clinical data whatsoever, you
25 postulated that reducing the concentration of halobetasol

1 would allow you to extend the duration of treatment, right?

2 A. Yes, that's the hypothesis. And most of all drug
3 development starts with a hypothesis. So that was the
4 hypothesis that we went in with, right?

5 Anybody -- I mean, you have to have something to tell
6 the FDA what this product is going to do or potentially will
7 do, yeah.

8 Q. If we look further down the paragraph, it says that:
9 IDP-118 will contain tazarotene, quote, at a concentration of
10 0.045 percent comparable to the listed drug Tazorac® cream
11 0.05 percent.

12 So you represented to the FDA that the 0.045 percent
13 and the 0.05 percent were, quote, comparable, right?

14 A. Close enough, yes.

15 Q. Now, you testified earlier, I believe, that Bausch didn't
16 optimize the concentration of tazarotene in IDP-118, correct?

17 A. Yes.

18 Q. So you'll agree with me that branded companies sometimes
19 don't optimize the concentration of active ingredient in their
20 marketed products, correct?

21 A. Can you repeat that question again?

22 Q. So you'll agree that branded pharmaceutical companies
23 sometimes don't optimize the concentration of API in their
24 products, right?

25 A. Again, you're saying branded. This is a big scope,

1 right? If you are developing a new chemical entity, you will
2 have to optimize. That is not a choice that any drug company
3 has.

4 Q. But for a combination product, you don't need to do that,
5 do you?

6 A. No, no, that is not -- that is not -- you have to justify
7 every strength that you specify for your product on a
8 combination or be it on an individual. There's a
9 justification that has to be written and accepted by the FDA.

10 Q. And the justification for the 0.045 was that it was
11 comparable to Tazorac®, right?

12 A. That's the IND, right? This is our first document that
13 we submitted to the FDA. But we had to conduct clinical
14 studies to show that what we were hypothesizing is correct,
15 right?

16 Just because we tell the FDA, they're not going to
17 approve the product and say it's comparable, you know, you can
18 go and market, right, because that's what I'm hearing from
19 you.

20 Q. No, no. So you had to do clinical studies, but your
21 rationale for picking 0.045 was not that you had optimized the
22 concentration. It was that it was comparable to the marketed
23 0.05 percent, right?

24 A. Correct, for an existing drug. If you look at
25 development from many companies, they work with the

1 concentration that is already being in the market on a
2 commercial product.

3 So -- but when it comes to a new chemical entity,
4 almost certain there is -- the FDA does not allow for you to
5 just come up with a concentration and just go ahead.

6 Q. Okay. If we could look at Page 2811 of JTX-009-3, Bausch
7 told the FDA, quote, Literature based on the daily combined
8 use of tazarotene and a mid-potent or potent corticosteroid
9 for plaque psoriasis for 12 weeks demonstrated enhanced
10 efficacy of the combination treatment over that of the
11 monotherapies with no significant safety issues.

12 Do you see that?

13 A. Yes. That's what the literature said, yes.

14 Q. And Bausch quoted that literature to the FDA before it
15 had done any clinical studies for IDP-118, right?

16 A. Correct.

17 Q. Now, if you turn to the next page, 2812, Bausch stated,
18 the reduced amount of halobetasol propionate in IDP-118 lotion
19 (0.01 percent or 0.025 percent) relative to Ultravate®
20 (0.05 percent) is intended to reduce systemic absorption of
21 the corticosteroid thereby reducing the potential for HPA axis
22 suppression.

23 Do you see that?

24 A. Yes.

25 Q. So that's saying that if you reduce the concentration of

1 halobetasol propionate that you will likely reduce the side
2 effect of HPA axis suppression, correct?

3 A. There's the potential for reducing the side effect, yes.

4 Again, it has to be studied, it has to be confirmed,
5 but, yes, that's the -- you know, and I said that in my -- and
6 I said it in the morning, too, yes.

7 Q. Bausch's expectation based on the literature, was that if
8 you lowered the concentration of halobetasol propionate, you
9 had the potential to reduce HPA axis suppression and extend
10 duration of treatment beyond two weeks, right?

11 A. I don't know if it was based on literature, but based on
12 just knowledge that if you reduce the drug, there is a
13 potential that you will reduce the adverse event in this case,
14 yes.

15 Q. Okay.

16 MR. ZIMMERMAN: If you could look at JTX-011-3.

17 BY MR. ZIMMERMAN:

18 Q. Do you recognize this document as containing the
19 pharmaceutical development history of IDP-118?

20 A. Is this from the NDA? I just want to make sure.

21 Q. I believe it's from the IND.

22 A. Oh, it's from the IND, okay.

23 Q. Give me one second to confirm.

24 A. Okay.

25 Q. It's from the IND, Dr. Pillai.

1 A. It is from the IND, okay.

2 Q. Now, the combination of halobetasol and tazarotene was
3 expected to have synergy with respect to reducing the side
4 effects, wasn't it?

5 A. You're saying something from the document?

6 Q. I'm asking you if that was the expectation?

7 A. Can you repeat that?

8 Q. Yes. The combination of halobetasol propionate and
9 tazarotene was expected to have synergy with respect to
10 reducing side effects, wasn't it?

11 A. No.

12 Q. If you can turn to page ending 957, you'll see there's a
13 table.

14 Do you recognize this as the quality target product
15 profile for IDP-118 from the pharmaceutical development report
16 in the IND?

17 A. I am not going to recall every aspect, but --

18 Q. I will represent to you that that's what it is.

19 A. Okay.

20 Q. And Bausch prepared this table and submitted it to the
21 FDA, right?

22 A. Yes.

23 Q. And you believe it would have been true at the time
24 Bausch submitted it, right?

25 A. Yes. I mean, what we -- whoever opined on that at that

1 point, yes.

2 Q. If you look under the quality target product profile, do
3 you see that it says: Synergy-selected APIs is expected as
4 the corticosteroid has shown to suppress epidermal irritation
5 related to tazarotene and the retinoid pro-drug is anticipated
6 to minimize skin atrophy associated with halobetasol
7 propionate?

8 A. Correct.

9 Q. So again, Bausch told the FDA that the APIs were synergy
10 selected prior to having any clinical data, right?

11 A. Again, I think I would go back to what I had said.
12 Synergy in this context was truly being used as the symbiotic
13 effect. As I said, each of the APIs will potentially reduce
14 the irritation of the other.

15 I mean, if you look at the way it is stated, that's
16 what -- the context in which this word "synergy" was used
17 here.

18 Q. So I want to be clear, it's your testimony that, despite
19 the documents not saying symbiotic or additive, but synergy,
20 that now synergy doesn't mean more than additive in all of
21 your FDA documents?

22 A. In -- when you say "all," in the IND, in the original
23 IND, right? And this was the document -- somebody wrote up a
24 quality target profile, which was a formulator, and this is
25 how he or she expressed this.

1 And it was, as I said, even based on the articles,
2 the general impression of synergy, as it is used a lot in the
3 literature, is that, you know, it can be used in many
4 different ways in the literature. And symbiotic,
5 complementary, these are some things that people -- that's how
6 they talk about this.

7 Q. And just so I'm clear, in the IND for IDP-118, Bausch
8 talked about synergistic efficacy and synergy with respect to
9 side effects prior to having any clinical data, right?

10 A. And again, I would say that when we are talking about
11 that, and nobody -- again, I can vouch for this, I consider
12 myself an expert -- but any expert in the world could not have
13 said that you would get synergy. There's no way.

14 Q. And despite your opinion that nobody could say you would
15 get synergy, Bausch told the FDA synergistic efficacy,
16 synergistic side effects prior to having any data, right?

17 A. So nobody could --

18 Q. It's a yes-or-no question.

19 That's what they told the FDA, right?

20 A. So nobody could get synergy as we defined in the patent.

21 So just so we are clear about that, right? And if
22 it's not defined -- because the word is used in literature in
23 multiple different ways.

24 Q. So you're saying -- now you're drawing a distinction that
25 when Bausch told the FDA about synergistic efficacy and

1 synergistic side effects, it meant something different than
2 synergy in the patents?

3 Is that your testimony?

4 A. What you said about synergistic efficacy, where was that?
5 I'm sorry.

6 I know this one, you're saying that there is this
7 reduction of adverse events of each other, right? It helps to
8 reduce the adverse events of each other.

9 Q. Right.

10 A. So when you look at that and you think about it, what are
11 we trying to say? It's basically helping each other. One is
12 helping the other, the other one is helping reduce the
13 irritation.

14 But synergy, as it is used in the context of patents,
15 and as we define in the patents, is different.

16 Q. Okay. Dr. Pillai, if you could look at Page 54964 of
17 this document, you'll see there's a statement --

18 A. 964.

19 Q. We can blow it up on the screen for you as well, if it
20 helps.

21 A. Yes, please.

22 Q. The sentence reads: Based on the second VCA results,
23 coupled with relatively high levels of halobetasol propionate
24 and tazarotene reported in the receptor phase, a decision was
25 made to replace propylene glycol, an ingredient believed to

1 induce irritation and permeation of compounds with sorbitol, a
2 nonirritating sugar with no history of induced drug
3 permeability or irritation.

4 Do you see that sentence?

5 A. Yes.

6 Q. And does that align with your recollection of the
7 development of IDP-118?

8 A. Yes, I think this aligns with my recollection. This was
9 Dr. Gordon Dow and Arturo who discussed this, yes.

10 Q. And so originally the formulation for IDP-118 contained
11 propylene glycol but not sorbitol, right?

12 A. Yes.

13 Q. And that formulation was later altered to remove the
14 propylene glycol and add sorbitol, correct?

15 A. Yes.

16 Q. And propylene glycol was known in the literature to be an
17 ingredient that induces skin irritation, right?

18 A. Yes.

19 Q. And sorbitol was known to be an inactive ingredient that
20 didn't have that effect, correct?

21 A. Not an inactive ingredient. It does have activity.
22 That's why it was added in, but it was not known to be
23 irritating, yes.

24 Q. Now, earlier today you talked about the clinical studies
25 for IDP-118, correct?

1 A. Yes.

2 Q. And specifically the 201 study?

3 If you look at Exhibit 4 -- I'm sorry, if you look at
4 Exhibit JTX-011-6.

5 A. Yes.

6 Q. Do you recognize the section entitled "2.7.6.1.6" to be
7 the study synopsis for the 201 study?

8 A. So this is a table from our NDA, right?

9 Q. Yes.

10 A. Okay.

11 Q. No, it should be -- I'm sorry, yes.

12 A. This has to be.

13 Q. Yes, because it's got the study results.

14 A. Okay.

15 Q. So you recognize this as the 201 study, correct?

16 A. Yes.

17 Q. And we can refer to Study V01-118-A-201 as the 201 study?

18 A. Yes.

19 Q. Now, the 201 study began on February 27, 2014, correct?

20 A. I believe so. I don't remember these dates by heart, but
21 yeah.

22 Q. And it ended in October of 2014?

23 A. Correct. That's what it says, yes. The last subject
24 exited, yes.

25 Q. And that's October 21st of 2014, right?

1 A. Yes.

2 Q. So prior to February of 2014, Bausch didn't have any data
3 from the 201 study, right?

4 A. No.

5 Q. Okay. And the study, the 201 study, was the only one
6 Bausch performed --

7 A. So let me just clarify. When you say "data" --

8 Q. There was no clinical data from the patients in the 201
9 study --

10 A. So one aspect of development is we do follow some of the
11 adverse events. These are stuff that has to be followed to
12 make sure that the patients are not -- you know, if we need to
13 stop the study or something severe.

14 So yes, we would. But not -- we didn't know which
15 arm. It's blinded yes.

16 Q. So the study started in February of 2014?

17 A. Yes.

18 Q. Prior to that date, you did not have any clinical data
19 for IDP-118?

20 A. We had a previous study to that which was done. It's a
21 different number. I don't know where it is, but -- oh, yeah.
22 DPS-IP-201.

23 Q. Let me see if I can clarify.

24 A. Okay.

25 Q. The 201 study was the only study Bausch performed

1 comparing IDP-118 to tazarotene alone and halobetasol alone,
2 correct?

3 A. Okay. Yes. That's the study.

4 Q. And even after the 201 study was completed, you never did
5 a further comparison of those, right?

6 A. For the comparison of 118 versus the two monads?

7 Q. Yes.

8 A. No, we did not do any more.

9 Q. And IDP-118 was the only combination product of
10 halobetasol and tazarotene that Bausch has any data for that
11 they allegedly believe demonstrates synergy, right?

12 A. The 201 study is the one we have that shows synergy, yes.

13 Q. And it's the only one that you allege shows synergy?

14 A. This is the only one which shows synergy, yes.

15 Q. Okay. And Bausch didn't generate clinical data in
16 patients for any other combination of tazarotene and
17 halobetasol other than IDP-118, right?

18 A. Can you again repeat? Sorry.

19 Q. You didn't do clinical tests on patients with alternative
20 formulations, did you?

21 A. Again, like I said, there were some alternative
22 formulations tested prior to that, the P-201 study. But after
23 201, we have not studied any other combination.

24 Q. Now, Dr. Pillai, you were involved in the prosecution of
25 the two patents referred to as the combination patents or the

1 Duobrii patents, right?

2 A. Yes.

3 Q. And you received office actions and responses, correct?

4 MR. BRUNO: Objection. Relevance and potentially
5 privileged. Outside the scope.

6 THE COURT: Sustained.

7 BY MR. ZIMMERMAN:

8 Q. So, Dr. Pillai, you testified in your direct about the
9 clinical study, the 201 study, correct?

10 A. Yes.

11 Q. And you also testified as to ClinicalTrials.gov, correct?

12 A. Yes.

13 Q. Okay. And Bausch posted the study report for the 201
14 study to ClinicalTrials.gov, didn't they?

15 A. Not the study report.

16 Q. They -- let me see if I can do this a different way.

17 If you'll look at DX-064.

18 A. Okay.

19 MR. BRUNO: Objection, Your Honor. We maintain our
20 objections to this document on grounds of authenticity, best
21 evidence, lack of foundation.

22 MR. ZIMMERMAN: Your Honor, those issues were
23 addressed by your motion in limine rulings to exclude this
24 document.

25 THE COURT: The objection is noted. I've already

1 ruled on it, if I recall correctly, in in limine motions,
2 correct?

3 MR. BRUNO: Your Honor, you've ruled on certain
4 aspects of it. That's correct.

5 THE COURT: I'm sorry?

6 MR. BRUNO: You've ruled on certain aspects of that
7 objection.

8 THE COURT: Well, in terms of the document being
9 admissible, I rejected your arguments, correct?

10 Is there any other basis for your objection at this
11 point?

12 MR. BRUNO: We still maintain our lack of foundation
13 objection for this particular witness.

14 THE COURT: And, as I decided in in limine motions,
15 my understanding is that this is identical to a document which
16 your 30(b)(6) witness already identified, correct?

17 MR. BRUNO: Your Honor, our 30(b)(6) witness did
18 testify about this document. That's correct.

19 THE COURT: Fine. Objection overruled.

20 BY MR. ZIMMERMAN:

21 Q. So, Dr. Pillai, this is the ClinicalTrials.gov page that
22 references the 201 study, correct?

23 A. So, yes. Just to be accurate, it's not the study report
24 that you were asking me.

25 Q. No. It's the filing with ClinicalTrials.gov before the

1 study was conducted, right?

2 A. Yes. So it's a short summary of what was the study going
3 to be about. Or what are we doing in this study, yes.

4 Q. And when information is submitted to ClinicalTrials.gov
5 they publish it, correct?

6 A. Yes. It is -- it is required for us to submit it and it
7 is required to be published.

8 Q. Okay. And when you submitted the 201 study information
9 to ClinicalTrials.gov, you expected that they would publish
10 it, right?

11 A. When I -- when we submitted it. So you're saying Bausch?

12 Q. Yes.

13 A. So when Bausch submitted the information that is required
14 to be published -- I mean, this is not an option, right?

15 Q. Right.

16 A. And, yeah, we would expect that ClinicalTrials.gov would
17 publish it.

18 Q. And so when Bausch made its ClinicalTrials.gov
19 submission, there was no expectation of confidentiality, was
20 there? You knew it was going to be published.

21 A. We knew it was going to be published.

22 Q. Okay. And Bausch included in its ClinicalTrials.gov
23 submission the concentration of halobetasol propionate as
24 0.01 percent and the tazarotene as 0.045 percent, didn't they?

25 A. I'm just going to take a look.

1 Q. And we can blow it up on the screen for you.

2 A. Oh, okay. Yes. So is that the submissions?

3 Okay. Yes.

4 Q. And Bausch wasn't required to disclose those
5 concentrations, was it?

6 A. I'm not clear on that. That is not clear. A lot of --
7 lot of companies actually do declare.

8 Q. Bausch has made a number of other submissions where they
9 disclose the actives but not the concentrations, right?

10 A. Right.

11 Q. Okay.

12 A. I believe that would be true. I'm not totally conversant
13 with that, but, yeah.

14 Q. And you'll recall there was a discussion inside the
15 company about whether you could pull this information about
16 the concentrations for tazarotene and halobetasol off of the
17 ClinicalTrials.gov submission, right?

18 A. You know, the -- again, I am trying to recall. But, yes,
19 there might have been some discussions. I don't know whether
20 it was specifically for this one or for some other study.

21 Q. Okay. And the reason you had those discussions was
22 because you didn't have to submit the concentrations and you
23 wanted to treat those as proprietary, right?

24 A. That would be the reason, yes.

25 Q. Okay. Now, if we look at this DX-64, it indicates that

1 the study's status was first submitted on January 22, 2014,
2 right? Version 1?

3 A. Okay. Yes.

4 Q. And it was first posted publicly January 24, 2014, right?

5 A. If it says so, yes. Oh, yeah. It was submitted -- was
6 posted, yes.

7 Q. Okay. Now, I just have a few questions about the earlier
8 two patents, the '307 and '502 that you refer to as the
9 halobetasol patents.

10 You're not an inventor on those patents, right?

11 A. I am not.

12 Q. Okay. If you could turn to JTX-001 and look at Table 1
13 in Column 9. And we'll go ahead and blow it up on the screen
14 for you.

15 MR. BRUNO: Objection. Outside the scope.

16 MR. ZIMMERMAN: Your Honor, it's questions about the
17 formulations that he testified to from the development.

18 MR. BRUNO: Your Honor, he didn't give any testimony
19 about any patents.

20 MR. ZIMMERMAN: He gave testimony about the
21 formulations that are in the patent.

22 THE COURT: Overruled.

23 BY MR. ZIMMERMAN:

24 Q. So, Dr. Pillai, if you look at Table 1 in Column 9 of the
25 '307 patent. Do you see that it lists Formulations A through

1 E?

2 A. Yes.

3 Q. And each of those formulations contains propylene glycol
4 at 7.5 percent, correct?

5 A. Yes.

6 Q. And none of those formulations contain sorbitol, do they?

7 A. No.

8 Q. And then if you look at Table 3 in Column 10, it provides
9 VCA scores for Formulations A through E, correct?

10 A. Yes.

11 Q. Then in Table 4, Column 11, you'll see two formulations,
12 4A and 4B.

13 Each of these includes sorbitol at a 70 percent
14 concentration -- I'm sorry -- 70 percent at 10.7 percent
15 concentration, right?

16 A. Yes.

17 Q. And Formulations 4A and 4B from the '307 patent don't
18 include propylene glycol, do they?

19 A. No.

20 Q. And the patent doesn't contain any VCA testing for
21 Formulation 4A or 4B, does it?

22 A. Can you repeat that?

23 Q. The patent doesn't contain any VCA testing for
24 Formulations 4A or 4B?

25 A. I mean, if you're saying if you've reviewed it, I don't

1 know the details --

2 Q. I will represent to you --

3 A. Yeah.

4 Q. -- that it doesn't.

5 A. Okay.

6 Q. Now, in your development work, did you perform any
7 testing of corticosteroids other than halobetasol propionate?

8 A. No. Other than halobetasol propionate, no.

9 Q. And so Bausch didn't conduct any clinical studies on any
10 other corticosteroids as part of it's IDP development, did it?

11 A. As part of this IDP-118 development.

12 Q. Right?

13 A. That's a true statement.

14 Q. Okay.

15 A. So the only thing I do want to talk about --

16 THE COURT: Doctor --

17 THE WITNESS: Sorry.

18 THE COURT: -- you answer questions.

19 THE WITNESS: I'm sorry, Your Honor.

20 BY MR. ZIMMERMAN:

21 Q. Now, Dr. Pillai, based on your experience with the
22 development of IDP-118 and Duobrii® and Bryhali®, can we agree
23 that Duobrii® and Bryhali® have the same vehicle?

24 A. Yes.

25 Q. And if we look at Formulation 4A in JTX-001, the '307

1 patent --

2 A. Are you going to pull up?

3 MR. ZIMMERMAN: If we can pull it up.

4 Yeah. Formulation 4A in Example 4.

5 BY MR. ZIMMERMAN:

6 Q. That is the vehicle for Bryhali® and Duobrii®, correct?

7 A. I believe so. I think. Again, I don't remember each
8 number by heart. But yeah, I believe that's close, yes.

9 Q. And Example 4 --

10 A. Oh. So this is the same vehicle, you're talking?

11 Q. Yes.

12 A. Yes. Yeah.

13 Q. And Example 4, if we look at the text surrounding the
14 table, tells you how to put the ingredients together to make
15 that vehicle, right?

16 A. Which paragraph are you referring to?

17 Q. I'm sorry. In Column 11. And it starts in Column 10.
18 It's Example 4.

19 So it provides you the instructions for how to
20 combine the ingredients to make the vehicle, right?

21 A. Yes.

22 Q. Okay. And earlier today you talked about the
23 conventional wisdom was to drive the drug all the way through
24 the skin into systemic circulation, correct?

25 A. Into the receptor phase in in vitro skin penetration,

1 yes.

2 Q. Now, isn't that contrary to the idea of reducing the
3 concentration in the blood to avoid the potential side effects
4 of the corticosteroid?

5 A. Correct. That's what -- that's what we said, yes.

6 Q. Isn't that what one of skill in the art would have said
7 knowing the HPA axis suppression issue?

8 MR. BRUNO: Objection. Calls for expert testimony.

9 Sorry. Calls for expert testimony.

10 MR. ZIMMERMAN: I'm sorry. I will rephrase.

11 BY MR. ZIMMERMAN:

12 Q. Isn't that what others in the field would have known from
13 the literature, that you want to reduce the concentration to
14 avoid systemic side effects?

15 MR. BRUNO: Same objection, Your Honor.

16 THE COURT: I don't understand the question.

17 Rephrase it.

18 MR. ZIMMERMAN: Okay. I will rephrase it.

19 BY MR. ZIMMERMAN:

20 Q. So, if you get more, a higher concentration of
21 corticosteroid in the bloodstream, you're at greater risk for
22 the side effects such as HPA axis suppression, right?

23 A. Yes.

24 Q. Okay. And so that would have been motivation to lower
25 the concentration in the blood rather than try to drive it to

1 a greater concentration, right?

2 MR. BRUNO: Objection. Calls for expert testimony
3 and expert opinion.

4 THE COURT: In light of his testimony as to the
5 development of this product, I don't find that's
6 objectionable. Overruled.

7 THE WITNESS: So your question was, again, can you --
8 I'm sorry. I got caught up.

9 BY MR. ZIMMERMAN:

10 Q. So wouldn't the known side effects with Ultravate® and
11 corticosteroids have driven you to try to reduce the amount of
12 corticosteroid reaching systemic circulation to reduce those
13 side effects?

14 A. Once we ran the experiment, yes. That's what we would
15 look for, to see if it would be lower. That's what we were
16 looking for.

17 Q. And, in fact, you made that representation to the FDA in
18 the IND before you had any data, right?

19 A. But that was -- when you say "representation," it was
20 what we thought it would, right? That's what we would hope,
21 that if you reduce the concentration, you would reduce the
22 amount of drug. That's just a logical concept that we have
23 put in, not knowing what would happen.

24 Q. Now, Dr. Pillai, earlier today you testified in your view
25 as to how amazing and unexpected and wonderful these products

1 are, right?

2 THE COURT: I think that's overdoing it. All right?

3 BY MR. ZIMMERMAN:

4 Q. Dr. Pillai, earlier today you talked about how the data
5 was clinically better than anything you expected for Duobrii®,
6 right?

7 A. Again, you're specifically talking about the 201 study?

8 Q. Yes.

9 A. Yes, I did express that.

10 Q. And you talked about how the efficacy from the VCA scores
11 from the halobetasol patents was more than you expected and
12 confirmed in the Phase 3 study, right?

13 A. In the Phase 2 study, you're saying --

14 Q. Phase 2 -- Phase 1 and then confirmed in the
15 second study?

16 A. Correct. Correct, correct.

17 Q. Okay. Now, are you familiar with the sales of these
18 products?

19 MR. BRUNO: Objection, outside the scope.

20 THE COURT: Sustained. He has not given any
21 testimony related to commercial success and there's no basis
22 for exploring it.

23 MR. ZIMMERMAN: Okay. With that, Your Honor, I have
24 no further questions.

25 THE COURT: Thank you.

1 MR. ZIMMERMAN: Thank you, sir.

2 MR. BRUNO: Redirect, Your Honor?

3 THE COURT: Any redirect?

4 REDIRECT EXAMINATION

5 BY MR. BRUNO:

6 Q. Dr. Pillai, do you remember being asked about your role
7 in the development history of Duobrii®?

8 A. Yes.

9 Q. When you testified in your deposition that you were not
10 involved in formulation aspects of developing Duobrii®
11 product, what did you mean by that?

12 A. What I meant was I was not in the lab. I was not
13 directing them to do what needs to be done.

14 I was just -- that's what I meant when I said in my
15 testimony that I'm not the formulation group lead. I'm not
16 the formulation person. I'm not directing them what to do.

17 Q. What kind of scientific background do you have?

18 A. I have a Ph.D. in pharmaceuticals, a master's in medicinal
19 chemistry. My core competency is formulation development.

20 Q. Were you involved in preparing the IND for Duobrii®?

21 A. Yes, I was.

22 Q. Did you review summaries of formulation development in
23 preparation of the NDA?

24 A. Yes, I reviewed.

25 Q. Did you personally formulate any prototypes on the

1 Duobrii® product?

2 A. No, I did not.

3 Q. Now, do you remember when Mr. Zimmerman asked you about
4 whether Bausch was telling the FDA about combining a
5 corticosteroid with a retinoid?

6 A. Correct. Yes, I remember.

7 Q. And do you remember him referring to sentences that cited
8 to a Lebwohl article?

9 A. Yes.

10 Q. Does that Lebwohl article include a single fixed-dose
11 combination product?

12 A. No, it does not.

13 Q. Do you remember him pointing you to sentences that
14 referred to a Menter 2011 article?

15 A. Yes.

16 Q. Does the Menter 2011 article refer to a fixed-dose
17 combination product?

18 A. No, it does not.

19 Q. Now, I'd like to ask you little bit about your
20 understanding of the word "synergy" as it's used in the
21 dermatological arts.

22 Can you explain what your view of "synergy" means?

23 A. In context when it is used in the literature, to me it
24 means that it's something like a symbiotic, you know,
25 something where you're getting benefit from both if -- you

1 know, the synergy of two things.

2 So you have one and the second one, and both of them
3 are mutually beneficial for each other. That's the general
4 interpretation in -- from the literature.

5 Q. And what's the kind of synergy that you're saying and
6 that defendants have stipulated to Duobrii® demonstrates?

7 A. So Duobrii®, as it is stipulated in the patent, as we
8 define the synergy in the patent, shows synergistic behavior
9 where if there's one contribution from the -- one and one --
10 one plus one would be greater than two.

11 So that's what we have defined in the patent and
12 that's what we showed.

13 Q. So in all those different Bausch FDA filings that you
14 saw, which version of synergy was Bausch referring to?

15 A. The symbiotic one, the one where there is mutual benefit
16 from -- to -- for each other.

17 Q. And are you aware of any literature that existed before
18 the publication of the results of the 201 study that showed
19 the kind of synergy that is claimed in the patents?

20 A. No. We have never seen any of that. You know, again,
21 that was why it was so dramatic for us.

22 MR. BRUNO: No further questions, Your Honor.

23 THE COURT: Any further recross?

24 MR. ZIMMERMAN: Your Honor, I don't have further
25 recross. But I am told that I forgot to admit the exhibits.

1 So I am moving to admit JTX-009-3, 011-3, 011-6, and
2 DX-064.

3 THE COURT: Any objection?

4 MR. BRUNO: We preserve our objection regarding
5 DX-64. But otherwise, no objections, Your Honor.

6 THE COURT: Okay. And that's the online publication.

7 MR. BRUNO: That's correct, Your Honor.

8 THE COURT: Okay.

9 MR. ZIMMERMAN: Thank you, Your Honor.

10 THE COURT: Admitted into evidence.

11 (Exhibit Number JTX-009-3 is received in evidence.)

12 (Exhibit Number JTX-011-3 is received in evidence.)

13 (Exhibit Number JTX-011-6 is received in evidence.)

14 (Exhibit Number DX-64 is received in evidence.)

15 THE COURTROOM DEPUTY: Next witness.

16 THE COURT: You may step down, Doctor. Thank you.

17 THE WITNESS: Thank you.

18 (Witness excused.)

19 MR. BRUNO: And, Your Honor, with that, Bausch would
20 like to identify that it has already admitted -- the
21 stipulations of infringement -- Bausch would like to identify
22 that it has already admitted -- or the Court has already
23 admitted stipulations of infringement and relating to the
24 commercial embodiments, that is, that Bryhali® and Duobrii®
25 are embodiments of their respective patents -- their

1 respective patents, as well as the fact that the Bryhali®
2 patents cover the Duobrii® product.

3 With that, Your Honor, Bausch rests its opening case.

4 MR. ZIMMERMAN: May we proceed with the next witness,
5 Your Honor?

6 THE COURT: You may.

7 MR. STEINDLER: May I approach just to clear the
8 binders out of the way?

9 THE COURTROOM DEPUTY: Yes.

10 MR. STEINDLER: Thank you. I have to earn my keep
11 somehow.

12 MR. ZIMMERMAN: Your Honor, I'm told they need just a
13 couple of minutes to set up the feed for the remote witness.

14 THE COURT: All right.

15 THE COURTROOM DEPUTY: It's two minutes for the
16 remote. Two minutes.

17 (Recess taken from 2:08 p.m. to 2:15 p.m.)

18 THE COURTROOM DEPUTY: All rise.

19 Counsel, are you ready to proceed? Everybody is here
20 ready to go?

21 MR. ZIMMERMAN: Yes.

22 THE COURTROOM DEPUTY: Call your next witness.

23 MR. ZIMMERMAN: Your Honor, I'm told that there was a
24 list of agreed-upon exhibits that defendants were admitting.
25 So I'd like to read those in and move them for admission.

1 THE COURT: Okay.

2 MR. ZIMMERMAN: JTX-009-5, DX-009, DX-142, DX-184,
3 DX-196, DX-201, DX-203, DX-208, DX-140 and 141, DX-10, DX-61,
4 DX-98, DX-104, DX-443, 444 and 445.

5 THE COURT: That was the most exciting testimony I've
6 heard all day.

7 MR. ZIMMERMAN: And I'm told that DX-2, 3, 4, 5, 6, 9
8 and 142 were previously agreed to be admitted, but I want to
9 make sure that they are.

10 THE COURT: Okay. They're all admitted into
11 evidence.

12 THE COURTROOM DEPUTY: Can I have a copy of that list
13 as well? The plaintiff should supply the list.

14 MR. ZIMMERMAN: Yes. We will get you a clean copy.

15 (Exhibit Number JTX-009-5 is received in evidence.)

16 (Exhibit Number DX-009 is received in evidence.)

17 (Exhibit Number DX-142 is received in evidence.)

18 (Exhibit Number DX-184 is received in evidence.)

19 (Exhibit Number DX-196 is received in evidence.)

20 (Exhibit Number DX-201 is received in evidence.)

21 (Exhibit Number DX-203 is received in evidence.)

22 (Exhibit Number DX-208 is received in evidence.)

23 (Exhibit Number DX-140 is received in evidence.)

24 (Exhibit Number DX-141 is received in evidence.)

25 (Exhibit Number DX-10 is received in evidence.)

1 (Exhibit Number DX-61 is received in evidence.)

2 (Exhibit Number DX-98 is received in evidence.)

3 (Exhibit Number DX-104 is received in evidence.)

4 (Exhibit Number DX-443 is received in evidence.)

5 (Exhibit Number DX-444 is received in evidence.)

6 (Exhibit Number DX-445 is received in evidence.)

7 MR. ZIMMERMAN: Your Honor, may I proceed?

8 Padagis's first witness is Dr. Robert Stern, Your
9 Honor.

10 Dr. Stern is a dermatologist and a professor of
11 dermatology at Harvard Medical School. He has specific
12 expertise in the treatment of psoriasis, and he will be
13 offered to present expert testimony regarding whether the
14 asserted patent claims would have been obvious and invalid.

15 THE COURT: Any objection to him being qualified as
16 an expert?

17 MR. STEINDLER: No, Your Honor.

18 THE COURT: He is deemed an expert in those areas.
19 Go ahead.

20 DR. ROBERT STERN, DEFENSE WITNESS,
21 having been duly sworn, testifies as follows:

22 DIRECT EXAMINATION

23 THE COURTROOM DEPUTY: Please state your full name
24 for the record.

25 THE WITNESS: Robert Stuart Stern.

1 THE COURTROOM DEPUTY: Thank you.

2 BY MR. ZIMMERMAN:

3 Q. Good afternoon, Dr. Stern.

4 A. Good afternoon.

5 Q. What is your current occupation?

6 A. I'm an attending dermatologist at the Beth Israel
7 Deaconess Medical Center and the Carl J. Herzog Professor of
8 Dermatology at Harvard Medical School.

9 Q. And are you a board-certified dermatologist?

10 A. Yes, I am.

11 Q. And how long have you been at Harvard Medical School?

12 A. Since 1973.

13 Q. And do you currently treat patients?

14 A. I did until mid-March of 2020. I had to curtail my
15 then-active practice because of the health risk to me and
16 COVID.

17 Q. Now, how long had you treated patients prior to stopping
18 in March of 2020?

19 A. Well, I did a dermatology residency that finished in
20 1976, and I treated patients continuously from 1976 to 2020 as
21 an attending.

22 Q. So in excess of 40 years? Would that be accurate?

23 A. Something more than 40 years, yes.

24 Q. And when you were treating patients, did you treat
25 patients suffering from psoriasis?

1 A. Yes, that was one of the foci of my practice.

2 Q. And during the time you were practicing, did you run a
3 psoriasis clinic?

4 A. For most of the years during those 40-plus years, I had a
5 weekly psoriasis clinic.

6 Q. And approximately how many patients a week would you see
7 at the psoriasis clinic?

8 A. About 10 or 12.

9 Q. And did you prescribe topical therapy for any of the
10 patients suffering from psoriasis that you treated?

11 A. Yes, a majority of the patients received topical therapy
12 either alone or in combination with other treatments.

13 Q. Dr. Stern, do you perform research at Harvard Medical
14 School?

15 A. I do.

16 Q. And what is the focus of your research?

17 A. My research over the years has focused on psoriasis's
18 adverse reactions to drugs and nonmelanoma skin cancer,
19 particularly from an epidemiologic perspective.

20 Q. And Dr. Stern, have you ever published any articles on
21 the treatment of psoriasis?

22 A. Yes, I have.

23 Q. Approximately how many?

24 A. About 70 original contributions that were peer reviewed
25 that concerned psoriasis.

1 Q. Dr. Stern, I'd like to direct your attention to DX-208.

2 Do you recognize this document in your binder?

3 A. Yes, I do.

4 Q. And can you tell us what it is?

5 A. It's my curriculum vitae.

6 Q. And is it an accurate summary of your education,
7 professional background and achievements?

8 A. It is as of the date of preparation.

9 Q. If we look at the education section on the first page of
10 your CV, what degrees have you obtained?

11 A. I received a bachelor of arts from Harvard College magna
12 cum laude, and then an M.D., a doctor of medicine, from Yale
13 University School of Medicine four years later.

14 Q. And in what year did you receive your M.D. from Yale?

15 A. 1970.

16 Q. And did you undertake any additional medical training
17 after receiving your M.D.?

18 A. Yes. Upon graduation I became an intern in internal
19 medicine at the Mount Sinai School of Medicine. I followed
20 that with two years as a research associate at the National
21 Institute of Neurologic Diseases and Stroke at the NIH in the
22 epidemiology and genetic section.

23 I then went to the Harvard program, the Harvard at
24 Mass General Hospital program in dermatology and a fellowship
25 at the Harvard Center For Community Health and Medical Care.

1 Q. Dr. Stern, if you look at pages 6 through 8 of your CV,
2 it lists professional societies. Are you a member of any
3 professional societies?

4 A. Yes, I am.

5 Q. Which ones?

6 A. Among them are the American Academy of Dermatology and
7 the American Dermatologic Association and the Photomedicine
8 Society.

9 Q. And pages 3 and 4 of your CV list other professional
10 positions. What other professional positions have you held?

11 A. I have served on the dermatology advisory panel to the
12 U.S. Food & Drug Administration between eight and ten years;
13 about half that time as chair of that panel.

14 I have also served for 15 years as the head of the
15 dermatology panel to the United States Pharmacopeia. I've
16 also served on the medical advisory panel for the National
17 Psoriasis Foundation for five years, from 1999 to 2004.

18 Q. And, Dr. Stern, looking at page 8 of your CV, are you a
19 reviewer or editor for any peer-reviewed journals?

20 A. Well, for 18 years, I served first as associate editor,
21 then as co-editor of the Archives of Dermatology, which is one
22 of the two principal clinical journals for dermatology in the
23 United States. It's now known as JAMA Dermatology.

24 I also was a founding editor of the review journal
25 called Medical and Surgical Dermatology. I'm also on the --

1 have served on the editorial board of Photomedicine Journal
2 and also the Journal of Investigative Dermatology.

3 I actively review for many dermatology journals and
4 also general medical journals, including the New England
5 Journal of Medicine, the Lancet, the British Medical Journal.

6 Q. Dr. Stern, looking at pages 18 through 44 of your CV, how
7 many publications have you written over the course of your
8 career?

9 A. Well, in terms of original distributions, that is
10 peer-reviewed, research-based contributions, a little over
11 180. In terms of book chapters, reviews, editorials, about
12 140.

13 Q. Dr. Stern, what were you asked to do in this case?

14 A. I was asked to review four patents.

15 Q. And what did those patents relate to?

16 A. So two of the patents relate to a 0.1 percent formulation
17 of halobetasol in a lotion. The other two patents relate to
18 that same lotion with the addition of 0.045 percent
19 tazarotene.

20 The first I referred to as the halobetasol patents,
21 and the second two that added the tazarotene, the combination
22 patents.

23 Q. Dr. Stern, have you had slides prepared that will help
24 you explain your opinions in this case?

25 A. I have.

1 Q. Can you briefly summarize what conclusions you drew based
2 on your analysis using DDX-2.2?

3 A. Yes. So I believe that the halobetasol patents, '307 and
4 '502, that their asserted claims would have been obvious to a
5 person of skill in the art.

6 Further, I believe that the other two combination
7 patents, '895 and '787, would have been obvious to a person of
8 skill in the art with respect to the asserted claims of those
9 two patents.

10 Q. Now, Dr. Stern, you mentioned that you formed opinions
11 regarding obviousness. Do you have an understanding of the
12 legal standards for obviousness?

13 A. Well, I'm not a lawyer, but counsel has educated me about
14 the legal standard for obviousness.

15 Q. And can you explain your understanding of that legal
16 standard, using slide 2.3?

17 A. Yes. A claim is obvious if the differences between the
18 subject matter of the claim and the prior art are such that
19 the subject matter of the claim as a whole would have been
20 obvious to a person of ordinary skill in the art at the time
21 the patent was filed.

22 In determining whether a claim is obvious, four
23 primary factors should be considered: the scope and content
24 of the prior art; differences between the prior art and the
25 claims; the level of skill in the pertinent art of a person of

1 ordinary skill in that art; and secondary considerations of
2 non-obviousness.

3 A person of skill in the art must have been motivated
4 to combine and/or modify prior art with reasonable expectation
5 of success in doing so.

6 Q. Now, Dr. Stern, I understand you're not a lawyer but a
7 practice dermatologist. Did you apply these standards as best
8 you could in forming your opinions?

9 A. I did.

10 Q. Okay. Now, you indicated that you analyzed the validity
11 of the halobetasol patents. From whose perspective did you
12 analyze validity?

13 A. From the perspective of a person of skill in the art.

14 Q. A person of skill in the art in what timeframe?

15 A. For those patents, November 2010.

16 Q. Okay. If we look at slide 2.4, Dr. Stern, what would
17 have been the qualifications of a person of ordinary skill in
18 the art?

19 A. A person of skill in the art would have a person working
20 as part of a multidisciplinary team. One member of that team
21 would be a person with an advanced degree in chemistry,
22 pharmacy or a related discipline, and several years of
23 experience developing topical pharmaceutical formulations; or,
24 alternatively, a person with a bachelor of arts or science in
25 those disciplines and greater experience developing topical

1 pharmaceutical formulations.

2 Another person, another member of that team, would be
3 a clinician with several years experience using topical
4 formulations to treat patients with skin disorders, including
5 psoriasis, and an understanding of the considerations relevant
6 to evaluating the clinical effects, including safety and
7 efficacy, of topical pharmaceutical formulations.

8 Q. Now, Dr. Stern, by November of 2010, would you have
9 satisfied this definition of a person of skill in the art?

10 A. Yes, as the clinician member of the team.

11 Q. Now, did you review the definition of a person of skill
12 in the art that Dr. Stein Gold proposed in this case?

13 A. I did.

14 Q. Would any of your opinions change if Dr. Stein Gold's
15 definition of the person of skill in the art were applied
16 instead of yours?

17 A. They would not.

18 Q. Dr. Stern, if you could look at JTX-001 in your binder
19 and JTX-004 in your binder.

20 And my question is, do you recognize these documents?

21 A. I do. They are, respectively, the -- they are together
22 the halobetasol patents, respectively '307 and '502.

23 Q. And in rendering your opinions, did you review the
24 halobetasol patents in their entirety?

25 A. I did.

1 Q. And do the halobetasol patents discuss similar subject
2 matter?

3 A. They do. In most aspects, they are nearly identical.

4 Q. And can you explain what that subject matter is, using
5 slide 2.5?

6 A. So they describe topical compositions of corticosteroids,
7 focusing on halobetasol propionate. They make various claims
8 on -- concerning amounts of halobetasol ranging from less than
9 0.05 percent to less than 0.01 percent.

10 Some of the claims require methods of treating skin
11 disorders by applying the composition.

12 Q. Now, Dr. Stern, do you know which claims of the '307
13 patent Bausch is asserting in this case?

14 A. I do.

15 Q. Can you explain which claims those are, using slide 2.6?

16 A. Yes. For patent '307, the asserted claims are 13, 16 and
17 20. All of these claims depend on claim 1, which recites a
18 pharmaceutical composition comprising halobetasol at a
19 concentration of .04 percent or less.

20 Claim 13 calls for halobetasol propionate at a lower
21 concentration, that is of .025 or less, and makes further
22 formulations and specifications.

23 Claim 16 calls for a method of treating a disorder of
24 the skin that is amenable to treatment with a topical
25 corticosteroid comprising a pharmaceutical composition of

1 claim 4 and claim -- that in claim 4 is also covered in
2 claim 13, and applying an amount to the skin that is effective
3 in ameliorating the signs or symptoms of that skin disorder.

4 Claim 20 is a -- calls for it to be a liquid with --
5 calls for various formulation aspects.

6 Q. And, Dr. Stern, do you know which claim of the '502
7 patent Bausch is asserting in this case?

8 A. Yes, I do.

9 Q. And can you explain which claims those are, using
10 slide 2.7?

11 A. Yes. They are asserting claim 4 and claim 16, both are
12 dependent on claim 1. Claim 1 differs from claim 1 of the
13 '307 patent in that it talks about 0.05 percent, less than
14 0.04 percent, and in addition to halobetasol, lists four other
15 topical corticosteroids.

16 Claim 4 talks about it being halobetasol and the
17 concentration being 0.01 percent or less.

18 And claim 13 is -- makes the claim of applying the
19 pharmaceutical composition over a period longer than two
20 weeks.

21 Q. Dr. Stern, have you formed any opinions as to whether the
22 asserted claims of the halobetasol patents would have been
23 invalid?

24 A. Yes, I have.

25 Q. And if we look at slide 2.8, would you please summarize

1 your opinions regarding the validity of the halobetasol
2 patents?

3 A. Yes. Prior to November 2010, a person of skill in the
4 art would have been motivated to use concentrations of
5 halobetasol propionate as low as 0.01 to treat psoriasis.

6 Prior to this date, a person of skill in the art
7 would have reasonably expected that concentrations of
8 halobetasol as low as 0.01 percent would be effective in
9 treating psoriasis.

10 Prior to November 2010, a person of skill in the art
11 would have been motivated to use a topical composition
12 comprising halobetasol at concentrations of 0.04 percent or
13 less to treat psoriasis for a period of longer than two
14 consecutive weeks with a reasonable expectation of success.

15 Q. So, Dr. Stern, now that we have the big-picture opinions,
16 I would like to go back and try to unpack the details that get
17 you to there in your analysis.

18 You mentioned that the claims recite a specific
19 corticosteroid, halobetasol propionate.

20 A. That's correct.

21 Q. Go ahead.

22 If you look at slide 2.9, can you explain what
23 halobetasol propionate is?

24 A. Yes. Halobetasol is a well-known corticosteroid used for
25 many years to treat psoriasis when applied topically. It has

1 anti-inflammatory and antipruritic effects. It's been
2 commercially available for, basically, about 30 years as
3 Ultravate® in a cream and ointment form, and also more
4 recently in a lotion form at 0.05 percent. It's classified as
5 a superpotent corticosteroid and, again, approved in the
6 United States since the 1990s.

7 Q. So, Dr. Stern, can you please look in your binder at
8 DX-009.

9 Do you recognize this document?

10 A. I do.

11 Q. Can you tell me what it is?

12 A. This is the label for Ultravate® 0.05 percent halobetasol
13 propionate cream, approved for psoriasis in the United States.

14 Q. And, Dr. Stern, if you look at slide 2.10, are there any
15 side effects associated with treating psoriasis with
16 Ultravate® or halobetasol propionate?

17 A. Yes. As indicated in the highlighting, superpotent
18 corticosteroids, including Ultravate®, have the possibility of
19 inducing suppression of the hypothalamic pituitary adrenal
20 axis. This risk is related to total dosage and to especially
21 with use beyond two weeks, which was not recommended by the
22 FDA in its labelling of Ultravate®.

23 Q. And, Dr. Stern, are the side effects associated with
24 corticosteroids concentration dependent?

25 A. They are dependent on the strength of the steroid and the

1 amount that enters into the systemic circulation and, hence,
2 into the body.

3 Q. Now, is psoriasis a chronic condition?

4 A. Yes.

5 Q. And in your clinical experience, is a two-week treatment
6 time sufficient to alleviate psoriasis for most patients?

7 A. Not in most cases.

8 Q. And is the risk of systemic side effects more pronounced
9 with any particular type of corticosteroid?

10 A. As I've mentioned, the higher the potency of the steroid
11 and the greater the amount applied particularly -- and the
12 longer the application, all of those three factors increase
13 the risk of systemic side effects with topical steroids, and
14 systemic steroids as well.

15 Q. Did you form any opinion on whether a person of skill in
16 the art would have been motivated to use concentrations of
17 halobetasol propionate as low as 0.01 percent to treat
18 psoriasis prior to November of 2010?

19 A. Yes.

20 Q. And can you explain your opinion, using slide 2.11?

21 A. Well, as we've just said, psoriasis often needs treatment
22 for more than two weeks. The higher potency steroids at
23 higher -- the more steroid that is available for absorption,
24 the higher the risks of -- the higher it is likely that
25 systemic levels will be. So, therefore, if you apply a lower

1 concentration, the person is exposed to less of that given
2 steroid, and you would have expected a lower concentration to
3 result in lower risk of systemic side effects. And lower
4 doses can be tolerated safely for longer treatment periods.

5 The key is that, as we know in general, that one can
6 often lower the concentration of a steroid such as halobetasol
7 propionate substantially with only modest effect on potency
8 and, thereby, reduce the risk of systemic adverse events and
9 extend the ability to treat the patient.

10 Q. So, Dr. Stern, can you please look at DX-002 in your
11 binder.

12 Do you recognize this document?

13 A. I do.

14 Q. What is it?

15 A. This is a 1986 publication by Blum and Yawalkar that
16 describes a multicentered, double-blind study comparing
17 0.02 percent, 0.05 percent halobetasol with Dermovate -- which
18 in the U.S. goes by the name of -- or the generic name is
19 clobetasol -- in the treatment of patients with chronic
20 psoriasis.

21 Q. And, Dr. Stern, if you could look at slide 2.12.

22 What did the results of the Blum study disclose?

23 A. So Blum showed, as is shown in the first three columns,
24 that 0.02 percent, about 81 percent of patients randomized to
25 that are -- had -- were cured or had significant improvement

1 in this three-week study. And that compared to 0.05 percent,
2 90 percent. Or what that says is that you could reduce the
3 amount of halobetasol by 60 percent and have an almost as
4 effective agent for the treatment of psoriasis, only a
5 9 percent reduction in efficacy.

6 It also showed that the lower concentration,
7 0.02 percent of halobetasol, was essentially equivalent to 81
8 versus 86 percent cured or significantly improved compared to
9 patients using clobetasol, which at the time of this paper was
10 the most widely used ultra-potent steroid.

11 Q. Dr. Stern, did the Blum article DX-002, contain a
12 statistical analysis comparing the three different test drugs?

13 A. Yes, it did.

14 Q. And what did that analysis conclude?

15 A. The analysis concluded that there was no statistically
16 significant difference between -- for the outcomes between the
17 three tested preparations: the 0.02, the 0.05 of halobetasol,
18 and the 0.05 percent clobetasol, which we called Temovate® in
19 this country.

20 Q. So statistically speaking, they were all the same?

21 A. They were indistinguishable statistically.

22 Q. Okay. Did you form any opinions regarding whether a
23 person of skill in the art would have expected concentrations
24 of halobetasol propionate as low as 0.01 percent to be
25 efficacious in treating psoriasis prior to November of 2010

1 based on what was disclosed in Blum?

2 A. Yes, I did.

3 Q. And what are those opinions?

4 A. My opinion is that this work that shows one could reduce
5 the concentration of halobetasol by 60 percent and lose very
6 little, if any, efficacy in the treatment of psoriasis would
7 have motivated an individual to further reduce the
8 concentration with the expectation that all or most efficacy
9 would be -- would be preserved. And this has been seen with
10 other steroids as well.

11 Q. And did you form any opinion regarding whether a person
12 of skill in the art would have been motivated to use
13 concentrations of halobetasol propionate as low as
14 0.01 percent to treat psoriasis for a period of longer than
15 two weeks prior to November of 2010?

16 A. Yes. One of the goals in reducing the concentration is
17 less exposure allows an individual to use the steroid for a
18 longer period with a lower risk of systemic and local side
19 effects.

20 Q. And was a two-week treatment sufficient for most
21 patients, or did they need a longer treatment?

22 A. No. As we've said, most patients with psoriasis treated
23 with almost anything need more than two weeks of therapy to
24 achieve certainly a cure and usually significant improvement.

25 Q. Dr. Stern, can you please look at DX-006 in your binder.

1 Do you recognize this document?

2 A. Yes. Yes, I do.

3 Q. And can you tell me what it is?

4 A. This is the label for Temovate E®, clobetasol propionate.
5 This is the cream form of the ointment that was the third
6 comparator in the Blum trial. And, again, is a superpotent
7 steroid which was, I believe, the first superpotent steroid
8 introduced in the United States.

9 Q. And, Dr. Stern, can you explain what DX-006 discloses to
10 a person of skill in the art, using slide 2.14?

11 A. So what it tells us is that another way to allow a person
12 to use this agent for more than two weeks with a reasonably
13 low risk of HPA axis suppression is to reduce the amount
14 applied by limiting the application to 5 to 10 percent of body
15 surface area.

16 So it tells us that the quantity applied is, as we
17 would know -- as is general medical knowledge, the quantity
18 applied affects how much is likely to get in. And two ways to
19 reduce the quantity applied is, one is to reduce the
20 concentration, and the other is to put it on a smaller area.

21 So this says that in treatment of psoriasis, the
22 superpotent steroid can be used for up to four weeks as long
23 as you don't apply it to more than 10 percent of body surface
24 area.

25 Q. And, Dr. Stern, did the Temovate E® Label, DX-006, inform

1 your opinion regarding whether a POSA would have reasonably
2 expected success in treating psoriasis for a period longer
3 than two weeks with concentrations of halobetasol propionate
4 as low as 0.01 percent prior to November of 2010?

5 A. Yes. This label tells me that certainly when applied to
6 body surface areas below 10 percent, lowering the
7 concentration to 0.01 percent of halobetasol would mean less
8 topical product applied and should further decrease the risks
9 of HPA axis suppression, making four weeks of therapy -- more
10 than two weeks of therapy even safer.

11 Q. Dr. Stern, I'd like to shift gears from the halobetasol
12 patents to the combination patents.

13 Have you formed any opinions relating to the validity
14 of the combination patents?

15 A. Yes, I have.

16 Q. And if you look at slide 215, would you please summarize
17 your opinions regarding the validity of the combination
18 patents?

19 A. So it is my opinion that patents '895 and '787, the
20 combination patents asserted claims, would have been obvious
21 over three combinations of the prior art. The first
22 combination is what I refer to as the '824 Publication plus
23 the Gollnick article plus the Tazorac® Label.

24 The second combination is the '824 Publication, the
25 Gollnick article and the IDP-118 study in ClinicalTrials.gov.

1 The third combination is the '824 Publication, the
2 Gollnick article and a patent -- a 2012 patent application
3 which I will refer to as Gandhi.

4 Q. Dr. Stern, can you please take a look at DX-142 in your
5 binder.

6 Do you recognize this document?

7 A. Yes, I do.

8 Q. Can you tell me what it is?

9 A. This is the '824 Publication, which is a patent
10 application concerning halobetasol 0.01 percent in the lotion.

11 Q. And do you have an understanding of whether the '824
12 Publication is related to the halobetasol patents that you
13 discussed earlier?

14 A. It is substantively the same particularly with --
15 substantively the same as to the two halobetasol patents I've
16 been discussing.

17 Q. And can you please look at DX-140 in your binder.

18 Do you recognize this document?

19 A. Yes, I do.

20 Q. And can you tell me what it is?

21 A. Yes. This is a publication in the British Journal of
22 Dermatology in 1999 by Gollnick and Menter that reports two
23 clinical trials that used combinations of topical
24 corticosteroids and tazarotene in patients with psoriasis.

25 These were vehicle-controlled -- I'm sorry. They

1 looked at the various combinations and compared them to
2 tazarotene and the vehicle.

3 Q. Dr. Stern, can you please look at DX-10 in your binder.

4 A. Yes.

5 Q. Do you recognize this document?

6 A. Yes, I do.

7 Q. And what is it?

8 A. This is the FDA labelling for Tazorac® Cream which is
9 0.05 percent and 0.01 percent tazarotene, which is approved
10 for psoriasis and other indications.

11 Q. And in the clinical trials section of the label, how long
12 was the treatment for?

13 A. 12 weeks, with a 12-week follow-up.

14 Q. Okay. And can you please look at DX-64.

15 Do you recognize this document?

16 A. Yes, I do.

17 Q. And what is it?

18 A. This is the ClinicalTrials.gov January publication of the
19 IDP-118 study which compared -- which set out for an analysis
20 of halobetasol tazarotene 0.01 and tazarotene 0.045 percent in
21 a lotion compared to each of the monads and the lotion alone.

22 Q. Dr. Stern, finally, can you please look as DX-141.

23 Do you recognize this document?

24 A. Yes, I do.

25 Q. And what is it?

1 A. This is a 2012 Indian patent application which describes
2 the combination of halobetasol and tazarotene in single
3 formulations, including lotions.

4 Q. And, Dr. Stern, if you could look at slide 2.16.

5 Would you please summarize your opinions regarding
6 the obviousness of the combination patents?

7 A. Yes. Prior to the '824 -- the '824 Publication discloses
8 every limitation except the simple addition of tazarotene and
9 the synergy limitations of the combination patents.

10 Prior to June 2015, a person of skill in the art
11 would have been motivated to add tazarotene to the '824
12 Publication's halobetasol lotion.

13 Prior to June 2015, a person of skill in the art
14 would have reasonably expected the combination to be capable
15 of providing synergistic efficacy and synergistic reduction in
16 an adverse event.

17 Synergies are an inherent property of IDP-118.

18 Q. Okay. From whose perspective did you analyze the
19 validity of the asserted claims of the combination patents?

20 A. From that of person of skill in the art.

21 MR. ZIMMERMAN: And if we could look at slide 2.17.

22 BY MR. ZIMMERMAN:

23 Q. A person of skill in the art at what time frame?

24 A. As of June 2015.

25 Q. And what would have been the qualifications of a person

1 of ordinary skill in the art in June of 2015?

2 A. The same as I listed earlier for the halobetasol patents.

3 Q. And would you have satisfied this definition of a person
4 of skill in the art in June of 2015?

5 A. Yes, I would have had an additional five years of
6 experience as a dermatologist and teacher.

7 Q. Dr. Stern, if you could look at JTX-002 in your binder
8 and JTX-003, and tell me when you're done.

9 THE COURTROOM DEPUTY: How much longer do you have?

10 MR. ZIMMERMAN: I would guess 30 to 40 minutes. So I
11 didn't know what time you were --

12 THE COURTROOM DEPUTY: Finish up with this line of
13 testimony.

14 BY MR. ZIMMERMAN:

15 Q. Dr. Stern, do you recognize these two documents?

16 A. I do.

17 Q. And what are they?

18 A. These are the '895 and the '787 patents, which I've
19 referred to as the combination patents.

20 Q. As in rendering your opinions, did you review the
21 combination patents in their entirety?

22 A. I did.

23 Q. And do the combination patents discuss similar subject
24 matter?

25 A. Yes.

1 Q. And can you explain what that subject matter is using
2 slide 18?

3 A. That the '895 patent makes claims of pharmaceutical
4 compositions containing a 0.045 percent tazarotene and a 0.01
5 percent halobetasol, and it refers to that as IDP-118.

6 The '787 patent claims methods of applying those
7 compositions to the human skin.

8 Q. And, Dr. Stern, do you know which claims of the '895
9 patent Bausch is asserting?

10 A. I do.

11 Q. And can you explain what those claims relate to using
12 slide 2.19?

13 A. Yes. For patent '895, they are asserting claims 3 and 6.
14 Those are dependent on claim 1, which calls for topical
15 pharmaceutical composition for treating psoriasis, which is
16 composed of 0.01 percent halobetasol and tazarotene at a
17 concentration of 0.045 percent.

18 And claim 1 further states that this combination is
19 capable of providing synergistic efficacy and synergistic
20 reduction of at least an adverse event selected from a group
21 of three.

22 Claim 3 is a formulation claim, which states that the
23 emulsion of claim 2 is, in fact, a lotion.

24 Claim 6 is a formulation claim that further describes
25 the lotion.

1 Q. Dr. Stern, do you know which claims of the '787 patent
2 Bausch is asserting?

3 A. I do.

4 Q. And can you explain which ones with regard to slide 2.20?

5 A. Yes. So, again, these claims 4, 5 and 6 are asserted.
6 These are all dependent on claim 1.

7 Claim 1 is -- also adds -- in addition to specifying
8 the concentrations of halobetasol and tazarotene, adds the
9 plot that is carried out one or more times per day for a
10 period of time sufficient to treat psoriasis and also mentions
11 the expectation of synergistic efficacy and synergistic
12 reduction of an adverse event.

13 Claim 3 is a formulation claim.

14 Claim 4 talks about the emulsion of claim 3 being the
15 lotion.

16 And claim 7 is the method of claim 2, which calls for
17 once a week -- which calls for once daily application for
18 eight weeks. And it says that: Wherein the method continues
19 to provide relief to said psoriasis for a period of four weeks
20 after the eight weeks of application of the composition called
21 for in claim 2.

22 Q. And, Dr. Stern, I may have misheard you. So I want to
23 make sure we have a clear record.

24 Did you say the asserted claims were 4, 5 and 7 or 4,
25 5 and 6?

1 A. I hope I said 4, 5 and 7, but I'm not sure. That's what
2 I meant.

3 Q. So we can agree that 4, 5 and 7 are the asserted claims?

4 A. Yes.

5 Q. Now, did you consider any claim constructions for the
6 terms in the combination patents in performing your analysis?

7 A. Yes, I did.

8 Q. And if you could look at slide DDX-2.21, are these the
9 constructions that you applied?

10 A. Yes. And it's my understanding that the Court has come
11 up with the constructions on the right-hand side of this slide
12 and those are the ones I used in terms of interpreting "is
13 capable of," "synergistic efficacy" and "is capable of
14 providing synergistic reduction."

15 It is also my understanding that the Court has ruled
16 that statistical significance is not required and is improper.

17 Q. And, Dr. Stern, that last piece about statistical
18 analysis being precluded, did that happen after you issued
19 your expert reports?

20 A. Yes, it did.

21 Q. And does it change the validity of anything you are
22 presenting today?

23 A. It does not.

24 Q. And earlier when you were going through the claims, you
25 identified some of the limitations as formulation limitations.

1 Are you a formulation expert?

2 A. I am not.

3 Q. Okay. And is it your understanding that there's a
4 separate expert that is addressing formulation limitations?

5 A. Yes.

6 MR. ZIMMERMAN: Now is a good stopping point, if that
7 is convenient for the Court.

8 THE COURTROOM DEPUTY: Sure. 15 minutes.

9 All rise.

10 (Recess taken from 3:02 p.m. to 3:25 p.m.)

11 THE COURT: Folks, we've been rolling along very
12 rapidly here. Tell me what you anticipate for the remainder
13 of the case.

14 MR. ZIMMERMAN: Your Honor, defendants have to finish
15 Dr. Stern. We have one more expert witness on formulation.
16 And that would be our case, with the exception that we have
17 two depositions, they run roughly 45 minutes.

18 We are happy to submit them on the papers, have you
19 charge us the time for them so that we get balance time, but
20 in an effort to move that along, we can do that.

21 I have both witnesses here. We can put them on
22 tonight, if you'd like.

23 Our rebuttal case is likely one commercial success
24 person and maybe a technical person.

25 So that's where we stand.

1 THE COURT: Those are your additional witnesses?

2 MR. ZIMMERMAN: Oh, I'm sorry. I've been corrected
3 that there are three depositions that go in.

4 MR. STEINDLER: So on our side, we've got obviously
5 crosses of their two experts, then they'll be done with their
6 case, apart from the depositions, which we've already talked
7 about them submitting, we have no problem with.

8 Then we put on our responsive case, which will
9 involve three experts. They're not short. I suspect we could
10 get them all done on and off in a day, but that doesn't leave
11 my learned friend here any time to put on his rebuttal case or
12 at least it might squeeze his rebuttal case if we tried to put
13 this all in on Friday. That would be my concern.

14 THE COURT: So we'll continue -- we'll continue as we
15 have currently scheduled.

16 MR. STEINDLER: Look, and we might want to talk
17 little bit more about this, you know, tonight, but as we stand
18 here right now, that would be our preference.

19 THE COURT: Let me just make a phone call.

20 THE COURTROOM DEPUTY: Judge, are you going to sit
21 past 5:00 o'clock, because I have to make arrangements with
22 security?

23 THE COURT: No. We're going to sit regular time.

24 THE COURTROOM DEPUTY: We're done at five.

25 THE COURT: We'll stop at five, yes.

1 (Recess taken from 3:28 p.m. to 3:31 p.m.)

2 THE COURT: Let's resume.

3 MR. ZIMMERMAN: May I proceed, Your Honor?

4 THE COURT: Yes, proceed. That's what I meant by
5 resume.

6 MR. ZIMMERMAN: Thank you.

7 BY MR. ZIMMERMAN:

8 Q. Dr. Stern, before the break we had talked about the
9 Court's constructions. I want to shift gears to the Gollnick
10 reference, DX-140 in your book.

11 Can you explain what was tested in the Gollnick
12 reference?

13 A. Yes. So the Gollnick is two independent clinical trials,
14 one done in the United States, one done in Europe. Each
15 enrolled a little bit over 300 patients.

16 Each trial -- so the first trial, the U.S. trial, had
17 patients -- everyone applied tazarotene, Tazorac®, once a day.
18 At the other end of the day, they applied either a topical
19 corticosteroid using different ones -- that is, each patient
20 was assigned one of varying strengths -- or the cream that
21 looked like the topical steroid. And they did this for
22 12 weeks and then were seen in follow-up four weeks later.

23 So this is a randomized, double-blind study comparing
24 tazarotene plus placebo versus tazarotene and one of three
25 topical corticosteroids.

1 The European trial, similar in sized, randomized,
2 different topical corticosteroids, same agent. But the
3 difference was that patients only apply on alternate nights
4 they would apply either a topical corticosteroid or, if they
5 were in the placebo group, just the vehicle cream on one night
6 and the next night they would apply the tazarotene.

7 So it was once-a-day application on alternative days,
8 again, looking at the effects in 12 weeks with no
9 post-follow-up period.

10 Q. And if you look at slide 2.22, what were the results of
11 the Gollnick studies?

12 A. So both studies showed that adding a high potency
13 corticosteroid to tazarotene significantly improved efficacy
14 and reduced local skin effects.

15 And, in fact, Gollnick states that combination
16 therapy with tazarotene and a topical corticosteroid is likely
17 to have additive or synergistic effects.

18 And both studies demonstrate that using a topical
19 corticosteroid in combination with tazarotene improved both
20 safety and -- improved both efficacy and tolerability,
21 tolerability really being the main safety issue with
22 tazarotene compared to just using tazarotene with the cream.

23 Q. And does -- go ahead, Dr. Stern.

24 A. This would have motivated a person of skill in the art to
25 think about even stronger steroids, such as halobetasol, to

1 combine the tazarotene to improve efficacy and reduce skin
2 irritation.

3 Q. Now, did you form any opinion regarding whether a person
4 of skill in the art would have been motivated to combine
5 0.01 percent halobetasol propionate and 0.045 percent
6 tazarotene in a single formulation to treat psoriasis?

7 A. Yes, I did.

8 Q. And what is your opinion?

9 A. My opinion is, patients prefer to apply one thing rather
10 than two. There's a long history of dermatologic products
11 being combined successfully. And, therefore, a person of
12 skill in the art would look towards a formulation expert to be
13 able to combine the halobetasol and the tazarotene in a single
14 product.

15 Q. Now, Dr. Stern, did you review any prior art that
16 discloses the specific combination of halobetasol propionate
17 and tazarotene?

18 A. Yes.

19 Q. And if you look at slide 2.23, can you explain what that
20 prior art is?

21 A. Yes. There's a 2012 Indian patent application, which, as
22 I mentioned, I referred to as Gandhi, that specifically talks
23 about formulations comprising halobetasol and tazarotene
24 together, including lotion formulas.

25 In addition, he states that: When combined in a

1 formulation, these compounds have synergistic effects, which
2 lead to more rapid clearing and are notably effective for
3 types of psoriasis which have not responded to corticosteroids
4 or retinoids alone.

5 Q. And, Dr. Stern, did you review any prior art references
6 that specifically disclose the combination of 0.01 percent
7 halobetasol propionate and 0.045 percent tazarotene?

8 A. Yes, I did.

9 Q. And can you explain that reference using slide 2.24?

10 A. So this is the -- what has the ClinicalTrials.gov posting
11 of January 2014, and it describes a Phase 2B study that would
12 include one -- 0.01 percent halobetasol and tazarotene in the
13 IDP-118 lotion and comparing it -- that to the monad, that is,
14 the lotion with just halobetasol at the same concentration,
15 and/or the lotion and tazarotene at 0.045 percent or just the
16 vehicle lotion in the treatment of psoriasis.

17 Q. And, Dr. Stern, how did the concentration of halobetasol
18 propionate and the concentration of tazarotene in this IDP-118
19 clinical study posting compare to that of asserted claims of
20 the combination patents?

21 A. They are identical to the claims of the combination
22 patents.

23 Q. Okay. Did you form any opinion on whether a person of
24 skill in the art would have been motivated to use 0.01 percent
25 halobetasol propionate as part of a combination product with

1 tazarotene to treat psoriasis in June of 2015?

2 A. Yes, I did.

3 Q. And can you explain that opinion using slide 25?

4 A. Yes. As we've heard earlier, the halobetasol -- what
5 I've referred to as the halobetasol patents, in fact, a
6 publication discloses that one can use -- that 0.01 percent is
7 nearly as efficacious as 0.05 percent and that the reduced
8 concentration allows for longer than two weeks of use, which
9 is, as we've talked about, important for treatment of
10 psoriasis.

11 So the person would have been motivated to use the
12 lower concentration with the expectation of greater safety
13 than the 0.05 percent with little loss in efficacy and the
14 ability to use for longer than two weeks.

15 Q. And, Dr. Stern, did you form any opinion regarding
16 whether a person of skill in the art would have been motivated
17 to use 0.045 percent to tazarotene to treat psoriasis based on
18 the concentration information in the Tazorac® label in June of
19 2015?

20 A. Yes, I did.

21 Q. Can you explain your opinion using slide 26?

22 A. Yes. As has been discussed, Tazorac® has a problem with
23 it causing irritancy. As is shown in the label, a higher --
24 as one would expect, the higher the concentration the more
25 irritating.

1 The label calls for reducing the use from
2 0.01 percent to 0.045 percent in order to reduce irritation.
3 For the patient who experiences irritation at the higher dose,
4 a person would have been motivated to try to slightly reduce
5 irritation further by a small reduction.

6 The Tazorac® label further shows that the reduction
7 from 0.01 percent to 0.05 percent, as shown in the next slide,
8 has a rather little impact on the efficacy of the tazarotene.

9 So as shown here, if you look at the first two
10 columns highlighted in yellow, it shows the efficacy of the
11 0.05 percent at the end of the double-blind placebo-controlled
12 trial.

13 And if you compare those percentages to the efficacy
14 in these same two trials, you can see that there's little
15 diminution in overall efficacy by lowering the concentration
16 from 0.1 to 0.05.

17 So one would have -- one would expect that a further
18 lowering of only 10 percent from 0.05 to 0.045 should lower
19 irritation and not substantially impact efficacy and thereby
20 improve the product.

21 Q. Dr. Stern, you mentioned the teachings of a number of
22 prior art references, namely the '824 Publication, Gollnick,
23 the IDP-118 study, the Tazorac® label and Gandhi.

24 Did you form any opinions regarding whether a person
25 of skill in the art would have been motivated to combine the

1 teachings of these references?

2 A. Yes, they would have.

3 Q. And can you explain those opinions using slide 28?

4 A. Yes. So the '824 Publication tells us about 0.01 percent
5 halobetasol in a lotion that can be used for more than two
6 weeks.

7 Gollnick tells us that combining Tazorac® and
8 tazarotene and halobetasol or topical steroids enhance the
9 activity of them in the treatment of psoriasis and give one a
10 reasonable expectation of synergy.

11 The Tazorac® label tells us that using 0.045 percent
12 is, in fact, reasonable and likely to be nearly as efficacious
13 as the higher concentrations.

14 The combination of the '824 Publication in Gollnick
15 and the IDP-118 study give us all the facts that I just
16 mentioned plus exactly specify the composition that is the
17 0.01 percent, the lotion that is in the '824 Publication and
18 0.045 percent tazarotene.

19 The '824 Publication, Gollnick and Gandhi, again,
20 tell us about a lotion of halobetasol 0.01 percent that can be
21 used for more than two weeks, that a potent topical
22 corticosteroids together with tazarotene are likely to lead to
23 synergy.

24 And Gandhi tells us that these agents are combined --
25 can be combined in a lotion with an expectation of synergy.

1 Q. So, Dr. Stern, if you look at slide 29, can you explain
2 any other reasons why a person of skill in the art might have
3 been motivated to combine these references in this way?

4 A. Well, all five references deal with --

5 Q. I'll repeat it.

6 Can you explain why you believe a person of skill in
7 the art would have been motivated to combine the references in
8 this way?

9 A. So as I mentioned, all five references deal with topical
10 treatments of psoriasis with corticosteroids and/or
11 tazarotene.

12 Gollnick, the Tazorac® label, the IDP-118 and Gandhi
13 all deal with treating psoriasis with tazarotene.

14 Gollnick combined tazarotene and potent steroids,
15 increased efficacy, and lowered skin irritation, which
16 demonstrated a person of skill in the art would have been
17 motivated to combine the '824 publication with the other four
18 references because it provides halobetasol propionate with
19 similar efficacy in a lower concentration.

20 Q. So, Dr. Stern, did you form any opinions regarding
21 whether a person of skill in the art would have been
22 reasonably expected the combination of 0.01 percent
23 halobetasol propionate and 0.045 percent tazarotene would be
24 capable of providing synergistic efficacy and a synergistic
25 reduction in an adverse event?

1 A. Yes, I did.

2 Q. And can you explain your opinions using slide 2.30?

3 A. As I mentioned previously, Gollnick, both through his
4 results and his exact statements, states that these
5 combinations of corticosteroid and tazarotene are likely to
6 have additive or synergistic effects. And this reflects the
7 fact that they have -- that it is logical based on their
8 mechanisms of action.

9 Gandhi further states that when combined in a single
10 formulation, this product has synergistic effects which may
11 lead to more rapid clearing and are notably more effective for
12 types of psoriasis.

13 So with these two statements, what we know about
14 mechanism, a person of skill in the art would have reasonably
15 expected the combination to provide synergistic efficacy and a
16 synergistic reduction of an adverse event.

17 Q. And, Dr. Stern, did you form any opinion on whether the
18 synergy limitations are related to an inherent property of
19 IDP-118?

20 A. Yes, I did.

21 Q. And can you explain your opinion using slide 2.31?

22 A. Yes. Applying IDP-118 to psoriasis patients naturally
23 and inherently results in any synergistic efficacy and any
24 synergistic reduction of adverse events.

25 If synergy is present, it is an inherent property of

1 IDP-118 formulation, which is, as I've said, an obvious
2 formulation.

3 Q. So, Dr. Stern, I'd like to turn to your opinion that the
4 asserted claims of the combination patents would have been
5 obvious based on the prior art references you've discussed
6 today.

7 I know this is kind of the tedious part, but did you
8 form an opinion regarding whether claim 3 of the '895 patent
9 would have been obvious to a person of skill in the art in
10 June of 2015?

11 A. I did.

12 Q. And can you explain that opinion using slide 2.32?

13 A. Yes. On the left-hand side, I divided the claim 3 into
14 claim limitations. If you look at the claim limitations that
15 make up claim 3, the first two deal with incorporating
16 0.01 percent halobetasol and 0.045 percent tazarotene.

17 As I've mentioned, a person of skill in the art would
18 have been motivated to use the 0.01 percent halobetasol based
19 on the '824 Publication and allows longer use and the IDP-118
20 study that specifically defines it, the combination of
21 halobetasol with tazarotene at 0.045 percent.

22 The person of skill in the art would have added
23 tazarotene to the halobetasol described in the '824. It would
24 have been logic based on Gollnick. The IDP-118 study and the
25 Tazorac® label would've all made that logical.

1 As I've mentioned before, when the composition is --
2 should be capable of providing synergistic efficacy and a
3 synergistic reduction in at least one adverse event and that
4 synergy is inherent to the formulation of the IDP-118
5 formulation; that is, it directly reflects the action of that
6 formulation containing the two agents, active agents in a
7 person with psoriasis.

8 And again, synergy has been -- would have been
9 expected, as is stated clearly in the prior art by Gollnick
10 and Gandhi.

11 The fourth, fifth and sixth aspects of the claim
12 notations of claim 3 are largely to deal with formulation.
13 And Dr. Michniak-Kohn has stated they would be obvious, that
14 the combined product is clearly defined, also, in the IDP-118
15 study. And Gandhi also discloses lotions for this combination
16 of halobetasol and tazarotene, making it obvious along with
17 the '824 Publication.

18 Q. And, Dr. Stern, did you form an opinion regarding whether
19 claim 6 of the '895 patent would have been obvious to a person
20 of skill in the art in June of 2015?

21 A. Yes, I did.

22 Q. And can you explain your opinion using slide 2.33?

23 A. Yes. The first three claim limitations I've just
24 discussed and why they would be obvious in my discussion of
25 claim 3 of the '895.

1 The fourth claim limitation is a -- I'm sorry. The
2 asserted -- the fourth claim limitation is obvious, according
3 to Dr. Michniak-Kohn.

4 The fifth and sixth, again, are formulations
5 limitations, which are not within my expertise, but have --
6 according to Dr. Michniak-Kohn, would have been obvious based
7 on the prior art with her as part of the team.

8 Q. And, Dr. Stern, did you form an opinion regarding whether
9 claim 4 of the '787 patent would have been obvious to a person
10 of skill in the art in June of 2015?

11 A. Excuse me.

12 Yes, I have.

13 Q. And can you explain your opinion using slide 2.34?

14 A. Yes. So claim 4, the first two aspects are as I've
15 addressed in claim 3 of the '895 patent as to why a person of
16 skill in the art would have been motivated to use 0.01 percent
17 halobetasol and 0.045 percent tazarotene and combine them.

18 And as I have also previously discussed, why one
19 would expect this combination would be capable of providing
20 synergistic efficacy and synergistic reduction in at least one
21 side effect.

22 Applying is carried out one or more times per day for
23 time sufficient to treat psoriasis. That's standard in the
24 application of -- in psoriasis products and basically common
25 knowledge within the art of dermatology.

1 Gollnick also discloses that applying combinations of
2 tazarotene and topical steroids once per day each was
3 effective at 8 and 12 weeks and were sufficient to treat
4 psoriasis.

5 The fifth claim limitation will be addressed by
6 Dr. Michniak-Kohn further and is stated in her report to be
7 obvious.

8 And similarly, the sixth claim limitation is also
9 obvious, according to Dr. Michniak-Kohn.

10 Q. And, Dr. Stern, did you form an opinion regarding whether
11 claim 5 of the '787 patent would have been obvious to a person
12 of skill in the art in June of 2015?

13 A. Yes, I did.

14 Q. And can you explain your opinion using slide 2.35?

15 A. Yes. So the first four claim limitations -- the first
16 three claim limitations are as I've previously discussed,
17 particularly in discussing claim 3 of the '895.

18 I've just discussed applying -- why the claim
19 limitation of applying once or more per day for a period of
20 time sufficient to treat psoriasis is obvious in my discussion
21 of claim 4 of the '787 patent.

22 The next claim limitation listed here as 5 is a
23 formulation claim limitation and is obvious according to
24 Dr. Michniak-Kohn, the formulation expert.

25 The final claim limitation is also a formulation

1 limitation, and that will be further discussed by
2 Dr. Michniak-Kohn.

3 A person of skill in the art would have been
4 motivated to combine halobetasol propionate and tazarotene in
5 a single lotion to improve convenience and patient adherence.

6 That we know from the practice of dermatology and the
7 dermatologic arts.

8 Q. And finally, Dr. Stern, I'd like to turn to claim 7 of
9 the '787 patent.

10 Can you explain whether the prior art, and
11 specifically the Gollnick reference, taught that an eight-week
12 period was enough to effectively treat psoriasis with a
13 combination of tazarotene and corticosteroid?

14 And you can look at slide 2.36 in explaining your
15 opinion.

16 A. If you look at this graph, which plots over time
17 treatment success, you can see in the red box that the
18 treatment success at weeks 8 and 12 -- 12 being the end of the
19 period of application of the agents -- are virtually the same.

20 That tells us that an eight-week period is one
21 adequate for treating psoriasis with a high success rate.

22 Q. And, Dr. Stern, using slide 2.37, can you explain whether
23 the prior art taught that 0.01 percent halobetasol propionate
24 could be safely used for an extended period?

25 A. Yes. So as we've spoken about, a person would have

1 reasonably expected the combination of 0.1 percent could be
2 given for an extended period of time without unreasonable risk
3 of side effects based on the '824 Publication that teaches
4 that this concentration allows for longer treatment and that
5 its concentration is only one-fifth that of the Ultravate®
6 that is approved through two weeks, and further based on the
7 Temovate E® label, which tells us that applying less is safer
8 for longer periods.

9 Q. And, Dr. Stern, did the prior art, specifically the
10 Gollnick reference, teach that a combination of 0.01 percent
11 halobetasol and 0.045 percent tazarotene would continue to
12 provide relief for four weeks after stopping the treatment?

13 A. Yes. It indicated that one should expect that to be the
14 case.

15 Q. And can you explain why it teaches that using slide 3 --
16 I'm sorry -- 2.38?

17 A. Yes. So as one -- so one can see here the -- that in the
18 four-week treatment period there is very little loss of
19 efficacy.

20 If you look at the triangles and the diamonds, you
21 can see that high and mid-potency steroids combined with
22 tazarotene had as almost many patients still being successful
23 as were successful at week 12, when they stopped using the
24 treatment.

25 So this combination of high-potency steroid and

1 tazarotene continues to control people's -- a person's
2 psoriasis for four weeks after treatment.

3 Q. Dr. Stern, did you form any opinion on whether any
4 sustained relief for psoriasis resulting from administering
5 IDP-118 was an inherent property?

6 A. Yes. I believe this would be an inherent property of the
7 IDP-118 applied to the skin for a person with psoriasis.

8 Q. And can you explain why? I'm sorry. Can you explain
9 why?

10 A. As we've seen in the prior slide, tazarotene and potent
11 topical steroids together continue to provide sustained
12 relief, as shown in the randomized controlled trial.

13 The length of relief of psoriasis symptoms is just
14 the result of the natural reactions of the patient's disease
15 to the IDP-118 formulation. And, in addition, the Tazorac®
16 label shows us that tazarotene is an agent that gives
17 sustained relief after cessation of therapy when used to treat
18 psoriasis.

19 So between Gollnick and the Tazorac® label, we
20 would -- one would believe that one would expect continued
21 relief after cessation of therapy for at least four weeks.

22 Q. And, Dr. Stern, finally, did you form an opinion
23 regarding whether claim 7 of the '787 patent would have been
24 obvious to a person of skill in the art in June of 2015?

25 A. Yes, I did.

1 Q. And can you explain your opinion using slide 2.40?

2 A. Yes. So the first three claims dealing with the
3 constituents of the product and the expectation of synergy I
4 previously discussed for claim 3 of the '895.

5 The fourth claim limitation, applying one or more
6 times a day for a sufficient period, I've previously discussed
7 in my discussion of claim 4 of the '787 patent.

8 Next, Claim Limitation Number 5, Dr. Michniak-Kohn
9 holds that it's obvious and discussed further applying is
10 carried out once a day for eight weeks.

11 I've shown that Gollnick gives us a reasonable --
12 would give a person of skill in the art a reasonable
13 expectation and that this length of time therapy for psoriasis
14 with topical agents is a usual time and would have been
15 obvious.

16 And that the method continues to provide relief for a
17 period of four weeks after said eight weeks of application,
18 I've just reviewed that in terms of the findings from Gollnick
19 of continued relief and that sustained relief is, in fact,
20 inherent to the IDP-118 formulation.

21 Q. Dr. Stern, can you summarize your conclusions regarding
22 the obviousness of the combination patents using slide 2.41?

23 A. Yes. Yes. The prior art taught us that combining
24 cortico -- topical corticosteroids and tazarotene led to
25 better efficacy and less skin irritation and is likely to

1 provide synergy.

2 0.1 percent halobetasol lotion had high potency and
3 less side effects, as shown in the '824 Publication of 2012.

4 Lowering the concentration of tazarotene lead --
5 should lead to less skin irritation but little to no change in
6 efficacy, as shown by the Tazorac® label.

7 Topical formulations with halobetasol and tazarotene
8 with synergistic effects which arises, including lotions, are
9 documented in Gandhi's 2012 publication.

10 A lotion with 0.1 percent halobetasol and
11 0.045 percent tazarotene in a Phase 2B trial for psoriasis is
12 explicitly published in a ClinicalTrials.gov in January 2014
13 as the IDP-118 study.

14 In conclusion, claims 3 and 6 of the '895 patent and
15 claims 4, 5 and 7 of the '787 patent would have been obvious
16 to a person of skill in the art.

17 Q. And, Dr. Stern, are you aware of any secondary
18 considerations of non-obviousness that change any of your
19 opinions with respect to the halobetasol patents or the
20 combination patents?

21 A. I am not.

22 MR. ZIMMERMAN: Your Honor, I have no further
23 questions at this time, and I tender the witness.

24 THE COURT: Thank you.

25 Plaintiff's witness.

1 CROSS-EXAMINATION

2 BY MR. STEINDLER:

3 Q. Good afternoon, Dr. Stern. I'm Thomas Steindler. I'm
4 hear to ask you a few questions on behalf of the Bausch
5 plaintiffs. Okay?

6 A. Yup. Good afternoon.

7 Q. Now, you've never served as a principal investigator on a
8 clinical trial for a topical fixed-dose single-combination
9 product, correct?

10 A. That is correct.

11 Q. You've never served as an investigator responsible for
12 the conduct of a clinical trial for a topical superpotent
13 corticosteroid product, right?

14 A. That's correct.

15 Q. You've never conducted an analysis of whether a
16 synergistic effect occurred in the context of a clinical trial
17 involving any single fixed-dose combination product, right?

18 A. That's correct.

19 Q. And you've never published any literature about a
20 synergistic effect in the context of a dermatological topical
21 single fixed-dose combination product, right?

22 A. In that area, I've published about -- about expectations
23 of synergy.

24 Q. You said, I believe, in your direct that you were a
25 member of the American Academy of Dermatology, right?

1 A. That's correct.

2 Q. You would agree it's the preeminent dermatological group
3 in the United States, right?

4 A. I would agree it's the largest group of dermatologists.

5 Q. And you've never served as an officer in the American
6 Academy of Dermatology, correct?

7 A. That's correct.

8 Q. All right. Now, you agree that a corticosteroid's
9 potency is influenced by numerous factors, correct?

10 A. Correct.

11 Q. One factor that influences a corticosteroid's potency is
12 the identity of the active ingredients, correct?

13 A. Correct.

14 Q. Another factor that influences a corticosteroid's potency
15 is the concentration of the active ingredient, correct?

16 A. Yes.

17 Q. Another factor that influences a corticosteroid's potency
18 is the type of formulation vehicle, right?

19 A. Yes.

20 Q. And you agree that two corticosteroid formulations with
21 the same active ingredient may have different potency
22 classifications, correct?

23 A. Would you define -- oh. Oh. "Potency classifications,"
24 would you define that for me?

25 Q. Well, you recall you were deposed in this case, right?

1 A. Yes.

2 Q. Right?

3 MR. STEINDLER: Why don't we play the deposition
4 transcripts starting at lines 122. We'll just play a brief
5 starting at line -- paragraph -- excuse me.

6 Let's just --

7 THE WITNESS: I just wanted your definition of
8 "potency."

9 BY MR. STEINDLER:

10 Q. All right. Let me ask this, Dr. Stern. Do you not know
11 what a potency classification is for a --

12 A. Well --

13 Q. -- corticosteroid?

14 A. So there are a variety. So if you're talking about the
15 usual one in the United States, the seven categories that are
16 typically used, and if that's what you mean by "potency
17 classification," yes, I understand that.

18 Q. And you agree with that understanding that two
19 corticosteroids -- strike that.

20 You agree that two corticosteroid formulations with
21 the same active ingredient may have different potency
22 classifications, right?

23 A. Yes.

24 Q. You also agree that two corticosteroid formulations with
25 the same active ingredient may have the same potency

1 classification, right?

2 A. Yes.

3 Q. And you also agree that two corticosteroid formulations
4 with the same active ingredient in the same concentration may
5 have different potency classifications, right?

6 A. Yes.

7 Q. And you agree that two corticosteroid formulations with
8 the same active ingredient in the same concentration may have
9 the same potency classifications, right?

10 A. Would you do that one again?

11 Q. Sure.

12 You agree that two corticosteroid formulations with
13 the same active ingredient in the same concentration may have
14 the same potency classification?

15 A. Yes. Yes.

16 Q. And you also agree that two corticosteroid formulations
17 with the same active ingredient in the same concentration,
18 with the same type of formulation vehicle of which are
19 different formulations, may have a different potency
20 classification, right?

21 A. Yes.

22 Q. All right. Thank you.

23 Now, I realize you're not a formulator. You said
24 that in your direct testimony.

25 But you understand, sir, that formulations are very

1 important to the performance of any topical treatment, right?

2 A. Yes.

3 Q. And the right formulation can make all the difference in
4 the performance of a topical treatment. Wouldn't you agree?

5 A. I don't know what you mean by the "right formulation."
6 Would you define that for me?

7 Q. Well, wouldn't you agree that formulations can make all
8 the difference in the performance of a topical treatment?

9 A. I don't know what you mean by "all the difference."

10 Q. Let me ask it this way.

11 Wouldn't you agree that the formulations can have a
12 material difference in the performance of a topical treatment?

13 A. You mean a material effect?

14 Q. Correct.

15 A. Yes.

16 Q. Now, with all this prior art that you've identified, you
17 don't know whether the formulations had any effect on the
18 performance of the various products that were addressed in
19 that prior art, right?

20 A. Well, no. I guess I -- if we're talking about the
21 combination patents, the formulation of IDP--- the formulation
22 of IDP-118 is, as I understand it, identical to that in the
23 '824 Publication, with the exception of the addition -- simple
24 addition of 0.045 percent tazarotene.

25 To me, that's a -- whether those are -- that addition

1 is a reasonable one is a question for a formulation expert.
2 But it's certainly not a complicated question. And the
3 vehicle and the halobetasol are there in the '824 as being
4 effective, usable for more than two weeks.

5 So if we're talking combination patents, I see that
6 it's -- that the combination patent product, the IDP-118,
7 which is specifically referred to, is already established by
8 2012.

9 Q. Well, we'll come back to that.

10 I'd like you to look at PTX-93, which is an article
11 by Barnes from 2021.

12 You're familiar with this?

13 A. I think that's in the other folder. Give me one sec.

14 Q. Okay.

15 A. I've got it. Thank you.

16 Q. You're familiar with this article, right?

17 A. I think it was presented to me at my deposition.

18 Q. Right. And you agree that Barnes 2021 teaches that
19 lotions are the least potent topical vehicle, right?

20 A. You know, that -- that's -- those questions at my
21 deposition prompted me to look further at the potency
22 classification for high-potency lotions.

23 And I noticed that, in fact, there are lotions
24 included among high-potency class 1 steroids including, for
25 clobetasol, the -- an agent that is very similar to

1 halobetasol.

2 Q. Okay. But that --

3 A. So --

4 Q. Sir, I'm asking a different question.

5 A. Well --

6 Q. I'm asking a different question, and I'd like you to give
7 the answer to my question.

8 Of the various formulations forms -- gels, ointments,
9 creams, lotions -- a lotion is being taught by Barnes as the
10 least potent topical vehicle, right?

11 A. Could you show me where he or she --

12 Q. Why don't we just go to your deposition.

13 MR. STEINDLER: And why don't we play something --
14 135: 6 to 8. I think that was the right one.

15 MR. ZIMMERMAN: Your Honor, this is improper
16 impeachment because he hasn't answered the question yet.

17 MR. STEINDLER: I can move on. I can move on.

18 BY MR. STEINDLER:

19 Q. Don't you agree that it was conventional understanding at
20 the time that lotions were the least potent of the various
21 types of formulation vehicles?

22 A. I agreed with that at the time of my deposition.

23 After I looked at the potency classifications --

24 THE COURT: Doctor. Doctor, it's very important that
25 you answer the question which was asked.

1 THE WITNESS: Okay.

2 THE COURT: Okay?

3 THE WITNESS: Okay. Great. I'm sorry, sir. I'm
4 sorry.

5 THE COURT: In your redirect --

6 THE WITNESS: I'm sorry.

7 THE COURT: -- and any additional information can be
8 brought out. But when you're being cross-examined, the
9 cross-examiner has the right to get a straight answer to his
10 or her question.

11 Please proceed.

12 THE WITNESS: Thank you, Your Honor.

13 MR. STEINDLER: Thank you, Your Honor.

14 BY MR. STEINDLER:

15 Q. Now, you spoke at length in your direct about the '824
16 Publication, right?

17 A. Yes.

18 Q. And that's the patent application that ultimately led to
19 the Bryhali® patents, right?

20 A. Yes.

21 Q. And in your view, sir, the lotion disclosed in the '824
22 Publication was not a conventional or standard lotion, right?

23 A. Yes. It was not a conventional or traditional or usual
24 lotion.

25 Q. Thank you very much.

1 MR. STEINDLER: Let us now turn to -- and if you can
2 pull up Dr. Stern's DDX-2.8.

3 BY MR. STEINDLER:

4 Q. And I'd like to turn to your opinions about what you call
5 the halobetasol patent.

6 You're aware that our side's been calling them the
7 Bryhali® patents, right?

8 A. Yes.

9 Q. Okay. You know, a rose by any other name. We're talking
10 about the same thing here, right? The '307 and '502 patents,
11 correct?

12 A. Yes.

13 Q. So I'm going to refer to them as the Bryhali® patents,
14 sir. You'll understand what I mean, right?

15 A. Yes.

16 Q. So you say that as of November 2010, a person of ordinary
17 skill in the art, or a POSA, would have been motivated to use
18 concentrations of halobetasol as low as 0.01 percent to treat
19 psoriasis, right?

20 A. Yes.

21 Q. And as to the method claims, which are claim 16 of the
22 '307 patent and claim 16 of the '502 patent, you're offering
23 the opinion that a POSA would have been motivated to use a
24 topical composition comprising halobetasol in these claim
25 ranges for longer than two weeks, right?

1 A. That's correct.

2 Q. But to be clear, apart from the concentration and method
3 limitations, you're not offering any opinions regarding the
4 other limitations of the Bryhali® patent claims. Is that
5 right?

6 A. I'm only talking about the obviousness as -- yes. You're
7 correct.

8 Q. Now, I'd like to talk to you about your opinion that a
9 POSA would have been motivated to lower the concentration of
10 halobetasol to as low as 0.01 percent to avoid the risk of
11 systemic side effects. Okay?

12 Now, you say it was well-known that super-high potent
13 corticosteroids posed a risk of systemic side effects, right?

14 A. That's correct.

15 Q. And you say that was reflected in the FDA's restriction
16 requirement that the commercial 0.05 percent halobetasol
17 product could not be used for longer than two weeks, right?

18 A. Yes.

19 Q. That product was Ultravate®, correct?

20 A. Correct.

21 MR. STEINDLER: Can we go to Dr. Stern's slide
22 DDX-2.9, please.

23 BY MR. STEINDLER:

24 Q. Now, in your slide, you point out, you say that
25 Ultravate® was FDA-approved since 1995, right?

1 A. That's what the slide says. I wasn't sure of that date,
2 so I think I said in my testimony today in the '90s, I
3 believe. But sometime around then.

4 Q. Well, you actually wrote this same statement, that it was
5 FDA-approved since 1995, in paragraph 58 of your expert report
6 in this case. Isn't that true, sir?

7 A. I'll take your word for it, sir.

8 Q. All right. And you're not telling the Court, to be
9 clear, that Ultravate® was approved in 1995. Is that correct,
10 sir?

11 A. When I saw this slide, as I said in my words, I believe
12 it was approved in the 1990s. And I wasn't sure about 1995,
13 and that's why I rephrased it.

14 Q. All right. Well, wouldn't you agree that Ultravate® is
15 central to your obviousness analysis?

16 A. It is central to -- yes.

17 Q. And it defines the problem you say would have motivated a
18 POSA to lower the concentration, right?

19 A. That's correct.

20 Q. And wouldn't you agree that the longer a problem goes
21 unsolved, the less obvious it is?

22 A. Yes.

23 Q. And in fact, sir, isn't it true that Ultravate® was
24 approved by the FDA half a decade before the date that you
25 have on your slide?

1 A. Again, I was unsure. And I think if you look at what I
2 said today, it reflected that uncertainty about the correct
3 date.

4 MR. STEINDLER: Could we pull up PTX-359, please?

5 And could you please blow up the top portion of
6 PTX-359 in the first page.

7 BY MR. STEINDLER:

8 Q. This is a pull from the FDA website about the Ultravate®
9 drug.

10 Are you familiar with this exhibit, sir?

11 A. I'm familiar with this kind of exhibit.

12 MR. STEINDLER: All right. Well, let's look in the
13 next page, please, of this document. And then blow up the
14 bottom portion.

15 Sorry. This is the -- I'm at the wrong part of this
16 document.

17 Is it in the top portion? Right.

18 BY MR. STEINDLER:

19 Q. This is the approval date for Ultravate®, right?
20 December 17, 1990.

21 A. Yes.

22 Q. That was 20 years before the invention date of the
23 Bryhali® patents. Isn't that true, sir?

24 A. That's correct.

25 Q. And this problem of systemic risk with corticosteroids,

1 and then halobetasol in particular, was long -- known for a
2 long time before Ultravate® came out. Isn't that true?

3 A. That's correct.

4 Q. This problem with halobetasol was known from the '70s.
5 Isn't that true, sir?

6 A. At least from then, yes.

7 Q. Right. And you say, for example, that Blum would have
8 taught a POSA to expect a lower concentration of HP may lead
9 to a slight decrease in potency and/or efficacy, right?

10 A. That's correct.

11 Q. But when Ultravate® came out in 1990, it used a
12 0.05 percent concentration, right?

13 A. Yes.

14 Q. And for the next 20 years, sir, no one ever made a
15 halobetasol product with a concentration of less than
16 0.05 percent. Isn't that true?

17 A. Yes.

18 Q. I put it to you, sir, that what happened in the real
19 world shows that your claim that a POSA would have been
20 motivated to develop a halobetasol product with a lower
21 concentration than Ultravate® is wrong. Wouldn't you agree?

22 A. No.

23 Q. Come, come, Dr. Stern. How can you say that a person of
24 ordinary skill in the art would have been motivated to lower
25 the concentration of halobetasol when nobody did it for

1 20 years?

2 THE COURT: Counsel, no summations here. All right?
3 That is a rhetorical question. Move on.

4 MR. STEINDLER: I'll move on.

5 THE COURT: You've made your point.

6 BY MR. STEINDLER:

7 Q. I'd like to turn to the Blum reference that you've cited
8 to.

9 MR. STEINDLER: Can you please pull up DX-002.

10 BY MR. STEINDLER:

11 Q. Now, we'll get to this article in detail in a minute.

12 But you say Blum supports your opinion that a POSA
13 would have been motivated to lower the halobetasol
14 concentration to as low as 0.01 percent, right?

15 A. Yes.

16 MR. STEINDLER: So I'd like to go to the first page
17 of the translation, please, which ends in Bates Number 2020 --
18 excuse me -- 20219.

19 And if you could go to the top of the second page
20 there and blow that up.

21 BY MR. STEINDLER:

22 Q. Do you see the --

23 MR. STEINDLER: No. The very top of the page,
24 please, sir.

25 BY MR. STEINDLER:

1 Q. Blum was published in 1986, right?

2 A. Yes.

3 Q. You don't know whether Blum was publicly available in
4 English before 2010, right?

5 A. The abstract was available.

6 Q. You don't know whether the article was publicly available
7 in English before 2010, right?

8 A. I do not know.

9 Q. Blum tested a 0.05 percent halobetasol formulation and a
10 0.02 percent halobetasol formulation, right?

11 A. Yes.

12 Q. Blum didn't test a 0.01 percent halobetasol formulation,
13 correct?

14 A. That's correct.

15 Q. And there's no disclosure in Blum at all of the
16 0.01 percent halobetasol formulation, correct?

17 A. That's correct.

18 Q. Now, Blum doesn't disclose the actual formulations for
19 either the 0.05 or the 0.02 percent halobetasol products,
20 right?

21 A. Only that they're an ointment and that it's the same
22 ointment for the two concentrations.

23 Q. And you would agree that Blum actually teaches that the
24 0.05 percent concentration is preferable to the 0.02 percent
25 concentration, right?

1 A. I interpreted the article somewhat differently.

2 Q. Well, let's take a look at it.

3 MR. STEINDLER: Can we go to the page with the Bates
4 number ending 20220, please?

5 BY MR. STEINDLER:

6 Q. And you see that abstract, it says there, right?

7 A. Right.

8 Q. And the abstract says in the highlighted passage:
9 Therefore, 0.05 percent ointment would be a welcome addition
10 to the therapeutic armamentarium for chronic, localized,
11 severe or recalcitrant dermatoses.

12 Do you see that?

13 A. Yes.

14 Q. Blum doesn't say that about the 0.02 percent
15 concentration, does he?

16 A. He says that there's no difference in --

17 Q. Sir, I just want to know. He doesn't say that about the
18 0.02 --

19 A. You're right.

20 Q. -- percent concentration, right?

21 A. Right.

22 Q. All right. And, in fact --

23 MR. STEINDLER: If you could go -- just bear with me
24 for one moment.

25 BY MR. STEINDLER:

1 Q. Blum also says --

2 MR. STEINDLER: Can you go to the top left-hand
3 column on the same page and blow up the top portion, please.

4 BY MR. STEINDLER:

5 Q. Now, again, Blum says in that first paragraph --

6 MR. STEINDLER: If you could highlight it.

7 BY MR. STEINDLER:

8 Q. It says the 0.05 percent ointment will provide a favorite
9 treatment weapon for chronic, localized, severe or refractory
10 skin diseases that have effect with corticosteroids, right?

11 A. Yes.

12 Q. And then it goes on to say that in the treatment of
13 severe chronic psoriasis vulgaris, that ointment with a lower
14 concentration, i.e., 0.02 percent, was less effective than the
15 concentration of 0.05 percent in Dermovate ointment. Although
16 he goes on to say the difference was not statistically
17 different, right?

18 A. That's correct.

19 Q. There is nowhere in Blum where he says that the
20 0.02 percent lower concentration would provide a favorite
21 treatment weapon. Isn't that true, sir?

22 A. He does not say so, yes.

23 Q. And it's your contention that even though Blum looked at
24 both the 0.02 percent concentration and the 0.05 percent
25 concentration and recommends the higher concentration, a POSA

1 would ignore Blum's recommendation and rely on this paper as
2 the motivation to pick the lower concentration.

3 That's your testimony, sir. Right?

4 A. Well, my testimony, a POSA takes the art together.

5 And taking the label for the 0.05 percent and the
6 fact that there's a limitation on the length of treatment
7 because of adverse effects, a person of skill in the art would
8 say, Gee, is there a way we could use it at lower
9 concentration for greater safety without losing too much
10 efficacy?

11 And this would tell that POSA, Well, I've got a
12 problem in this label. Only can use it for two weeks for
13 psoriasis. Not long enough. Is there any other information I
14 have?

15 Blum, that says you don't lose that much in efficacy,
16 and you can use a heck of a lot lower concentration.

17 So, to me, Blum, together with, in fact, the label in
18 the United States tells me combining those things, let's look
19 for a lower concentration. And the lower you go, the
20 likelihood of safer it will be with respect to HPA axis.

21 So that's combining things.

22 But you're right. Looking at this alone before we
23 knew about the restrictions the FDA would put on it, this was
24 his favorite. You're absolutely correct.

25 Q. Right. So -- and Blum is published in 1986, right?

1 A. Yes.

2 Q. And Ultravate® came out in 1990, right?

3 A. Right.

4 Q. And Ultravate® has that higher 0.05 percent
5 concentration, right?

6 A. Yes.

7 Q. So the developers of Ultravate® didn't follow what you
8 contend is the motivation of Blum to lower the concentration
9 below 0.05 percent. Isn't that correct?

10 A. They -- they were --

11 THE COURT: We want to know the answer to the
12 question. Answer it.

13 THE WITNESS: Yes.

14 BY MR. STEINDLER:

15 Q. And what the Ultravate® developers did was consistent
16 with the express teaching of Blum; that the higher
17 0.05 percent concentration was preferable. Right?

18 A. Yes.

19 MR. STEINDLER: Now, can we turn to Dr. Stern's slide
20 DDX-2.14, please, pertaining to the Temovate® Label.

21 BY MR. STEINDLER:

22 Q. You recall that you gave testimony about the Temovate®
23 label on your direct, right?

24 A. Yes.

25 Q. And Temovate® is a commercial clobetasol product,

1 correct?

2 A. That's correct.

3 Q. And Temovate E® in the label means emollient or emulsion,
4 right?

5 A. Emollient, I believe. Yes.

6 Q. So this is the emollient cream version of 0.05 percent
7 clobetasol, right?

8 A. Yes.

9 Q. Now, under the indications and usage section, the label
10 restricts usage to two weeks but says it can be used for up to
11 four weeks if the application is limited to 5 to 10 percent of
12 body surface area, correct?

13 A. Yes.

14 Q. Now, you don't contend that the Temovate E® label
15 provides a motivation to lower the concentration of a
16 halobetasol product to less than 0.05 percent, right?

17 A. No, it only says that if you apply less drug, you can use
18 it for longer.

19 Q. If anything, the Temovate® label is teaching a way to use
20 a high potency steroid product for longer than two weeks
21 without lowering the concentration. Isn't that true?

22 A. In this case, yes.

23 Q. Now, Ultravate® does not have a comparable four-week
24 exception for using halobetasol on a limited body area, right?

25 A. Not that I'm aware of.

1 Q. So that exception has never been applied to halobetasol.

2 A. I have not reviewed all of the labels, but not that I'm
3 aware of.

4 Q. But now your contention is that if a POSA has been
5 motivated to and did lower the concentration of halobetasol to
6 less than 0.05 percent, they would have expected the lower
7 concentration halobetasol could be used safely for longer than
8 two weeks by applying it to a limited body surface area,
9 right?

10 A. Yes.

11 Q. But you don't offer any data to support your contention
12 that a low concentration halobetasol would be expected to
13 perform in the same way as the 0.05 percent clobetasol, right?

14 A. That's correct.

15 Q. Would a POSA expect that a halobetasol composition could
16 be used safely for longer than two weeks if the concentration
17 was lowered to, say, 0.04 percent?

18 A. One would think it might be possible, but you'd have to
19 test that.

20 Q. Right. And you didn't do any of that kind of testing,
21 right?

22 A. No, I did not.

23 Q. So you don't actually have any experimental evidence to
24 support your contention with respect to this argument, right?

25 A. That's correct.

1 Q. And to be clear, you didn't do any experimental testing
2 at all in this case to establish that there was test evidence
3 to support the propositions that you're citing. Is that
4 correct?

5 A. Yes.

6 Q. And, in fact, nobody on the Padagis side did any actual
7 experimental testing to support their arguments in this case
8 about obviousness, right?

9 A. You know, that, I don't know.

10 Q. Well, you haven't seen any. Isn't that fair to say?

11 A. I have not seen any such information, that's correct.

12 Q. I'd like to turn to the Duobrii® patents now and to your
13 opinions that the asserted claims of the Duobrii® patents
14 would have been obvious.

15 Now, again, I understand you call these the
16 combination patents, we call them Duobrii® patents, but you'll
17 understand what I'm referring to, right?

18 A. Yes.

19 MR. STEINDLER: Could we go to Dr. Stern's slide
20 DDX-2.15.

21 BY MR. STEINDLER:

22 Q. Now, what you see on this slide are the various
23 combinations that you assert against the Duobrii® patents,
24 right?

25 A. Yes. Yes.

1 MR. STEINDLER: Could you turn to Dr. Stern's slide
2 DDX-2.16.

3 BY MR. STEINDLER:

4 Q. Now, you say that the '824 Publication discloses every
5 limitation except the 0.45 percent -- strike that.

6 You say that the '824 Publication discloses every
7 limitation except the 0.045 percent tazarotene and synergy
8 limitations, right?

9 A. Yes.

10 Q. And it's your contention that a POSA would have been
11 motivated to add them, right?

12 A. Yes.

13 Q. And I just want to clarify exactly what you're arguing.

14 You're only arguing that a POSA would have been
15 motivated to arrive specifically at IDP-118 and that the
16 synergies are inherent properties of --

17 THE COURT REPORTER: Can you go back?

18 MR. STEINDLER: Sure.

19 BY MR. STEINDLER:

20 Q. You're only contending that a POSA would have been
21 motivated to arrive specifically at the IDP-118 formulation
22 and that the synergies are inherent properties of IDP-118,
23 correct?

24 A. Yes.

25 MR. STEINDLER: Would you please turn now to

1 Dr. Stern's Exhibit DDX-2.31.

2 BY MR. STEINDLER:

3 Q. And just for clarity, in this second bullet, this is
4 exactly what you're arguing. You're only arguing that if
5 synergy is present, it is an inherent property of IDP-118
6 formulation and not any other formulations that might fall
7 within the claims of the Duobrii® patent, right?

8 A. I -- I think so. I don't mean to be difficult, but what
9 I'm talking about is IDP-118 and synergy limitations being an
10 inherent property, yes.

11 Q. All right. That's fine.

12 MR. STEINDLER: Let's go to Dr. Stern's slide
13 DDX-2.16, please.

14 BY MR. STEINDLER:

15 Q. Now, again, your contention here is with respect to the
16 '824 Publication disclosing the limitations -- strike that.

17 What you mean to be saying here is that the '824
18 Publication discloses every limitation of IDP-118. Is that
19 your testimony, sir?

20 A. Except for the addition of tazarotene, yes.

21 Q. Understood. Understood.

22 A. And the synergy limitations.

23 Q. Understood. Right.

24 MR. STEINDLER: So let's go to the '824 Publication.
25 It's DX-142.

1 BY MR. STEINDLER:

2 Q. Now, your analysis begins with this '824 Publication. As
3 we've seen, it's the patent application that ultimately led to
4 the Bryhali® patents, right?

5 A. That's correct.

6 Q. Now, you don't contend that the '824 Publication stood
7 out amongst a crowded field of topical psoriasis treatments,
8 right?

9 A. It is what it is.

10 Q. Let me ask it again.

11 You don't contend that the '824 Publication stood out
12 amongst the crowded field of topical psoriasis treatments.

13 Isn't that correct, sir?

14 A. Yes.

15 Q. It was just another reference in what was already a very
16 crowded field, right?

17 A. It was interesting to a person of skill in the art
18 because it brought forward a claim -- claims of a superpotent
19 steroid that could be used for longer than two weeks and be as
20 nearly efficacious as 0.05 percent.

21 Q. Now, you're relying on the '824 Publication only for the
22 0.01 percent concentration of halobetasol in IDP-118, right?

23 A. Yes.

24 Q. And you're not relying on the '824 Publication to address
25 the other formulation limitations of IDP-118, right?

1 A. Anything -- other than the formulation limitations, which
2 are -- you know, it's the same formulation in '824 and
3 IDP-118. So that's -- I'm sorry. If that's what you mean,
4 I'm only relying on it for its defining a formulation in the
5 0.01 percent halobetasol.

6 Q. All right.

7 MR. STEINDLER: Well, let's go to example 1, table 1,
8 at paragraph 37 of the '824 Publication.

9 BY MR. STEINDLER:

10 Q. Are you with me?

11 A. Yes.

12 Q. It's a little difficult to see here on the slide, but
13 example 1, table 1 sets out a series of example formulations
14 which are listed as formulations A, B, C and D right here,
15 right?

16 A. Hmm-hmm.

17 Q. And there's also a formulation E which is stated to be
18 outside the scope of the invention, right?

19 A. Yes.

20 Q. Formulations A, B and C each have different
21 concentrations of halobetasol, correct?

22 A. Well, there are -- three of them are the same and two
23 different parts.

24 Q. So let me try that again.

25 Formulations A, B and C --

1 A. I'm sorry, yes, you're correct. The yellow went over
2 further.

3 Q. Just so the record is clear, let me just ask it again.
4 Formulations A, B and C each have different
5 concentrations of halobetasol, correct?

6 A. Yes, yes.

7 Q. Formulation A has 0.035 percent halobetasol. Formulation
8 B has 0.025 percent halobetasol. And formulation C has
9 0.01 percent halobetasol, right?

10 A. That's correct.

11 Q. Now, IDP just has -- strike that.

12 IDP-118 just has 0.01 percent halobetasol, right?

13 A. Yes.

14 Q. Not 0.035, not 0.025. Right?

15 A. That's correct.

16 MR. STEINDLER: So now let's go to table 3 and
17 Paragraph 40.

18 BY MR. STEINDLER:

19 Q. You've seen that table 3 sets out the test results using
20 a VCA test for the different halobetasol concentrations,
21 correct?

22 A. Correct.

23 Q. And as we've discussed earlier today, VCA is a test for
24 potency, right?

25 A. Yes.

1 Q. Paragraph 40 states that each of the formulations, A to
2 D, provided a VCA score similar to that of the prior art
3 formulation of Ultravate®, right?

4 A. Yes.

5 Q. And that includes the 0.035 percent concentration, the
6 0.025 percent concentration, and the 0.01 percent
7 concentration, correct?

8 A. Yes.

9 Q. The '824 Publication does not state that any one of these
10 concentrations is a preferred or a particularly preferred
11 embodiment of the invention, correct?

12 A. That's correct.

13 Q. It just says that all three of them had VCA scores that
14 were similar to the commercial product, right?

15 A. Yes.

16 Q. Now, is it your contention that a person of ordinary
17 skill in the art would have picked out formula C as the
18 concentration? Strike that. Strike that.

19 Is it your contention that a person of ordinary skill
20 in the art reading the '824 Publication would have picked
21 formula C to experiment with?

22 A. I believe if we go on further in the patent, it shows the
23 0.01 percent in the final formulation, which I believe is -- I
24 took to be the preferred one. So if you continue on the
25 patent, I think it's table 4A.

1 Q. So you say it shows the final formulation, which you took
2 to be the preferred one. Why did you -- what was the basis
3 for that, sir?

4 A. I -- if we could turn to -- to the -- further on, where I
5 believe it demonstrates the exact formulation that is used in
6 the combination patents and, by its use, seemed to me to be
7 the selection of the preferred one.

8 Q. All right. Well, why don't we keep going and take a look
9 to see what '824 actually teaches?

10 MR. STEINDLER: Let's go to Stability Testing in
11 example 5. And if you could --

12 BY MR. STEINDLER:

13 Q. Can you see this? I just want to be sure that you can
14 see it. And if you need to get your patent, please, go right
15 ahead and do it.

16 A. Would you -- the '824 is which exhibit? It's --

17 Q. '824 is DX-142. It should be in your binder.

18 A. It is. It's in the other binder. I've got it out now.
19 I'm sorry.

20 Q. Okay.

21 A. It wasn't in the binder that you sent me.

22 Okay. I'm there now. Thank you.

23 Q. All right.

24 Now, in example 5, the inventors actually made an
25 example lotion and tested it to see whether it met the FDA's

1 stability requirements, right?

2 A. Right.

3 Q. And if you go to the last line in Paragraph 47 --

4 MR. STEINDLER: If you can just highlight that.

5 BY MR. STEINDLER:

6 Q. -- it says that the inventors set out stability
7 specifications for the halobetasol lotion that would be
8 required for a commercial product, right?

9 A. Right.

10 Q. And if you go to the next page --

11 MR. STEINDLER: And blow up table 7, please.

12 BY MR. STEINDLER:

13 Q. -- the inventors in the '824 Publication set out the
14 stability test results for this example lotion.

15 You see that in table 7, right?

16 A. Yes.

17 Q. And in paragraph 49, the inventors state that this lotion
18 would, in fact, meet FDA's stability requirements, right?

19 A. Yes.

20 Q. And this is the formulation the inventors chose to test
21 and disclose in the '824 Publication to see whether the
22 formulation would meet the FDA requirements for a commercial
23 product, right?

24 A. Yes.

25 Q. And wouldn't you agree that it shows the inventors had a

1 particular preference for this formulation if they're testing
2 it to see whether it met FDA standards?

3 A. I think this -- this is a formulation question that I'm
4 not the person to ask. I mean, I don't hold myself out as a
5 formulation expert.

6 Q. Well, you have read this patent, right?

7 A. Yes.

8 Q. And you've told the Court at some length in your direct
9 testimony what you understood when you were reading this
10 patent, right?

11 A. I believe in the summary of my testimony I was very
12 explicit about saying formulation claims are not ones that I
13 would address, that Dr. Michniak-Kohn would address, and from
14 her report I understood them to be obvious.

15 That's, I think, what I said multiple times in my
16 presentation.

17 Q. But just a few moments ago, you said the '824 patent
18 discloses the specific formulation of IDP-118, right?

19 A. I did say that, and that was my understanding.

20 Q. And I'm trying to find out whether you think that a
21 person of ordinary skill in the art reading this would be led
22 to that particular formulation. Is that fair enough?

23 A. As I mentioned, the person of ordinary skill in the art,
24 one of those people, one of those persons would be essentially
25 a formulation expert, which I am not. And working in

1 conjunction with a clinician, which I am.

2 And, therefore, I cannot really -- you know, I'm not
3 -- I'm not sufficiently skilled in the art of formulation to
4 answer your questions.

5 Q. So when the '824 patent has only one formulation that
6 they test to see whether it meets FDA requirements, you don't
7 feel that you're competent to form an opinion as to whether
8 that is a formulation that the inventors are expressing a
9 preference for.

10 Is that your testimony, sir?

11 A. I would rather leave it to the member of the team who's
12 an expert in that area.

13 Q. Now, just for completeness, we can go back to table 5 and
14 look at the formulation the inventors chose to test.

15 MR. STEINDLER: Could you blow up table 5, please.

16 BY MR. STEINDLER:

17 Q. That is the 0.025 halobetasol propionate concentration.
18 Isn't that correct, sir?

19 A. That's listed in table 5, yes.

20 Q. That is the -- that is the formulation that the inventors
21 chose to test to see whether it met FDA standards, right?

22 A. I accept your word.

23 Q. And it is not, of course, a 0.01 percent halobetasol
24 formulation, correct?

25 A. That's correct in table 5.

1 Q. And, in fact, you've mentioned earlier a different
2 0.01 percent concentration that you say has the formulation of
3 IDP-118, right?

4 A. I did. And I was probably incorrect.

5 MR. STEINDLER: Your Honor, it's getting very close
6 to 5:00. I'm not -- I've got quite a bit before I'm done
7 here.

8 THE COURT: You've got more to do?

9 MR. STEINDLER: Yeah. I've got more than five
10 minutes, I'm sorry to say.

11 THE COURT: Okay. We'll break for the day.

12 MR. STEINDLER: Shall I just proceed for five more
13 minutes and -- or shall we stop now?

14 THE COURT: Go five more minutes, and then we'll
15 break.

16 MR. STEINDLER: Thank you, Your Honor.

17 Can you turn, please, to Dr. Stern's slide DDX-2.25.

18 BY MR. STEINDLER:

19 Q. Again, this is your slide about the '824 Publication.

20 A. Yes.

21 Q. Right?

22 A. Yes.

23 Q. But what you're saying is you actually have no basis to
24 conclude that a person of ordinary skill in the art reading
25 the '824 patent would have picked out the formulation of

1 IDP-118.

2 Isn't that what we just talked about, sir?

3 A. I thought what I said is that, as I said in a person of
4 skill in the art, that there would be at least two members of
5 that team, one of which would be a formulation expert with the
6 background I mentioned and the other a clinician with the
7 experience in evaluating these agents in the treatment of
8 persons with this skin disease. So...

9 BY MR. STEINDLER:

10 Q. Sir, I don't see any mention on this slide of a
11 formulator or that you're relying on a formulator for any of
12 the opinions that you gave to this Court about the meaning of
13 the '824 patent. Isn't that true?

14 A. About the meaning of it, no. About the findings in terms
15 of the VCA and the relation to concentration, no. That's --
16 that, I interpreted.

17 Q. And, in fact, in your second bullet there, you say --
18 strike that.

19 In the third bullet down, you say '824 Publication
20 discloses formulations of 0.01 percent HP with similar potency
21 and efficacy as Ultravate®, right?

22 A. Right.

23 Q. In fact, there's only one formulation, formulation C,
24 that is disclosed in the '824 Publication that has similar
25 potency and efficacy as Ultravate®. Isn't that true, sir?

1 A. That's the one that was tested in the data you -- we just
2 discussed.

3 Q. So that slide is incorrect. It does not disclose plural
4 formulations of 0.01 percent HP with similar potency and
5 efficacy as Ultravate®, right?

6 A. Right. Of the 0.01 percents, only one is disclosed where
7 it was tested versus Ultravate®.

8 Q. Right. And in your bottom slide -- bullet there --
9 strike that.

10 In your bottom bullet there, you say a POSA would
11 have been motivated to use the -- strike that.

12 In the bottom bullet, you say a POSA would have been
13 motivated to use the 0.01 percent HP lotion from the '824
14 Publication.

15 A. Yes.

16 Q. What -- strike that.

17 You say "the 0.01 percent HP lotion." Do you mean
18 the lotion of formula C?

19 A. I'd have to ask the formulation person.

20 Q. All right. So you don't know what you're talking about.

21 Strike that. Strike that.

22 You don't actually know what you've said here when
23 you say "motivated to use the 0.01 percent HP lotion." You
24 don't have a basis for knowing what that is, right?

25 A. In terms of which was the final and specific

1 constituents, no.

2 MR. STEINDLER: All right. Judge, I think I've run
3 out of time.

4 THE COURT: We'll break for the day.

5 MR. STEINDLER: Obviously ask for an instruction
6 he's -- he can't talk --

7 THE COURT: We'll resume on Thursday.

8 MR. STEINDLER: Right. Just ask for instruction that
9 he not be speaking with counsel.

10 THE COURT: That's fine.

11 I'm not going to use the depositions in written form.
12 We'll play the depositions, then we will proceed just as we
13 had previously discussed. Okay?

14 MR. STEINDLER: That's -- those are Mr. -- my learned
15 friend's depositions.

16 MR. ZIMMERMAN: That's fine, Your Honor. No problem.

17 THE COURT: Okay.

18 MR. STEINDLER: Thank you, Your Honor.

19 THE COURT: See you all Thursday.

20 What time, Theresa? 9:30?

21 THE COURTROOM DEPUTY: 9:15, if they have matters.
22 9:30 start.

23 MR. STEINDLER: Thank you, Your Honor.

24 THE COURT: See you then.

25 THE WITNESS: Thank you.

1 (Proceedings concluded at 5:01 p.m.)

2 - - - - -

3
4 FEDERAL OFFICIAL COURT REPORTER'S CERTIFICATE

5
6 I certify that the foregoing is a correct transcript
7 from the record of proceedings in the above-entitled matter.

8
9 /S/ Mary Jo Monteleone, RMR, CCR, CRCR
10 Official Court Reporter

11 10/04/2022
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1 UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF NEW JERSEY

3 BAUSCH HEALTH IRELAND
4 LIMITED, et al.,

5 Plaintiff,

6 v.

7 PADAGIS ISRAEL
8 PHARMACEUTICALS LTD, et al.,

9 Defendant.

CIVIL ACTION NUMBER:

2:20-cv-05426

BENCH TRIAL (VOLUME II)

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10 Frank Lautenberg Post Office & U.S. Courthouse
11 2 Federal Square
12 Newark, New Jersey 07102
13 Thursday, October 6, 2022
14 Commencing at 9:25 a.m.

15 **B E F O R E:**

16 **THE HONORABLE STANLEY R. CHESLER,**
17 **UNITED STATES DISTRICT JUDGE**

18
19
20
21 Mary Jo Monteleone, Official Court Reporter
22 maryjomonteleone@gmail.com
23 (973) 580-5262

24 Proceedings recorded by stenographically;
25 transcript produced by computer-aided transcription.

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WITNESSES FOR THE PLAINTIFFS				

DR. MAJELLA LANE

467

	<u>DIRECT</u>	<u>CROSS</u>	<u>REDIRECT</u>	<u>RECROSS</u>
WITNESSES FOR THE DEFENSE:				

DR. ROBERT STERN

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DR. BOZENA B.
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1 (PROCEEDINGS held in open court before **The Honorable**
2 **STANLEY R. CHESLER**, United States District Judge, at
3 9:25 a.m.)

4 THE COURTROOM DEPUTY: All rise.

5 THE COURT: Be seated, everybody. All right. Are we
6 ready to proceed?

7 MR. STEINDLER: We are.

8 THE COURT: Good.

9 By the way, I know this -- I'm setting a horrible
10 example, but I've concluded that I'm far enough away from all
11 of you that if I am infected, I won't infect all of you. So
12 I'm taking my mask off so I can see.

13 MR. STEINDLER: It's good to be the judge.

14 THE COURT: That is an example of do what I say, not
15 what I do.

16 MR. STEINDLER: Thank you, Your Honor.

17 THE COURT: Okay. Let's proceed.

18 MR. STEINDLER: Are we ready to resume the
19 cross-examination of Dr. Stern?

20 THE COURT: Yes.

21 DR. ROBERT STERN, DEFENSE WITNESS,
22 having been previously sworn, testifies as follows:

23 CROSS-EXAMINATION

24 BY MR. STEINDLER:

25 Q. Good morning, Dr. Stern. Can you hear me?

1 A. Yes. Good morning. I can. Thank you.

2 Q. And you recall that you're under oath, right?

3 A. Of course, yes.

4 Q. Now, for the record, Dr. Stern, did you speak with any of
5 the attorneys between the time your testimony concluded on
6 Tuesday and now?

7 A. Only with respect to logistics, like when I should come
8 to the room.

9 Q. Sure. I didn't ask you what you talked about. I just
10 asked, did you speak with any of the attorneys?

11 A. Yes.

12 Q. Who did you speak with?

13 A. I believe with Brian Barnes and also Mr. Zimmerman.

14 Q. And is Mr. Barnes an attorney for Padagis?

15 A. He is.

16 Q. And Mr. Zimmerman is also one of the attorneys for
17 Padagis.

18 Is that correct?

19 A. That's correct.

20 Q. And Mr. Barnes is physically present in the room with you
21 now.

22 Is that correct?

23 A. That is not correct.

24 Q. Has Mr. Barnes physically been present with you in the
25 room this morning?

1 A. Yes.

2 Q. And have you communicated by e-mail with any of the
3 attorneys for Padagis between the time your testimony
4 concluded and now?

5 A. By e-mail, no.

6 Q. Just verbally?

7 A. Verbally and, I believe, a message. I wanted to be sure
8 I was awoken. I'm sorry. I did verbally. I got a phone
9 call -- a wake up phone call from one of them.

10 Q. All right. And you recall that at the end of your
11 testimony there was an instruction that you not speak with any
12 of the attorneys for Padagis, right?

13 MR. ZIMMERMAN: Objection, mischaracterizes.

14 THE WITNESS: Yeah. I had interpreted -- I had
15 thought it had said that I would not speak about the case with
16 any of the attorneys.

17 BY MR. STEINDLER:

18 Q. All right. Well, let's move on.

19 As a housekeeping matter, you'll recall that one of
20 the topics that we discussed on Tuesday was the date on which
21 Ultravate® was approved by the FDA, right?

22 A. That's correct.

23 Q. And I showed you an exhibit which had a December 17,
24 1990, date, right?

25 A. That's my recollection.

1 Q. And you recollect that that was with respect to the
2 Ultravate® ointment form of Ultravate®?

3 A. Correct.

4 Q. And you're aware that the Ultravate® Cream was approved
5 10 days later by the FDA?

6 A. I didn't know the interval. But the document you showed
7 me said -- or a document in the files that you provided said
8 that there was an application pending for the cream.

9 Q. Let me show you PTX-360.

10 MR. STEINDLER: And if we could just blow up the
11 bottom portion of 360.

12 BY MR. STEINDLER:

13 Q. You see this is the FDA website document identifying the
14 approval of Ultravate® Cream, right?

15 A. Let me -- yes.

16 Q. And you see that Ultravate® Cream was approved on
17 December 27, 1990, correct?

18 A. Yes.

19 Q. All right. Thank you.

20 Now, when we left off, we were discussing your
21 opinions that the Duobrii® patents would have been obvious
22 based on three sets of combinations that are set out in your
23 Slide DDX-215, right?

24 A. Correct.

25 Q. Now, the first combination that you're asserting is the

1 '824 Publication plus Gollnick plus the Tazorac® label,
2 correct?

3 A. Yes.

4 Q. And you recall that we've already discussed the
5 '824 Publication, right?

6 A. Yes.

7 Q. Now, the '824 Publication doesn't disclose tazarotene,
8 correct?

9 A. It discloses everything in the combination patents except
10 the addition of 0.045 percent tazarotene to the
11 '824 Publication's lotion.

12 Q. Nothing in the '824 Publication suggests any benefits of
13 combining a corticosteroid and a retinoid in a combination
14 product, correct?

15 A. That's correct.

16 Q. And nothing in the art provided any information on the
17 compatibility of tazarotene with any of the formulations
18 disclosed in the '824 Publication, right?

19 A. Actually, it's my recollection that Lebwohl did a study
20 that looked at tazarotene and topical corticosteroids put on
21 together in terms of their effect.

22 And it's my recollection that it showed that they
23 were generally, in most cases, compatible. But that's clearly
24 an issue for the formulation expert.

25 Q. Right. But Lebwohl, just to be clear, doesn't provide

1 any information on the compatibility of tazarotene with the
2 formulations disclosed in the '824 Publication, right?

3 A. That's correct. That's a formulation question.

4 Q. You don't rely on the '824 Publication as providing
5 motivation to combine tazarotene and halobetasol, right?

6 A. I rely on those three together to motivate a person to
7 add tazarotene to the lotion described in '824 with
8 halobetasol 0.01 percent.

9 Q. Let me ask my question again.

10 You don't rely on the '824 Publication as providing
11 motivation to combine tazarotene and halobetasol, correct?

12 A. By itself, no, I do not.

13 MR. STEINDLER: Let's go to DDX-2.22, your slide.

14 BY MR. STEINDLER:

15 Q. You will recollect this is one of your slides that you
16 used in your testimony on direct, right?

17 A. Yes.

18 Q. And you do rely on Gollnick as providing motivation to
19 combine halobetasol and tazarotene, correct?

20 A. That's correct.

21 Q. Now, both you and your counsel said a number of times on
22 Tuesday that Gollnick discloses a combination of a
23 corticosteroid and tazarotene.

24 Do you recall that?

25 A. I will -- as it says here, combination therapy, yes.

1 Q. But, for clarity, Gollnick does not disclose a
2 combination product with both a corticosteroid and tazarotene,
3 like the one that we're talking about in this case.

4 Isn't that correct?

5 A. That's correct.

6 Q. It describes alternating therapies using different
7 products at different times, not a combination product,
8 correct?

9 A. It describes the two being used on the same day.

10 THE COURT: Doctor, I want to remind you, please,
11 when you're asked a question which is specific, answer the
12 question, not the question you wish was asked.

13 THE WITNESS: I'm sorry.

14 MR. STEINDLER: Thank you, Your Honor.

15 THE WITNESS: I'm sorry, sir -- Your Honor.

16 MR. STEINDLER: Let's turn to Gollnick, to DX-140 and
17 take a look at it. Okay?

18 BY MR. STEINDLER:

19 Q. Now, if you can go ahead and look at -- well, strike
20 that.

21 Gollnick was published in 1999, correct?

22 A. That's correct.

23 Q. And that is 16 years before the invention date of the
24 Duobrii® patents, correct?

25 A. Yes.

1 Q. Gollnick discloses two separate alternating studies where
2 tazarotene and a corticosteroid were applied at different
3 times, correct?

4 A. Correct.

5 Q. In one study the corticosteroid was applied in the
6 morning and tazarotene was applied in the evening, while in
7 the other study the corticosteroid and tazarotene were applied
8 on alternating days, correct?

9 A. Yes.

10 Q. The tazarotene used in both studies was the higher
11 0.1 percent concentration, correct?

12 A. Yes.

13 Q. Halobetasol was not used in either study, correct?

14 A. Yes.

15 Q. Gollnick wasn't even talking about use of super-high
16 potency corticosteroids like halobetasol in combination with
17 tazarotene, correct?

18 A. Yes.

19 MR. STEINDLER: Let's turn to the summary on the
20 first page of the Gollnick article.

21 BY MR. STEINDLER:

22 Q. And you see in that first sentence it says that studies
23 show that both the efficacy and tolerability of tazarotene
24 therapy can be further improved when it is used in combination
25 with certain topical corticosteroids.

1 Do you see that?

2 A. Yes.

3 Q. And then a few lines later, it tells you what that means,
4 right?

5 In the first study they use tazarotene plus a mid- or
6 high-potency topical corticosteroid, right?

7 A. Yes.

8 Q. And in the second study they used a high-potency topical
9 corticosteroid, correct?

10 A. Yes.

11 Q. And then if you go to the page Bates-marked 19244, the
12 last page of the article, in its concluding sentence, Gollnick
13 says: The addition of a mid- or a high-potency topical
14 corticosteroid to tazarotene therapy offers a valuable means
15 of optimizing efficiency and tolerability of treatment for
16 plaque psoriasis.

17 Correct?

18 A. Yes.

19 Q. So, as we've said, Gollnick is talking about mid- or
20 high-potency steroids.

21 Right?

22 A. Yes.

23 Q. It's not talking about super-high potency steroids such
24 as halobetasol, correct?

25 A. Yes.

1 Q. But your contention is that Gollnick would motivate a
2 POSA to combine halobetasol and tazarotene in a single
3 product, even though Gollnick is not talking about super-high
4 potency corticosteroids like halobetasol and is not talking
5 about combination products.

6 Is that correct?

7 A. That is correct.

8 MR. STEINDLER: Let's turn to your Slide DDX-2.15.

9 BY MR. STEINDLER:

10 Q. And again focusing on this first combination that you're
11 asserting, the last reference is the Tazorac® label, correct?

12 A. Yes.

13 Q. And if you go to your Slide DDX-2.26, your contention is
14 that the Tazorac® label would have motivated a POSA to use
15 0.5 percent -- strike that.

16 Your contention is that the Tazorac® label would have
17 motivated a POSA to use 0.045 percent tazarotene, correct?

18 A. Yes.

19 Q. And so, for clarity, you're not relying on the Tazorac®
20 label to say a POSA would have been motivated to combine
21 tazarotene and halobetasol, correct?

22 A. Not by itself. That's correct.

23 Q. And, for clarity, in your first combination, you're not
24 relying on either the '824 Publication or the Tazorac® label
25 to provide the motivation to combine tazarotene and

1 halobetasol, correct?

2 A. I'm sorry. Could you repeat that more slowly?

3 Q. Sure.

4 MR. STEINDLER: Let's go back to Stern DDX-2.15.

5 BY MR. STEINDLER:

6 Q. In your first set of combinations that you're asserting,
7 it's the '824 Publication plus Gollnick plus the Tazorac®
8 label, right?

9 A. Yes.

10 Q. And you're not relying on the '824 Publication or the
11 Tazorac® label to provide a motivation to combine halobetasol
12 and tazarotene in a single product.

13 Is that correct?

14 A. That's correct.

15 Q. All right.

16 MR. STEINDLER: Let's go back to Slide 2.26.

17 BY MR. STEINDLER:

18 Q. Now, in your first bullet, you note that Tazorac® comes
19 in two concentrations, a 0.05 percent and a 0.01 percent
20 tazarotene, correct?

21 A. Yes.

22 Q. Now, in your third bullet, you say a POSA would have been
23 motivated by the Tazorac® label to use 0.045 percent
24 tazarotene to reduce irritation, correct?

25 A. Yes.

1 Q. But there's nothing in the Tazorac® label that would
2 teach a POSA to use the specific 0.045 percent concentration
3 of tazarotene that's in IDP-118, correct?

4 A. That -- by the label itself, that's correct.

5 Q. Tazorac® already came in both a higher and a lower
6 concentration, right?

7 A. Yes.

8 Q. The lower concentration was 0.05 percent, correct?

9 A. Yes.

10 Q. If a POSA wanted to reduce irritation, they would use the
11 lower 0.05 percent concentration Tazorac®, correct?

12 A. A POSA would use that as a starting point.

13 Q. So Tazorac® was approved in 1997, correct?

14 A. Yes.

15 Q. That was 18 years before the invention date of the
16 Duobrii® patents, right?

17 A. Yes.

18 Q. And in those 18 years, no one ever made a tazarotene
19 product with less than this lower 0.05 percent concentration
20 in order to reduce irritation, right?

21 A. Not to my knowledge.

22 Q. So, again, you say a POSA would have been motivated to
23 lower the concentration. But nobody ever did it in 18 years,
24 right?

25 A. I said to consider lowering it, yes.

1 Q. Now, even if a POSA had been motivated to consider
2 lowering the concentration of tazarotene, there's nothing in
3 the Tazorac® label that would have led a POSA to the specific
4 0.045 percent concentration, correct?

5 A. That is correct.

6 Q. And you don't have any evidence that an optimal
7 concentration of these formulations for the tazarotene
8 component would have been 0.4 -- strike that.

9 You don't have any evidence that 0.045 percent is the
10 optimal concentration for tazarotene in this combination,
11 correct?

12 A. That's correct.

13 Q. And you don't have any evidence that the optimal
14 concentration isn't some other concentration, like
15 0.040 percent or 0.035 percent, right?

16 A. That's correct.

17 Q. You didn't do any optimization testing yourself, correct?

18 A. That's correct.

19 Q. And as far as you know, no one at Padagis did any
20 optimization testing, correct?

21 A. Correct.

22 Q. So you don't actually have any -- strike that.

23 You don't have any actual evidence that a POSA would
24 have arrived at the specific 0.045 percent concentration,
25 correct?

1 A. That's correct.

2 MR. STEINDLER: Let's turn now to your demonstrative
3 DDX-2.15 again.

4 BY MR. STEINDLER:

5 Q. I would like to discuss your second set of combinations,
6 the '824 Publication plus Gollnick plus the IDP-118 study.

7 All right?

8 A. Yes.

9 Q. Now, we've already discussed the '824 Publication and
10 Gollnick, so I'd like to turn to the IDP-118 study. All
11 right?

12 A. Yes.

13 MR. STEINDLER: Let's go to Dr. Stern's Slide
14 DDX-2.24, please.

15 BY MR. STEINDLER:

16 Q. Now, the IDP-118 study discloses a combination of
17 0.01 percent halobetasol and 0.045 percent tazarotene,
18 correct?

19 A. Yes.

20 Q. The IDP-118 study does not disclose the vehicle used with
21 these actives other than to say it's a lotion, correct?

22 A. That's correct, by itself.

23 Q. Now, you say in the bottom bullet on the left side of the
24 slide that the IDP-118 study would have further motivated a
25 POSA to combine 0.01 percent halobetasol and 0.045 percent

1 tazarotene, correct?

2 A. Yes.

3 Q. And by "further" motivation, you mean motivation in
4 addition to the motivation to combine you say is provided by
5 Gollnick.

6 Is that right?

7 A. That's correct.

8 Q. Now, in the real world, people in the field would not be
9 motivated to make the same product that some other company
10 already has in a Phase 2 clinical trial, correct?

11 A. I'm -- you know, I don't work for the pharmaceutical
12 industry, so I don't know.

13 Q. Wouldn't you agree that there's no motivation in the
14 pharmaceutical industry for someone to make a drug that
15 somebody else already has that far along in the development
16 process?

17 A. That's probably correct.

18 Q. Now, the IDP-118 study does not disclose any safety or
19 efficacy data regarding IDP-118, correct?

20 A. It does not. But by being -- it does not.

21 Q. And a POSA would have to under -- strike that.

22 A POSA would have understood that many drugs fail
23 Phase 2 clinical studies, right?

24 A. Yes.

25 Q. Now, you contend that a POSA would have relied on the

1 disclosure of the 0.045 percent concentration of tazarotene to
2 arrive at the 0.045 percent tazarotene as used in IDP-118,
3 right?

4 A. Yes. In combination with the others, yes.

5 MR. STEINDLER: So I'd like to turn again to your
6 demonstrative 2.15.

7 BY MR. STEINDLER:

8 Q. Now, we've been focusing on your second set of
9 combinations here, right?

10 A. Yes.

11 Q. Now, I want you to assume with me for a moment that the
12 IDP-118 study was not available as prior art for a POSA.

13 A. Okay.

14 Q. With that assumption, there would be no basis for a POSA
15 to arrive at the specific 0.045 percent tazarotene
16 concentration in your second set of combinations based just on
17 the '824 Publication and Gollnick, correct?

18 A. That's correct.

19 Q. So if IDP-118 is not available as prior art, your second
20 combination would not have led a POSA to the 0.045 percent
21 concentration, correct?

22 A. Not to the -- not directly to that combination, yes.

23 Q. All right. I'd like to now turn to your third asserted
24 combination, the '824 Publication plus Gollnick plus Gandhi.
25 All right?

1 A. Yes.

2 Q. Now, as we just discussed, you don't contend that the
3 '824 Publication or Gollnick would have motivated a POSA to
4 use the specific 0.045 percent tazarotene, right?

5 A. Correct.

6 Q. But you contend that Gandhi would have motivated a POSA
7 to combine halobetasol and tazarotene, right?

8 A. Yes.

9 Q. But you don't contend that Gandhi would have motivated a
10 POSA to use the specific 0.045 percent concentration of
11 tazarotene, correct?

12 A. Yes.

13 Q. So none of the three references -- strike that.

14 So none of the three references you cite in your
15 third set of combinations would have motivated a person of
16 ordinary skill in the art to use the specific 0.045 percent
17 concentration of tazarotene, correct?

18 A. Yes.

19 MR. STEINDLER: Let's turn now to the Gandhi
20 reference, which is DX-141.

21 And just blow up the top portion so we can just see
22 that.

23 BY MR. STEINDLER:

24 Q. This is the Gandhi reference, right?

25 A. Yes.

1 Q. Now, Gandhi discloses combination products with
2 halobetasol in a concentration of between 0.025 percent and
3 0.05 percent and tazarotene at 0.5 percent to 0.1 -- strike
4 that. Let me start again. Forgive me.

5 MR. STEINDLER: Why don't we go to the page
6 Bates-marked 18567 and blow up that last paragraph of Gandhi.
7 And let me start again.

8 BY MR. STEINDLER:

9 Q. Gandhi discloses combination products with halobetasol in
10 a concentration of between 0.025 percent and 0.05 percent and
11 tazarotene at 0.05 percent to 0.1 percent, correct?

12 A. Yes.

13 Q. Gandhi does not disclose 0.01 percent halobetasol,
14 correct?

15 A. That's correct.

16 Q. And Gandhi does not disclose 0.045 percent tazarotene,
17 correct?

18 A. Yes.

19 Q. Gandhi also does not disclose the formulations used in
20 IDP-118 for the Duobrii® patents, right?

21 A. That's my recollection. But again, I'm not a formulation
22 person.

23 Q. And no one has ever put any of the compositions disclosed
24 in Gandhi through clinical trials anywhere in the world,
25 correct?

1 A. Not to my knowledge.

2 Q. And no one has ever sold a commercial product with any of
3 the compositions disclosed in Gandhi, right?

4 A. I don't know.

5 Q. No one has even published any articles on Gandhi anywhere
6 in the world, right?

7 A. Not to my knowledge.

8 MR. STEINDLER: Let's now turn to your DDX-2.30.

9 BY MR. STEINDLER:

10 Q. You testified on direct that a POSA would have reasonably
11 expected the combination of halobetasol and tazarotene would
12 have provided synergistic efficacy and synergistic reduction
13 of an adverse event, correct?

14 A. Yes.

15 Q. You rely on Gollnick and Gandhi for that proposition,
16 right?

17 A. Yes. That -- yes. As well as my knowledge as a POSA.

18 Q. Now, you're aware that when the FDA is evaluating
19 combination products, it's looking to see whether the
20 combination is better than the individual monads, right?

21 A. Yes.

22 Q. So with halobetasol and tazarotene, the FDA is looking to
23 see whether -- strike that.

24 So with halobetasol and tazarotene, the FDA is
25 looking to see whether the combination is better than

1 halobetasol alone and better than tazarotene alone, right?

2 A. Yes.

3 Q. In other words, the FDA looks to see whether 1 plus 1
4 equals, say, 1 1/2. Right?

5 A. No.

6 Q. But you would agree that it's looking to see whether the
7 combination is better than either of the monads alone,
8 correct?

9 A. Yes.

10 Q. But in the patents, this Court is -- strike that.

11 But in the patents, as the Court has construed them,
12 "synergy" means something different.

13 Isn't that true?

14 A. Yes.

15 Q. In the patents, "synergy" means that the combination
16 works better than the combined monads, not just better than
17 either one, right?

18 A. Correct.

19 Q. And now, these two uses of the word "synergy" are
20 different.

21 Wouldn't you agree?

22 A. I don't believe that the FDA talks about synergy as the
23 application in the way you have it. So one is "synergy" as
24 defined by the Court and the other is approval basis. So I
25 disagree.

1 Q. Don't you agree that the word "synergy" as it's sometimes
2 used in the literature doesn't necessarily have the same
3 meaning as it's used in the patents?

4 A. To me, "synergy," both as defined by the Court in this
5 matter and as I've learned throughout my life, has a specific
6 interpretation, a specific definition which is consistent with
7 that that the Court defined.

8 Q. So let me ask my question again.

9 The word "synergy" as it's sometimes used in the
10 literature doesn't necessarily have the same meaning as it's
11 used in the patents, correct?

12 A. It has been used incorrectly in the literature, that's
13 correct.

14 Q. Now, you rely on statements made by Gollnick and Gandhi
15 about the likelihood of additive or synergistic effects,
16 right?

17 A. Yes.

18 Q. You don't have any way to know what these authors mean by
19 synergy or synergistic when they use those terms in the
20 articles, right?

21 A. That's correct.

22 Q. There's no data in either of these publications that
23 would show what they mean by synergistic effects, right?

24 A. That's correct.

25 Q. So in the absence of any data, you can't know what

1 Gollnick or Gandhi mean when they say the combination is
2 likely to have synergistic effects, right?

3 A. Correct.

4 MR. STEINDLER: Now, let's go back to DDX-2.30,
5 please.

6 BY MR. STEINDLER:

7 Q. Now, in the passage quoted from Gollnick, in the top of
8 your Slide 2.30, Gollnick writes that the combination therapy
9 of tazarotene and a mid- or high-potency topical
10 corticosteroid is likely to have additive or synergistic
11 effects, right?

12 A. Right.

13 Q. But Gollnick just poses this as a hypothesis, right?

14 A. Right, a reasonable expectation, correct.

15 Q. Let me ask my question again.

16 Gollnick just poses this as a hypothesis, correct?

17 A. No --

18 MR. ZIMMERMAN: Objection, asked and answered.

19 THE WITNESS: He states that they are likely to have
20 additive or synergistic effects or a reasonable expectation of
21 that.

22 BY MR. STEINDLER:

23 Q. When you say "reasonable expectation," Gollnick doesn't
24 say, I have a reasonable expectation. That's you talking.

25 Isn't that correct?

1 A. No. "Are likely," to me, means reasonably expecting it.

2 Q. All right. And Gollnick didn't actually test that
3 hypothesis, right?

4 A. That's correct.

5 Q. Because studies weren't set up to test that hypothesis,
6 correct?

7 A. Correct.

8 Q. And Gandhi says in the passage quoted in that bottom box
9 that halobetasol and tazarotene have synergistic effects,
10 right?

11 A. That's correct.

12 Q. But as we said, there's no data in Gandhi to show what
13 type of synergistic effects they're talking about, correct?

14 A. Yes.

15 MR. STEINDLER: Pass the witness.

16 THE COURT: Thank you.

17 Your witness.

18 REDIRECT EXAMINATION

19 BY MR. ZIMMERMAN:

20 Q. Good morning, Dr. Stern.

21 A. Good morning.

22 Q. So I just have a few follow-up questions for you.

23 You were asked a number of questions about the
24 approval date of Ultravate®, correct?

25 A. Yes.

1 Q. And you wrote on your slide that the approval date was
2 not at least '95, and I think the exact statement was
3 "approved in '95," correct?

4 A. Yes.

5 MR. STEINDLER: Objection, mischaracterizes the
6 slide.

7 THE COURT: The demonstrative stands for itself. All
8 right.

9 MR. ZIMMERMAN: Thank you.

10 BY MR. ZIMMERMAN:

11 Q. Dr. Stern, I'd like to direct your attention to DX-212.
12 It's not in your binder, but we're going to put it on the
13 screen.

14 Do you recognize this as the label for Ultravate®
15 Cream?

16 A. I do.

17 Q. If we go to the second page and look in the bottom
18 left-hand corner, does it say who makes Ultravate® Cream?

19 A. Yes, it does.

20 Q. And who is that?

21 A. Westwood-Squibb, which was a division or part of
22 Bristol-Myers Squibb Company.

23 Q. And is that consistent with your understanding of who
24 developed Ultravate®?

25 A. Yes, it is.

1 Q. Okay. And what is the date, the copyright date of the
2 Ultravate® Label?

3 A. That's not showing here, but it's my recollection --

4 MR. ZIMMERMAN: If we could blow it up bigger for
5 Dr. Stern.

6 THE WITNESS: Yeah, I'm sorry, I just can't see it.
7 1995.

8 BY MR. ZIMMERMAN:

9 Q. Thank you, Dr. Stern.

10 Now, there was a lot of debate about whether it was
11 1990 or 1995. I have a question for you.

12 Whether Ultravate® was approved in 1990 or 1995, does
13 that in any way change of HPA axis suppression that you
14 testified about associated with Ultravate®?

15 A. No, it does not.

16 Q. And does it in any way change the two-week limitation on
17 the treatment with Ultravate®?

18 A. No, it does not.

19 Q. And does whether Ultravate® was approved in 1990 or '95
20 impact any of your opinions in this case?

21 A. No, it does not.

22 Q. Okay. Now, there was some discussion in your
23 cross-examination about the '824 publication and which
24 formulation a person of skill in the art would look at.

25 Do you recall that?

1 A. I do.

2 MR. ZIMMERMAN: If we could bring up DX-64.

3 BY MR. ZIMMERMAN:

4 Q. Do you recall this is the IDP ClinicalTrials.gov study?

5 A. Yes.

6 Q. And does it give a concentration of the halobetasol
7 propionate in the IDP-118?

8 A. It does.

9 Q. And what is that concentration?

10 A. 0.01 percent.

11 Q. Now, if a person of skill in the art looked at this
12 document and knew that the concentration was 0.01 percent and
13 wanted to find a vehicle that had been used with 0.1 percent
14 halobetasol propionate and they were aware of all the prior
15 art, is there any publication or patent that would have shown
16 a vehicle with 0.01 percent halobetasol propionate in it?

17 A. Yes, the 2012 '824 publication or patent application
18 would have shown a vehicle with 0.01 percent halobetasol in a
19 lotion form.

20 Q. And so would the IDP-118 study have motivated a person of
21 skill in the art to look at a particular concentration of
22 halobetasol in the '824 publication?

23 A. Yes.

24 Q. And what concentration is that?

25 A. 0.01 percent halobetasol.

1 Q. And in your review of the materials in this case, is
2 there any other prior art that discloses a vehicle containing
3 0.01 percent halobetasol propionate in it?

4 A. Prior to --

5 Q. Prior to 2010?

6 A. Prior -- not -- not to my knowledge, no.

7 Q. Okay.

8 MR. ZIMMERMAN: Dr. Stern, I'd like to turn to your
9 Slide 15.

10 BY MR. ZIMMERMAN:

11 Q. You'll recall Mr. Steindler asked you a question about
12 the third bullet point and the combination of the '824
13 publication, Gollnick and Gandhi?

14 A. Yes.

15 Q. And whether Gandhi itself motivated 0.045 percent
16 tazarotene.

17 Do you recall that?

18 A. Yes.

19 Q. Does Gandhi expressly teach 0.05 percent tazarotene?

20 A. No.

21 Q. Gandhi does not?

22 A. Oh, I'm sorry, he includes that percentage, yes. I'm
23 sorry.

24 Q. Okay.

25 MR. ZIMMERMAN: If we could bring up DX-141 at

1 Page 18567.

2 BY MR. ZIMMERMAN:

3 Q. Dr. Stern, does Gandhi expressly teach 0.05 percent
4 tazarotene?

5 MR. STEINDLER: Objection, leading.

6 THE WITNESS: Yes, yes, I'm sorry.

7 THE COURT: Direct the witness to the portion of the
8 exhibit that you wish him to take a look at.

9 MR. ZIMMERMAN: I will.

10 BY MR. ZIMMERMAN:

11 Q. So if we look at the Page 18567 -- and I apologize for
12 not getting there faster, Dr. Stern -- and we look in the very
13 last paragraph, what concentrations of tazarotene does Gandhi
14 disclose?

15 A. 0.05 percent to 0.1 percent.

16 MR. ZIMMERMAN: I have no further questions at this
17 time, Your Honor.

18 THE COURT: Any further cross?

19 MR. STEINDLER: Very briefly, Your Honor.

20 Can we go to Dr. Stern's Slide DDX-2.9?

21 RECROSS-EXAMINATION

22 BY MR. STEINDLER:

23 Q. Now, you'll recall that counsel just asked you a few
24 questions about Ultravate® and the statements that you made,
25 right?

1 A. Yes.

2 Q. And the statement that was actually on your slide was
3 that Ultravate® was FDA approved since 1995, right?

4 A. Yes.

5 Q. And we know that's not a correct statement, right?

6 A. It was approved in 1990 and that is since 1995, at least.
7 But I was mistaken in the preparation of this, and I admit
8 this.

9 Q. Understood. I'm not giving you a hard time about it.

10 I just want to be sure that we have the record clear
11 that Ultravate® was approved in 1990, not in 1995, right?

12 A. You're absolutely correct.

13 Q. Right. Now, your counsel showed you a label with a date
14 on it, right?

15 A. Yes.

16 Q. It had -- strike that.

17 That label had a 1995 date, right?

18 A. Yes.

19 Q. But there are labels that come out periodically over the
20 course of the life cycle of any product.

21 Isn't that true, sir?

22 A. That's correct.

23 Q. And the fact that there was a label that you happened to
24 have that was dated 1995 didn't mean that that was when the
25 FDA approved it, right? You know that?

1 A. Yes.

2 Q. And this mistake that you made means that Ultravate® and
3 the two-week limitation and the problem that it presented was
4 out there for five longer years than is presented in your
5 slide, right?

6 A. Yes.

7 Q. All right. And you were also asked a few questions about
8 the '824 publication.

9 Do you recall that?

10 A. Yes.

11 Q. And you testified that the '824 publication, coupled with
12 the -- strike that.

13 You testified that you had looked to the '824
14 publication to find a formulation with a 0.01 percent
15 halobetasol concentration, right?

16 A. That's correct.

17 Q. But there are, in fact, multiple formulations disclosed
18 in the '824 publication that have 0.01 percent halobetasol.

19 Isn't that true, sir?

20 A. Yes.

21 MR. STEINDLER: No further questions.

22 THE COURT: Okay. I have one, Doctor, just so I
23 understand, all right?

24 Ultravate® is approved by the FDA in 1990.

25 THE WITNESS: Yes.

1 THE COURT: The invention date of the patents
2 involved here is 2010.

3 Is that correct?

4 THE WITNESS: For the single product, 2010; for the
5 duo product, 2015.

6 THE COURT: Okay. So if I understand your testimony,
7 for 20 years it's been known that Ultravate® at the
8 0.05 concentration can only be used for two weeks at a stretch
9 and that that is a very serious drawback because of the side
10 effects that would occur if you used it beyond two weeks.

11 Is that correct?

12 THE WITNESS: Yes.

13 THE COURT: And are you aware of whether or not in
14 that 20-year period any commercial product was approved for
15 use to treat this disease with a concentration of less than
16 0.05 percent HP?

17 THE WITNESS: Not with halobetasol, no.

18 THE COURT: Thank you.

19 THE WITNESS: Not --

20 THE COURT: Anything further from anybody else?

21 MR. STEINDLER: No, Your Honor.

22 MR. ZIMMERMAN: No, Your Honor.

23 THE COURT: Thank you, Doctor.

24 THE WITNESS: Thank you.

25 (Witness is excused.)

1 MR. STEINDLER: Your Honor, I'm told I'm remiss on a
2 housekeeping matter with respect to some exhibits. Would you
3 mind if I --

4 THE COURT: Oh, yes, we're in for more excitement.

5 MR. STEINDLER: Lots of exciting. I need to move in
6 three exhibits, which I understand not to be objected to with
7 respect to my cross of Dr. Stern.

8 They are: PTX-93, PTX-359 and PTX-360.

9 THE COURT: Thank you. They're admitted into
10 evidence.

11 MR. STEINDLER: Thank you.

12 (Exhibit Number PTX-93 is received in evidence.)

13 (Exhibit Number PTX-359 is received in evidence.)

14 (Exhibit Number PTX-360 is received in evidence.)

15 THE COURTROOM DEPUTY: And just for clarification,
16 DX-212 is just for identification?

17 MR. ZIMMERMAN: I would go ahead and move it in if
18 it's unopposed.

19 MR. STEINDLER: No objection.

20 THE COURT: It's admitted in the evidence.

21 (Exhibit Number DX-212 is received in evidence.)

22 MS. PITZEL CRUZ: Your Honor, we'd like to call our
23 next witness, Dr. Michniak-Kohn.

24 THE COURT: I'm sorry?

25 MS. PITZEL CRUZ: We'd like to call our next witness.

1 THE COURT: Please go ahead.

2 MS. PITZEL CRUZ: May I approach, Your Honor?

3 THE COURT: Go ahead.

4 DR. BOZENA B. MICHNIAK-KOHN, DEFENSE WITNESS,
5 having been duly sworn, testifies as follows:

6 DIRECT EXAMINATION

7 THE COURTROOM DEPUTY: Please state your full name
8 for the record.

9 THE WITNESS: Bozena Michniak-Kohn.

10 THE COURTROOM DEPUTY: Please spell your first and
11 last name.

12 THE WITNESS: B-O-Z-E-N-A, M-I-C-H-N-I-A-K-K-O-H-N.

13 THE COURTROOM DEPUTY: Thank you.

14 MS. PITZEL CRUZ: Good morning, Your Honor.
15 Padagis's next witness is Dr. Bozena Michniak-Kohn.

16 THE COURT: Good morning, Doctor.

17 THE WITNESS: Good morning, Your Honor.

18 MS. PITZEL CRUZ: Dr. Michniak-Kohn has expertise in
19 the field of pharmaceutical science, especially in the area of
20 development and evaluation --

21 MR. STEINDLER: Judge --

22 THE COURT: Take your mask down.

23 MR. STEINDLER: I'm sorry, Judge.

24 Normally one asks the witness these questions rather
25 than having counsel testify. I realize we're trying to do

1 things as expeditiously as possible, but it's --

2 THE COURT: Are you going to be objecting to your
3 qualifications as an expert?

4 MR. STEINDLER: I am not going to be objecting to her
5 qualifications.

6 THE COURT: Is the CV going to be offered in
7 evidence?

8 MS. PITZEL CRUZ: Your Honor.

9 THE COURT: Fine. The CV will be admitted into
10 evidence. We'll assume that she is, indeed, one of the
11 world's leading experts in whatever field of expertise you're
12 offering her in and let's proceed.

13 MS. PITZEL CRUZ: Yes, Your Honor.

14 And just for the record, Dr. Michniak-Kohn's CV is
15 Exhibit DX-184.

16 THE COURTROOM DEPUTY: 184?

17 MS. PITZEL CRUZ: 184.

18 THE COURTROOM DEPUTY: Thank you.

19 (Exhibit Number DX-184 is received in evidence.)

20 BY MS. PITZEL CRUZ:

21 Q. And, Dr. Michniak-Kohn, have you prepared any slides to
22 help you with today's presentation?

23 A. Yes, I did.

24 Q. Okay. And if I can direct your attention to the screen,
25 are those the slides that you prepared?

1 A. These are the slides I prepared.

2 Q. And, Dr. Michniak-Kohn, what were you asked to do in this
3 case?

4 THE WITNESS: If I can have the next slide, I have a
5 summary.

6 So, first of all, I was asked to provide opinions
7 regarding the knowledge in the art of the patents in suit and
8 the validity of the asserted claims of the two patents that we
9 call "halobetasol patents," which is the '307 and the '502.

10 I was asked for my opinions regarding the knowledge
11 in the art related to formulations that are recited in the
12 asserted claims of U.S. Patent Numbers '895 and '787, that I'm
13 going to call the "combination patents."

14 I was also asked to provide background information to
15 explain the technology at issue.

16 BY MS. PITZEL CRUZ:

17 Q. Dr. Michniak-Kohn, can you briefly summarize any
18 conclusions you drew based on your analysis?

19 THE WITNESS: If I can have the next slide, please.

20 So the conclusions were the following: That the
21 asserted claims of the halobetasol patents would have been
22 obvious over the prior art and also that the asserted claims
23 of the halobetasol patents are indefinite and the formulation
24 limitations of the combination patents would have been obvious
25 over the prior art.

1 MS. PITZEL CRUZ: If we can pull up JTX-001, please.

2 BY MS. PITZEL CRUZ:

3 Q. Do you recognize this document, Dr. Michniak-Kohn?

4 A. Yes, I do. This is the '307 patent that issued
5 August 19th of 2014.

6 MS. PITZEL CRUZ: If we could pull up JTX-004.

7 BY MS. PITZEL CRUZ:

8 Q. Do you recognize this document, Dr. Michniak-Kohn?

9 A. Yes, I do. This is the '502 patent that issued
10 November 19, 2019.

11 Q. And what is the priority date for the halobetasol
12 patents?

13 THE WITNESS: If we can have the next slide.

14 We see both of those patents displayed. And the
15 provisional application that's listed there was filed on
16 November the 22nd, 2010. So that is the priority date.

17 BY MS. PITZEL CRUZ:

18 Q. Can you describe generally the asserted claims of the
19 halobetasol patents?

20 A. Yes, I can. And to help with that...

21 THE WITNESS: Can I have the next slide?

22 Thank you.

23 We start off with the '307 patent -- if you can go
24 back one, please. Thank you.

25 So this is the high-level summary for the '307

1 patent. It describes halobetasol propionate at a
2 concentration of 0.04 percent or less and 0.025 or less.

3 It mentions a liquid oil component comprising a
4 dicarboxylic acid ester, specifically diethyl sebacate.
5 Additionally, it includes light mineral oil.

6 Halobetasol propionate is solubilized in the liquid
7 oil component.

8 If we move on to the '502 patent, they are similar to
9 the '307 claims. Again, we have the halobetasol propionate at
10 a concentration of less than 0.05 percent and 0.01 percent or
11 less.

12 It again mentions a liquid oil component comprising
13 diethyl sebacate, an aqueous phase comprising water, excludes
14 the use of white petrolatum, and it describes a method for
15 treating longer than two weeks.

16 And in the next slide -- if I can have the next
17 slide, please. Thank you.

18 What I've done here -- and this is the '307 and the
19 asserted claims. So we have Claim 13 that's asserted and
20 Claim 16 that's asserted and Claim 20 is asserted. And some
21 of those claims are dependent on other claims of the '307
22 patent, and that's why I've listed Claim 1, Claim 4 and
23 Claim 19. And everything that is underlined in red I have
24 just covered in the summary slide.

25 If I can have the next slide, please. Thank you.

1 This is the '502 patent done in the same way. We
2 have asserted Claim 4 and Claim 16, that's the other asserted
3 claim. And both of those are listed together with the claims
4 that they are dependent upon, which is Claim 1 and Claim 13.
5 And we see again, underlined in red, the highlights that I
6 just presented two slides ago.

7 BY MS. PITZEL CRUZ:

8 Q. And do the halobetasol patents include any information
9 regarding the claimed formulations?

10 A. Of course, they do.

11 THE WITNESS: If I can have the next slide, please.

12 Okay. So here we have the '307 patent and we have
13 Example 1 on the left-hand side and Table 1 on the right-hand
14 side. And what we see is that '307 lists in Table 1 several
15 formulations that are labelled A, B, C, D and E and
16 ingredients in those formulations.

17 The first ingredient, in fact, is halobetasol
18 propionate, which is a corticosteroid. And we see that in
19 those formulations we have various concentrations listed, from
20 0.035 going up to 0.0 -- or going down to 0.01.

21 We also have a vehicle listed, the diethyl sebacate,
22 sometimes abbreviated for DCAE, and also light mineral oil.

23 And, in fact, formulations A to D are formulations of
24 the invention.

25 BY MS. PITZEL CRUZ:

1 Q. Are there any other examples of the halobetasol patents
2 that you reviewed?

3 THE WITNESS: If I could have the next slide, please.

4 So here we have example 3 from the '307 patent on the
5 left, and on the right we have table 3 from the same patent.

6 Now, what this is describing is something that's
7 abbreviated to VCA. VCA stands for vasoconstrictor assay, and
8 this is a semiquantitative assay that is used with a scale of
9 0 to 4 to basically look at the skin of patients that have had
10 a corticosteroid applied. And when that corticosteroid is
11 applied to the skin, it blanches the skin or whitens the skin.
12 And that amount of production of white color of the skin is
13 given a score.

14 So what we see here is the score being 0 to 4. In
15 table 3, we have the formulations that we just had from the
16 last slide with the concentration of halobetasol and the
17 corresponding VCA or vasoconstrictor assay mean score.

18 And if we look down in the numbers there and also at
19 the conclusion that was drawn, formulations A to D of this
20 present invention had a VCA score very similar to a prior art
21 formulation that is already being discussed this morning
22 called Ultravate®.

23 And that, by the way, of course, is the 0.05
24 halobetasol that was on the market.

25 This high level -- I'm reading from the underlined

1 red portion.

2 This high level of VCA score which is indicative of
3 the local desired response of the corticosteroid. But what we
4 notice here, that the VCA scores were very similar.

5 BY MS. PITZEL CRUZ:

6 Q. And does the patent describe anything about the
7 similarity of those VCA scores?

8 A. Yes. They are saying that they are similar to the prior
9 art formulation Ultravate®.

10 Q. And, Dr. Michniak-Kohn, how did you conduct your analysis
11 of the halobetasol patents with respect to obviousness?

12 THE WITNESS: If I can have the next slide.

13 So, again, I'm obviously not a lawyer, I'm a
14 formulator. So legal counsel advised me on what the standards
15 were, and I'm summarizing them here.

16 That a claim is obvious if the differences between
17 the subject matter of the claim and the prior art are such
18 that the subject matter of the claim as a whole would have
19 been obvious to a person of ordinary skill in the art at the
20 time the patent was filed.

21 And four primary factors have to be considered: The
22 scope and content of the prior art; differences between the
23 prior art and the claims; the level of ordinary skill in the
24 pertinent art; and finally, the second area considerations of
25 non-obviousness.

1 And a POSA must have motivation to combine or modify
2 the prior art with a reasonable expectation of success.

3 BY MS. PITZEL CRUZ:

4 Q. And did you apply this framework in your analysis?

5 A. That is exactly what I did.

6 Q. And you mentioned the level of ordinary skill. Can you
7 explain what you meant?

8 A. In the next slide --

9 THE WITNESS: If I can have that, it would be very
10 helpful.

11 So we're looking here at the definition of a POSA --
12 a person of ordinary skill in the art at the relevant time
13 period of November 2010, and we see that a POSA would have
14 worked as a part of a multidisciplinary team of scientists and
15 medical professionals that included at least a person with an
16 advanced degree in chemistry, pharmacy or a related
17 discipline, or several years experience of developing topical
18 pharmaceutical formulations; or, alternately, a person with a
19 bachelor's degree in the same disciplines that I just
20 mentioned and a greater degree of experience developing
21 topical pharmaceutical formulations; and then also a clinician
22 with several years of experience using topical pharmaceutical
23 formulations to treat patients with skin disorders that would
24 have included psoriasis and an understanding of the
25 considerations relevant to evaluating those clinical effects,

1 for example, safety and efficacy, of these topical
2 formulations.

3 BY MS. PITZEL CRUZ:

4 Q. Dr. Michniak-Kohn, do you consider yourself to be one of
5 skill in the art under this definition in November 2010?

6 A. Yes, I would.

7 Q. And would you also consider yourself to be one of skill
8 in the art under this definition in 2015?

9 A. Yes, I would.

10 Q. And did you review information from plaintiff's experts
11 regarding their definition of one of skill in the art?

12 A. I did.

13 Q. Would your analysis change if plaintiff's experts
14 definitions were applied?

15 A. No, my opinion would not change.

16 Q. And were there any claim terms that you focused on in the
17 halobetasol patents?

18 A. Yes, I did, and we've already got the slide. And the
19 claim term is "liquid oil component."

20 So what we see on the right-hand side is the portion
21 from the '307 patent, Column 4, Line 17 to 27, and we read:
22 The liquid oil component of the present application includes
23 all ingredients of the formulation that are practically
24 insoluble or insoluble in water and which are liquid at room
25 temperature of 22° degrees Centigrade.

1 And on the left-hand side, we have the opinion and
2 order regarding claim construction DI 83 at 23 to 24, and the
3 Court's construction, and we read, actually, something very
4 similar.

5 The Court's construction is: The liquid oil
6 component includes all ingredients of the formulation that are
7 practically insoluble or insoluble in water in which a liquid
8 at room temperature of 22° degrees Centigrade.

9 And this is the construction that I applied while
10 evaluating the patents.

11 Q. Do the halobetasol patents include additional information
12 regarding the liquid oil component?

13 A. Yes, they do.

14 THE WITNESS: If I can have the next slide, please.

15 Okay. So we look for what is said in the patents on
16 this phrase "liquid oil component." So we see that in the
17 '307 patent at Column 4, Lines 35 to 45, it says that: The
18 liquid oil component and the corticosteroid may interact in
19 the formulation in order to dissolve or substantially dissolve
20 the corticosteroid. It is hypothesized that in this
21 solubilization within the formulation, that it provides
22 delivery of the corticosteroid preferentially into the skin
23 rather than providing transdermal delivery through the skin
24 and into the systemic circulation.

25 BY MS. PITZEL CRUZ:

1 Q. Is there anything in the patent addressing this
2 preferential delivery?

3 A. No. As it says, it's a hypothesis only.

4 Q. And is there anything in the asserted claims that require
5 preferential delivery?

6 A. No, there is not.

7 Q. Dr. Michniak-Kohn, can you provide some additional
8 background regarding what was known about halobetasol prior to
9 2010?

10 A. Absolutely. So here I have a summary slide of what was
11 known about the corticosteroid in question prior to 2010.

12 Corticosteroids have been known for a long, long
13 time. They're old drugs that have been around, they're
14 effective. And corticosteroids, obviously, is the description
15 of a class of drugs in which halobetasol propionate is one of
16 them.

17 We've already heard that it's commercially available
18 in a topical formulation at that time and before under the
19 trade name Ultravate® which was 0.05 halobetasol propionate.
20 So there's already a marketed formulation.

21 Corticosteroids and halobetasol are known to have a
22 problem being dissolved in water. They're compounds that are
23 known as lipophilic as opposed to hydrophilic. Lipophilic
24 means that they like to be dissolved in oily, fat-liking
25 environments rather than water that we think - another name is

1 aqueous environments, which are the opposite side of the
2 lipophilic.

3 Also the POSA would know that these corticosteroid --
4 corticosteroids as a class carry a risk of adverse effect, and
5 particularly halobetasol at 0.05 percent.

6 Its use is limited to two weeks at that concentration
7 of 0.05.

8 Q. And, Dr. Michniak-Kohn, if we could turn to DX-009.

9 Do you recognize this document?

10 A. Yes, I do.

11 Q. And what is this document?

12 A. This is the Ultravate® Label, package insert.

13 Q. And does this document, this Ultravate® Label, provide
14 any information to one of skill in the art?

15 A. Yes, it does.

16 MS. PITZEL CRUZ: Maybe if we could blow up the
17 portion underneath the chemical structure, if we could see
18 that a little easier.

19 MR. ZIMMERMAN: Technology.

20 THE COURT: I'm sorry, I couldn't hear that.

21 THE COURTROOM DEPUTY: Technology.

22 THE COURT: Oh.

23 MS. PITZEL CRUZ: Your Honor, I'm being told that
24 they need to change the computer over to address the
25 technology.

1 THE COURT: Go right ahead.

2 MR. STEINDLER: Shall we take our morning break in
3 order to accommodate that? I realize it's a little early.

4 THE COURT: Morning break.

5 MS. PITZEL CRUZ: Thank you, Your Honor.

6 THE WITNESS: Thank you, Your Honor.

7 (Recess taken from 10:35 a.m. to 10:53 a.m.)

8 THE COURTROOM DEPUTY: All rise.

9 THE COURT: Be seated.

10 Technological issues revolved?

11 MS. PITZEL CRUZ: That is my understanding. We'll
12 see how it goes.

13 And just one formality, Your Honor. We'd like to
14 offer Dr. Michniak-Kohn as an expert in the field of
15 pharmaceutical science, particularly in the area of the
16 development and evaluation of dermatologically formulations.

17 MR. STEINDLER: No objection.

18 THE COURT: So stipulated.

19 I apologize for cutting short your effort to
20 explicate her qualifications.

21 MS. PITZEL CRUZ: We appreciate moving forward.

22 If we could bring up DX-009 on the screen, please.

23 BY MS. PITZEL CRUZ:

24 Q. And, Dr. Michniak-Kohn, do you recognize this document?

25 A. Yes, I do. This is the Ultravate® Cream 0.05 percent

1 label.

2 Q. And does this document provide any information to one of
3 skill in the art?

4 A. Yes, it does.

5 MS. PITZEL CRUZ: And if we could look at the portion
6 underneath the chemical structure.

7 BY MS. PITZEL CRUZ:

8 Q. Could you let us know what information this label
9 provides to one of skill in the art.

10 A. So it says -- it talks about, obviously, about
11 halobetasol propionate and the fact that this compound is
12 insoluble in water, as we see at the end of that sentence.

13 Q. And is there any information in the indications and usage
14 section that is useful?

15 A. Yes. If we look at that, it talks about the fact the
16 treatment beyond two consecutive weeks is not recommended and
17 the total dosage should not exceed 50 grams per week because
18 of the potential for the drug to suppress the
19 hypothalamic-pituitary-adrenal, excuse me, HPA axis.

20 Q. And, Dr. Michniak-Kohn, was the use of corticosteroids
21 and dicarboxylic acid esters known before 2010?

22 A. Yes, it was.

23 And here we see, again, a high-level summary of the
24 use of these corticosteroids and dicarboxylic acid esters
25 before 2010.

1 Dicarboxylic acid esters are a group of compounds.
2 And within that group, the diethyl sebacates are a subgroup of
3 compounds in that family of these dicarboxylic acid esters.

4 We will see from the '295, '566 patents, and the JP
5 '228 Publication, that it was known to use corticosteroids in
6 topical formulations for the treatment of skin disorders.

7 And I need to add here that person of ordinary skill
8 in the art would have also known very well that
9 corticosteroids are well known and have been used and are
10 useful topical formulations for various skin disorders,
11 including psoriasis.

12 Dicarboxylic acid esters themselves are liquids and
13 liquid oils, and they are lipophilic. And I think I've kind
14 of explained that lipophilic means liking oily, fatty
15 environments. And they are commonly used in topical
16 formulations to dissolve ingredients and drugs such as
17 corticosteroids that we already decided are themselves
18 lipophilic and like -- likes like environments.

19 And a POSA would have understood that different
20 concentrations of the same corticosteroid may also exhibit a
21 similar pharmacodynamic response, as we will see in a minute
22 in Gao, which is DX-196.

23 Q. And, Dr. Michniak-Kohn, can you explain to me the
24 relationship between diethyl sebacates and dicarboxylic acid
25 esters?

1 A. Diethyl sebacates are basically a subset of the larger
2 class of dicarboxylic acid esters which were known to be
3 solvent and also -- and we will go into that in a minute --
4 chemical penetration enhancers for topical formulations.

5 Q. And is diethyl sebacate a dialkyl sebacate?

6 A. Yes, it is.

7 MS. PITZEL CRUZ: If we could pull up the DX-196
8 reference you had mentioned.

9 BY MS. PITZEL CRUZ:

10 Q. Do you recognize this reference, Dr. Michniak-Kohn?

11 A. Yes. This is the publication by Gao and Po entitled:
12 Topical formulations of fluocinonide acetone of creams,
13 gels, ointments bioequivalent, and does dilution affect
14 activity.

15 Q. And, Dr. Michniak-Kohn, you mentioned that a person of
16 skill in the art would have understood that different
17 concentrations of the same corticosteroid may exhibit a
18 similar pharmacodynamic response.

19 Can you explain what you meant by that?

20 A. Yes.

21 THE WITNESS: If I can have the next slide.

22 So first of all, Gao was published in 1994 so
23 obviously is prior art. I already mentioned they looked at a
24 corticosteroid called fluocinolone acetone. It was a cream.
25 The brand name was Synalar, and if that's not familiar it's

1 because this probably was a trade name that was used in the
2 UK. We see the papers from the UK.

3 And it was at a concentration of 0.025, and what they
4 did is they made several cream dilutions containing this
5 steroid at concentrations of .0065, which was a four-fold
6 dilution, and .0025, which was a tenfold dilution. And then
7 tested them and that's was DX-196 at 73.

8 And they also did, as commonly was used,
9 vasoconstrictor assay testing that we already discussed before
10 the break, and those VCA results showed, and I quote: That
11 although there was a trend towards less activity at lower
12 concentrations, there was no significant difference in the
13 activities of the three dilutions of the cream.

14 So even though the numbers could have been slightly
15 less, statistics proved that there was no difference at all
16 between those particular values.

17 And the authors concluded, and that's the last,
18 fourth bullet point that: Our data would suggest that perhaps
19 even at the 0.0025 percent level, sufficient steroid is
20 present to saturate receptors in the skin so that an increase
21 in concentration would not produce any enhancement in
22 activity. And that's at 74.

23 BY MS. PITZEL CRUZ:

24 Q. Dr. Michniak-Kohn, did you form any opinions regarding
25 whether the asserted claims of the halobetasol patents would

1 have been obvious?

2 A. Yes, I did.

3 THE WITNESS: If I can have the next slide, please.

4 So this is a high-level summary looking at the '307
5 and '502 patents, and that they are invalid is obvious over
6 the prior art. And we see four bullet points here.

7 The '295 patent, or DX-003, in view of Blum -- and by
8 the way, obviously, we'll be discussing all of these very,
9 very soon.

10 In view of Blum, which is DX-002; the '295 patent in
11 view of Blum, and the '566 patent, which is DX-004; the '295
12 patent in view of Blum, and JP '228 Publication, which is
13 DX-005; and the '295 patent in view of Blum and the Temovate®
14 Label, which is DX-006.

15 MS. PITZEL CRUZ: If we could turn to DX-002.

16 BY MS. PITZEL CRUZ:

17 Q. Do you recognize this document, Dr. Michniak-Kohn?

18 A. Yes, I do. This is the publication by Blum, and it's
19 entitled: Multicenter, double-blind comparative observation
20 of application of 0.02 percent, 0.05 percent CGP14458 -- and
21 that is just the code for halobetasol propionate -- ointments
22 and Dermovate® ointment in the treatment of chronic psoriasis.

23 Q. Dr. Michniak-Kohn, can you describe the contents of the
24 Blum reference?

25 A. Yes.

1 THE WITNESS: I can, if I can have the next slide.

2 So we, first of all, established that Blum was
3 published in 1986, which makes it prior art. We also need to
4 mention that it does a comparison with Dermovate®, which is
5 clobetasol.

6 And, again, if you're unfamiliar with the name of
7 Dermovate®, it's basically the UK version, or the UK brand
8 name, for clobetasol propionate. And, of course, the paper
9 actually originates in the UK as well.

10 BY MS. PITZEL CRUZ:

11 Q. Dr. Michniak-Kohn, can you explain what the Blum article
12 would have disclosed to a person of ordinary skill in the art?

13 THE WITNESS: If I can have the next slide, please.

14 So what we see that the Blum article discloses, as I
15 mention already, a coded version, the CCGP14458, which is
16 halobetasol, at two different concentrations: at 0.02 percent
17 and 0.05 percent for treating psoriasis in patients for
18 approximately 21 days. And that's DX-002 at 139 to 140, and
19 we're going to look at Table 1.

20 And Table 1 has extent of clinical improvement on the
21 left-hand side. It goes from cured, significantly cured to a
22 moderate effect, to poor, and a total.

23 And along the top, the evaluation of the three
24 formulations, we see the 0.02 percent ointment, the
25 halobetasol ointment, the 0.05 halobetasol ointment, and

1 finally, on the right-hand side, we see the Dermovate®
2 ointment, which is the clobetasol.

3 And what we see, that going from 0.05 to 0.02, which
4 is actually lowering the concentration by more than half,
5 produces only a 9 percent difference in efficacy among the
6 patients treated because the difference between the
7 0.05 ointment, we see highlighted that 90.2 of the patients
8 were either cured or significantly cured.

9 When the concentration went down to 0.02, yes, there
10 was a lowering in the absolute number of the patients that
11 were cured, it went down only to 81.4.

12 But that's still a pretty good number of cured or
13 significantly cured patients.

14 So, again, the POSA is very interested in this; that
15 lowering the concentration was still effective.

16 BY MS. PITZEL CRUZ:

17 Q. And, Dr. Michniak-Kohn, is there any other information in
18 Blum that would be relevant to one of skill in the art?

19 A. Yes, indeed.

20 THE WITNESS: If I can have the next slide.

21 And we read in the Blum article: In the treatment of
22 severe chronic psoriasis vulgaris, which is the disease of
23 interest in this case, the ointment with the lower
24 concentration, i.e., the 002 CGP 14 458, was less effective
25 than the concentration of 0.05 percent and Dermovate®

1 ointment.

2 As we saw from the last table, the absolute number
3 was a little lower. However, what they found was that the
4 difference among the three groups was not statistically
5 significant. And that's important to the POSA. He's getting
6 the message, or she's getting the message, that going down in
7 the concentration to 0.02 halobetasol propionate was effective
8 in treating psoriasis in these patients and in this
9 multicenter trial.

10 BY MS. PITZEL CRUZ:

11 Q. And, Dr. Michniak-Kohn, you also mentioned the '295
12 patent earlier.

13 MS. PITZEL CRUZ: Could we pull of DX-003, please.

14 BY MS. PITZEL CRUZ:

15 Q. Do you recognize this document, Dr. Michniak-Kohn?

16 A. Yes, I do. This is the '295 patent that issued
17 November 11th of 1980.

18 Q. And can you describe what the '295 patent disclosed to a
19 person of skill in the art?

20 THE WITNESS: If I could have the next slide, please.

21 One more slide. Thank you.

22 Okay. So we saw that the '295 patent issued in 1980.
23 Obviously it is prior art. It discloses various
24 corticosteroid lotion formulations comprising a liquid-oil
25 phase and an aqueous phase.

1 And by the way, lotions are also emulsions, and
2 emulsions are mixtures of lipophilic and hydrophilic
3 components in their formulation.

4 It also discloses that corticosteroid steroid is
5 entirely solubilized, which means dissolved, at room
6 temperature in the liquid oil phase that comprises the
7 sebacate.

8 And in the bottom of the slide, I've included the two
9 excerpts from the '295 patent, which is DX-003, at Column 2,
10 Lines 22 to 26, and the '295 patent at Column 3:68, 4 to 10.

11 BY MS. PITZEL CRUZ:

12 Q. Dr. Michniak-Kohn, does the '295 patent provide any
13 additional information relevant to one of skill in the art?

14 A. Yes, it does.

15 THE WITNESS: If I can have the next slide, please.

16 So what we will see here, again, at the top are two
17 excerpts from the '295 patent. The one on the left is
18 Column 1:45 to 51, and '295 being DX-003, and on the
19 right-hand side we see an excerpt from Column 2:61 to 3:2.

20 And what we see underlined in red, we see that it
21 teaches a range of corticosteroid concentrations that overlap
22 with the claimed ranges of 0.04 percent or less and
23 0.25 percent or less, less than 0.05 percent and 0.01 or less.

24 And on the left-hand side -- let's go back to the
25 box -- on the left-hand side from the patent, we see that it

1 mentions a steroid, and I've made things easier, I've
2 underlined it in red, where the concentration is 0.001 to
3 about 3 percent by weight. It's also mentioning 0.025 to
4 about 0.2 percent, and then depending upon the type of steroid
5 employed and its solubility in the sebacate vehicle.

6 On the right-hand side we see the reference to the
7 lotion formulation, and the concentrations that are mentioned
8 here are 0.005 to about 0.6 percent, and 0.02 percent to about
9 0.5 percent.

10 BY MS. PITZEL CRUZ:

11 Q. And are there any other portions of the '295 patent that
12 would provide information to one of skill in the art?

13 A. And I've already got my next slide.

14 THE WITNESS: Thank you.

15 It teaches the use of sebacates, such as dialkyl
16 sebacate, sebacates with corticosteroids.

17 And, of course, the excerpt from the '295 patent,
18 Column 1, 40 to 44, mentions dialkyl sebacates wherein the
19 alkyl chain, the alkyl, contains 1 to 10 carbons.

20 Now when a POSA would have seen that, first of all,
21 they know that we're talking about the group of dialkyl
22 sebacates that are a subgroup of the main solvents that we
23 just mentioned, and the disclosure would include diethyl
24 sebacate. And the reason is, that diethyl sebacate has two
25 carbons.

1 So it's one of the compounds that would have fitted
2 into the class where the underlining is carbon chains 1 to 10.

3 BY MS. PITZEL CRUZ:

4 Q. Would the '295 patent have provided any motivations to
5 one of skill in the art regarding formulating a corticosteroid
6 formulation?

7 A. Actually if we go back to the last slide, I just wanted
8 to make one more point. And my apologies.

9 The last bullet, of course, says: The selection of
10 the diethyl sebacate would have been a matter of routine
11 optimization based on the solubility of the corticosteroid.

12 So then the conclusion is that since we have the
13 disclosure of the 1 to 10 carbons, diethyl sebacate is
14 2-carbon. It would have been easy to test just the few
15 sebacates and would have come up with diethyl sebacate.

16 And you're looking, obviously, as a POSA, for
17 compounds to dissolve the corticosteroids that are lipophilic,
18 and you also know that this class of compounds is already
19 well-known in the art.

20 THE WITNESS: Next slide, please.

21 So I was asked about the motivation to combine or
22 modify Blum and the '295 patent.

23 So the '295 patent, first of all, explicitly states
24 in its disclosures that they are applicable to any topically
25 active antiinflammatory steroid. And below it we see an

1 excerpt that reads: Steroids are meant to be exemplary only
2 and it is not meant to limit this invention.

3 And this is from DX-003, the '295 patent at Column 2,
4 Lines 6 to 10.

5 And first of all, the POSA already knows that
6 halobetasol is a corticosteroid, that structure is similar, it
7 is in the class of corticosteroids in the examples of the '295
8 patent. And that's DX-003 at 6:60 to 10:68.

9 A skilled artisan preparing a topical halobetasol
10 formulation at a lower concentration would have been motivated
11 to select a vehicle that would facilitate adequate drug
12 delivery. We see that in the '295 patent at Column 1, Lines
13 12 to 16. And that was obviously well known anyway to the
14 POSA; that they needed a vehicle that delivers the drug.

15 So a POSA would have also had a reasonable
16 expectation that solubilizing halobetasol in a dialkyl
17 sebacate, as taught by the '295 patent, would have improved
18 the release of halobetasol from the formulation and improved
19 the penetration into the skin.

20 They would have also had Blum. And from that they
21 would have known that 0.02 halobetasol was effective in
22 treating psoriasis. We just saw that in the last few slides.
23 And it would have provided the POSA a motivation to formulate
24 a lower dose of halobetasol formulation with an expectation of
25 success.

1 Both the '295 patent and Blum, of course, are
2 discussing the use of corticosteroids to treat skin disorders
3 such as psoriasis.

4 BY MS. PITZEL CRUZ:

5 Q. And would a POSA have had any other motivations to
6 combine the Blum reference and the '295 patent?

7 A. Of course.

8 So there was a problem. I think it's already been
9 mentioned, but I will review this again.

10 In the '307 patent, for example, we see certain
11 excerpts that we will return to in a minute. But overall, the
12 POSA would have known the problem with corticosteroids that
13 were out and being used; that the concentrations,
14 corticosteroids, if they're high enough concentrations, they
15 will get absorbed into the systemic circulation. And what I
16 mean by that, they get absorbed into the body and they cause
17 major side effects, certainly untoward side effects that are
18 very undesirable in patients.

19 So there's a motivation -- and also, by the way,
20 there's a restriction, which we've mentioned already, on how
21 much the steroid and how long the steroid can be used.

22 So the motivation to formulate a lower concentration,
23 to minimize this risk of these side effects, while still
24 maintaining efficacy, would have been a motivation for the
25 POSA. And, in fact, we even see in the '307 patent, Column 2,

1 Lines 33 to 51, that the patentees specifically discussed
2 these problems with the 0.05 halobetasol and they recommended
3 limits on the duration for superpotent corticosteroids.

4 So if we look at the right-hand side, we have the
5 background of the invention in the '307, and underlined we
6 read that the patentee say: Unfortunately, because of the
7 high potency of Class 1 corticosteroids, which correlates with
8 a high incidence and severity of systemic side effects,
9 including hypothalamic-pituitary-adrenal HPA axis suppression,
10 topical treatment with superpotent corticosteroids is
11 generally limited in duration to two weeks.

12 But we also know, and the POSA would have known, that
13 chronic skin conditions like psoriasis that carry on through a
14 whole lifetime for a lot of patients, treatment for this would
15 be longer than two weeks. And we see that underlined below.
16 We read: Require long periods of treatment, greater than two
17 weeks.

18 They themselves say: It would be desirable to have a
19 superpotent corticosteroid formulation with a reduced
20 incidence and/or severity of systemic side effects so that
21 therapy could be continued for durations longer than two
22 weeks.

23 Q. Dr. Michniak-Kohn, you heard Dr. Stern's testimony
24 earlier today and on Tuesday.

25 Is that correct?

1 A. I did.

2 Q. And did Dr. Stern's opinions inform your analysis of the
3 halobetasol patents?

4 A. Yes, they did. And, in fact, we both agreed on the fact
5 that psoriasis is chronic; that it needs treatment for longer
6 than two weeks; and that there's a problem with adverse side
7 effects with a corticosteroid such as halobetasol of
8 0.05 percent, as we found in Ultravate®, and that there was a
9 motivation to decrease the dose to solve those problems.

10 Q. And, Dr. Michniak-Kohn, you mentioned a need to decrease
11 the dose.

12 Would a skilled formulator have known how to achieve
13 an effective lower dose formulation of halobetasol?

14 A. Absolutely.

15 THE WITNESS: If I can have the next slide.

16 So the POSA would have known, as we mentioned, that
17 one of the approaches to solve problems with a particular dose
18 or concentration of a drug is to decrease that concentration.
19 It's common sense, but it's also, obviously, part of POSA's
20 skill to know that that would be more than likely effective.

21 Now, yes, there is criticism, and I'm sure I will
22 have it at cross, about what the problems could be with the
23 lowering of the concentration, if any. But it's an obvious
24 thing to do because a formulator has skills. And they know
25 that they can make formulations that decrease concentrations

1 of corticosteroids or other drugs, but they have a lot of
2 other knowledge as well.

3 They know how to formulate, and that is what is known
4 as the art of formulation that's unique to formulators, which
5 is a bit of chemistry, pharmacology, and the clinical aspects
6 of pharmaceuticals. They know that they can optimize the level
7 of drug saturation in the vehicle, for example. They can also
8 improve the dissolution of the active ingredient in the
9 formulation. In other words, they can dissolve and look at
10 other vehicles to dissolve at a certain concentration, whether
11 it be lower or higher, actually, in a vehicle and have the
12 drug release.

13 And they can even realize that if they go too low in
14 their formulation of the drug that there are compounds that
15 allow the formulator to control the amount of drug that will
16 go into the skin. And those are known as chemical, sometimes
17 shortened to, penetration enhancers. And those are used in
18 formulations.

19 In fact, the vehicle in the case right now is one of
20 them. So it has an action of both a vehicle and a chemical
21 penetration enhancer.

22 So what are these chemical penetration enhancers?
23 These are compounds that we add to formulations that can act
24 as a vehicle for a drug and that affect the top-most layer of
25 the skin. Our top-most layer is, in fact, a dead layer, but

1 it is a pretty important one. It's extremely thin, and it
2 contains fatty substances called lipids, proteins, and water.

3 And when chemical penetration enhancers go out of the
4 formulation into that top layer of the skin, what they do is
5 that they are known to fluidize the lipids. And I'll try to
6 put this in more simple terms.

7 The lipids are organized in the skin. The
8 penetration enhancers come in there, and they basically open
9 up the lipids, and they allow more of the drug to pass through
10 this topmost layer of the skin called the stratum corneum.

11 Just to summarize, the penetration enhancers working
12 on the topmost layer of the skin allow the formulator to
13 control how much drug enters the skin layers below the stratum
14 corneum. I can spell it for you later.

15 So it gives the formulator control of how much drug
16 goes in. And we'll return a little bit to penetration
17 enhancers in a few slides.

18 So knowing all of this and having this armament of
19 information, formulators can control how much drug will go
20 into the skin layers and how much will go across the skin.

21 BY MS. PITZEL CRUZ:

22 Q. And, Dr. Michniak-Kohn, earlier you mentioned the '566
23 patent.

24 MS. PITZEL CRUZ: Can we turn to DX-004, please.

25 BY MS. PITZEL CRUZ:

1 Q. Do you recognize this document, Dr. Michniak-Kohn?

2 A. Yes, I do.

3 This is the '566 patent, and its date is July 5,
4 1994.

5 Q. And what, if anything, would the '566 patent have
6 disclosed to a person of skill in the art?

7 THE WITNESS: If I can have the next slide.

8 So the '566 patent, as I mentioned, issued in 1994,
9 so it is prior art.

10 And it teaches that by optimizing the vehicle of a
11 topical formulation to increase absorption, drug concentration
12 could be reduced without a significant, if any, reduction in
13 potency.

14 And we'll see in the '566 patent at Column 4:37 to
15 49, and Column 8:20, and 17:56 in DX-004.

16 BY MS. PITZEL CRUZ:

17 Q. And, Dr. Michniak-Kohn, what else would the '566 patent
18 have disclosed to one of skill in the art?

19 THE WITNESS: If we could have the next slide,
20 please.

21 So on the left-hand side we see the excerpt from the
22 '566 patent, DX-004, at Column 3, Lines 20 to 25.

23 It teaches that the use of dibutyl adipate or dibutyl
24 adipate and isopropyl myristate against specific agents in
25 that class of solvents that we've been discussing can enhance

1 as well as control the epidermal, dermal, and transdermal
2 penetration of various topically applied pharmacological
3 agents. And that is the '566 patent, 3, Lines 20 to 25.

4 And, of course, dibutyl adipate that it mentions is a
5 dicarboxylic acid ester, that overall class of solvents that
6 we just discussed.

7 And just to explain the kind of new terminology that
8 has come upon this slide, we see reference to epidermal,
9 dermal, and transdermal penetration. And I had already
10 mentioned the stratum corneum, the topmost layer on the skin.

11 So we have a diagram, a kind of rudimentary figure,
12 of our skin.

13 You see at the top the stratum corneum. It's meant
14 to be the very thinnest top layer, where the penetration
15 enhancers are working.

16 Below it is the living epidermis. As opposed, by the
17 way, to the stratum corneum that are just dead skin layers.

18 We then see this wavy pink sinus wave, which is the
19 epidermal-dermal junction.

20 And below it we see the thicker dermis and below it
21 the fat layer. And both the dermis, of course, and the fatty
22 layer support our skin's -- portions of our skin on our body
23 and give it the mechanical strength.

24 So we now, hopefully, understand what the term in the
25 '566 patent means when it talks about epidermal, epidermal

1 layer; dermal, the dermal layer. And "transdermal
2 penetration" means transdermal, across the skin.

3 MS. PITZEL CRUZ: And if we could look at --

4 BY MS. PITZEL CRUZ:

5 Q. Does the '566 patent disclose anything else you found
6 relevant to your analysis?

7 A. Yes, it does.

8 So, first of all, the POSA would have noticed in the
9 '566 patent that there are numerous examples of formulations,
10 most of which, if not all, include halobetasol propionate as
11 the active ingredient. The '566 patent at Column 8, 19 and
12 14-58.

13 It teaches the POSA that topical corticosteroid
14 formulations are oil-in-water emulsions.

15 It teaches that corticosteroids dissolved in a liquid
16 oil phase containing dibutyl adipate or dibutyl adipate and
17 isopropyl myristate are useful.

18 It teaches that the dibutyl adipate or the
19 combination of that and the isopropyl myristate solvent system
20 should solubilize the active ingredient, in other words,
21 dissolve the active ingredient, the steroid.

22 And that it is preferred that no more than 50 percent
23 more than the amount of solvent required for complete the
24 dissolution be used.

25 It also teaches the advantages of preparing the

1 disclosed formulations without petrolatum.

2 And I quote: Petrolatum-based ointments are greasy.

3 And I think if we've ever used Vaseline, we know that
4 that's pretty nasty, to say the least. It's very greasy.

5 And in certain instances, it may be desirable to have
6 cosmetically elegant (less greasy) topical products (such as
7 creams, lotions, gels and solutions).

8 That's the '566 at Column 11:23 to 27.

9 Q. And, Dr. Michniak-Kohn, earlier you also mentioned the
10 JP '228 reference.

11 MS. PITZEL CRUZ: Could we pull up DX-005?

12 BY MS. PITZEL CRUZ:

13 Q. And do you recognize this document, Dr. Michniak-Kohn?

14 A. Yes, I do.

15 This is the Japanese publication that I gave the
16 abbreviation to JP '228. And the publication date is
17 October 21, 1988.

18 Q. And can you tell us what JP '228 would have informed one
19 of skill in the art?

20 THE WITNESS: If I can have the next slide, please.

21 So we've established already what the publication
22 date was, October 21, 1988. Obviously, it's prior art.

23 It teaches topical preparations where the steroid is
24 dissolved in the oil phase by one or more solvents. And it
25 mentions diisopropyl adipate, diethyl sebacate, and triacetin.

1 That's JP '228, Page 2, Example 3, that uses diethyl sebacate.

2 And, by the way, to the left on the slide are the
3 appropriate references to what I'm highlighting.

4 It also teaches the use of light mineral oil, which,
5 if we look across -- it's not underlined. I apologize.

6 But you will see a mention of higher paraffin
7 hydrocarbon -- that's not mineral oil -- in the oil phase.
8 And that's JP '228 at pages 2 to 4.

9 And it teaches also oil-in-water cream emulsions
10 where the steroid is dissolved nearly to saturation in the
11 oil, otherwise known as the discontinuous phase. And that's
12 JP '228 at Page 3.

13 BY MS. PITZEL CRUZ:

14 Q. Does the JP '228 reference disclose any additional
15 information for one of skill in the art?

16 A. Yes, it does.

17 THE WITNESS: Next slide, please.

18 It also provides the person of ordinary skill in the
19 art some information on something that we've already come
20 across, and that's the vasoconstrictor assay testing.

21 Just to review that, we see on the right-hand side
22 that they mention, obviously, that it's an assessment method
23 that looks at the extent of blanching of the skin that causes
24 blood vessels basically to constrict and causes the whitening.

25 And that whitening is given a score that we see

1 below, from nothing to intense blanching or whitening of the
2 skin.

3 And what we find that the quote below that's
4 underlined in red, that the present invention exhibits
5 extremely good vasoconstrictor act/action, has a good drug
6 release behavior and transdermal absorption, and hence has a
7 significant pharmacological effect.

8 Of course, the POSA reads the term "transdermal"
9 here, so let's -- let's just pause and consider that.

10 Again, there's various definitions. Some people use
11 transdermal that it crosses the stratum corneum, which was
12 that top layer of the skin. Some people talk about
13 transdermal absorption, when you're using a nicotine patch,
14 where the nicotine is not meant to be in skin but just go
15 across the skin and get absorbed into the circulation.

16 And, obviously, these authors used this term
17 "transdermal." But, of course, a POSA would realize
18 immediately they're not talking about systemic absorption.
19 They're doing the VCA testing. They're looking at the skin
20 layers and delivering to the skin layers.

21 And we've already established that the VCA assay is
22 used for corticosteroids to determine as a surrogate whether
23 the corticosteroid is being absorbed into the skin layers.

24 THE COURT: We have to take a five-minute break.
25 Thank you.

1 THE COURTROOM DEPUTY: All rise.

2 (Recess taken from 11:34 a.m. to 11:42 a.m.)

3 THE COURT: Sorry about that, folks. A little
4 domestic emergency.

5 All right. Let's proceed.

6 THE WITNESS: And I hopefully won't fall off this
7 chair.

8 I'm ready.

9 BY MS. PITZEL CRUZ:

10 Q. Dr. Michniak-Kohn, would a person of skill in the art
11 have a reason to combine or modify the '295 patent and '566
12 patent, and JP '228 that we've been discussing?

13 A. Yes, they would.

14 THE WITNESS: If I can have the next slide.

15 So here we see the person of ordinary skill would
16 have been motivated to combine the teachings of the '566 and
17 the '295 in combination with Blum; and, secondly, the '295
18 patent that we discussed and JP '228 publication in
19 combination with Blum.

20 And the reasons being that the '566, the '295, and
21 JP '228 publication are all directed to improving release
22 and/or penetration of corticosteroids from topical
23 formulations.

24 All three achieve this goal by completely dissolving
25 the steroid in a liquid oil phase containing a dicarboxylic

1 acid ester.

2 And, of course, the POSA knows that you have to
3 dissolve the steroid. In fact, any drug needs to be dissolved
4 to pass through a membrane like skin.

5 So that's the basic fundamental knowledge that they
6 would also know.

7 And one of skill would have further understood that
8 these teachings were applicable to halobetasol given the
9 knowledge in the art and examples that we have in the '566
10 patent.

11 BY MS. PITZEL CRUZ:

12 Q. And, Dr. Michniak-Kohn, did you prepare any charts that
13 describe the combinations of prior art as compared to the
14 asserted claims?

15 A. Yes, I did.

16 And I apologize. I know I've done this before. I
17 will be reading these claim charts, so please bear with me.

18 We will start with Claim 13 of the '307 patent and
19 the fact that it would have been obvious over the prior art.

20 I've arranged all of these charts in a similar
21 pattern. We will see the claim on the left-hand side and
22 claim limitations. And on the right-hand side, we'll see the
23 rationale for the obviousness.

24 We're starting with Claim 13, which has four claim
25 limitations that are listed on the left.

1 I'll start with limitation Number 1: A
2 pharmaceutical composition for topical application to the skin
3 of an individual comprising halobetasol propionate at a
4 concentration of 0.04 percent or less.

5 On the right-hand side, we see that a POSA would have
6 been motivated to use halobetasol propionate -- abbreviated
7 here to HP -- topical formulations with halobetasol of
8 0.04 percent or less. As we saw from Blum, '295, '566 and
9 JP '228. And Blum disclosed effective 0.02 percent
10 halobetasol formulations.

11 Claim 13 claim limitation Number 2: A liquid oil
12 component comprising one or more dicarboxylic acid esters,
13 wherein the dicarboxylic acid esters are selected from diethyl
14 sebacate, diisopropyl adipate and dibutyl sebacate and wherein
15 at least 25 percent of the halobetasol propionate is
16 solubilized in the liquid oil component at 22° degrees
17 Centigrade.

18 A POSA would have been motivated to use a liquid oil
19 component comprising one or more dicarboxylic acid esters, as
20 we've already discussed from the '295, '566, and JP '228.

21 The '295, the '566, and JP '228 all disclose
22 dicarboxylic acid esters -- we remember that's the main class
23 of all of the solvents we've discussed -- to dissolve and
24 deliver corticosteroids.

25 Claim 13 claim limitation Number 3 reads: The

1 halobetasol propionate is at a concentration of 0.025 percent
2 or less.

3 A POSA would have been motivated to use halobetasol
4 topical formulations with halobetasol at 0.025 or less in
5 Blum, '295, '566, and JP '228. And we already read that Blum
6 discloses 0.02 percent halobetasol formulations.

7 The final claim limitation is Number 4: The liquid
8 oil component comprises diethyl sebacate and wherein at least
9 50 percent of the halobetasol propionate is solubilized in the
10 liquid oil component at room temperature.

11 The POSA would have been motivated to use liquid oil
12 component comprising diethyl sebacate. The '295, '566, and
13 JP '228.

14 The POSA would have been motivated to solubilize at
15 least 50 percent of the halobetasol in the liquid oil
16 component at room temperature. The '295, the '566, and
17 JP '228.

18 THE WITNESS: If I can have the next slide, please.

19 This slide looks at Claim 16 of the '307 patent. And
20 again, the claim limitations are listed on the left-hand side
21 going from 1 to 4.

22 Claim Number 1, a pharmaceutical composition for
23 topical application to the skin of an individual comprising
24 halobetasol propionate at a concentration of 0.04 or less, we
25 have already addressed for Claim 13 of the 307.

1 Limitation Number 2, a liquid oil component
2 comprising one or more dicarboxylic acid esters wherein the
3 dicarboxylic acid esters are selected from diethyl sebacate,
4 diisopropyl adipate and dibutyl sebacate, and wherein at least
5 25 percent of the halobetasol propionate is solubilized in the
6 liquid oil component at 22° degrees Centigrade, we have again
7 addressed for Claim 13 of the '307 patent.

8 Limitation Number 3: The concentration of the liquid
9 oil component is sufficient to dissolve the amount of
10 halobetasol propionate in the composition at a temperature of
11 22 plus or minus 2 degrees Centigrade.

12 The POSA would have been motivated to use a
13 concentration of the liquid oil component sufficient to
14 dissolve the halobetasol propionate. '295, '566 and JP '228.

15 The '295, '566 and JP '228 all teach dialkyl
16 sebacate, sebacates such as diethyl sebacate and dibutyl
17 sebacate, as a liquid oil phase that completely dissolves the
18 corticosteroid at room temperature.

19 And, finally on this chart, claim limitation Number
20 4: A method for treating a disorder of the skin that is
21 amenable to treatment with a topical corticosteroid comprising
22 providing a pharmaceutical composition of Claim 4 and applying
23 an amount to the skin that's effective in ameliorating the
24 signs or symptoms of the disorder.

25 It's obvious to use the composition of Claim 4 to

1 treat psoriasis from Blum, '295, '566 and JP '228.

2 And Blum discloses effective 0.02 percent halobetasol
3 propionate formulations.

4 If I can have the next slide, please.

5 We now move on to Claim 20 of the '307 patent. And
6 we see the claim limitations, again, are listed on the left
7 and the obvious rationale on the right.

8 We start with claim limitation Number 1: A
9 pharmaceutical composition for topical application to the skin
10 of an individual comprising halobetasol propionate at a
11 concentration of 0.04 percent or less.

12 We have addressed this for Claim 13 of the '307
13 patent.

14 Limitation Number 2: A liquid oil component
15 comprising one or more dicarboxylic acid esters, wherein the
16 dicarboxylic acid esters are selected from diethyl sebacate,
17 diisopropyl adipate and dibutyl sebacate and wherein at least
18 25 percent of the halobetasol propionate is solubilized in the
19 liquid oil component at 22° degrees Centigrade.

20 That was also addressed previously for Claim 13 of
21 the '307.

22 Limitation Number 3: Wherein the liquid oil
23 component further comprises light mineral oil.

24 It's obvious to add light mineral oil to a liquid oil
25 component. Use was well-known prior to 2010.

1 DX-201, it's the *Handbook of Pharmaceutical*
2 *Excipients* at 11 and 12. And we'll be looking at that in a
3 minute.

4 And also JP '228 discloses the use of a liquid oil
5 component that includes both diethyl sebacate and light
6 mineral oil.

7 And the final claim limitation, Number 4: Wherein
8 the liquid oil component comprises diethyl sebacate and light
9 mineral oil.

10 It's obvious to use diethyl sebacate in liquid oil
11 component for reasons explained for Claim 13 of the '307.

12 It's obvious to add light mineral oil to liquid oil
13 component comprising diethyl sebacate. Use was well-known
14 prior to 2010. The '295, '566 and JP '228.

15 And the JP '228 Publication discloses the use of a
16 liquid oil component that includes both diethyl sebacate and
17 light mineral oil.

18 BY MS. PITZEL CRUZ:

19 Q. And, Dr. Michniak-Kohn, you mentioned the *Handbook of*
20 *Pharmaceutical Excipients*.

21 MS. PITZEL CRUZ: Can we pull up DX-201, please.

22 BY MS. PITZEL CRUZ:

23 Q. Can you describe what this document is,
24 Dr. Michniak-Kohn?

25 A. Yes. This is a copy of the front of the *Handbook of*

1 *Pharmaceutical Excipients*, Sixth Edition. It's a commonly
2 used textbook on most bookshelves or E-shelves, as the case
3 may be these days, of the formulators.

4 MS. PITZEL CRUZ: And if we could turn to Page 3 of
5 DX-201.

6 BY MS. PITZEL CRUZ:

7 Q. When was this edition published?

8 A. This sixth edition, we see, was published in 2009.

9 MS. PITZEL CRUZ: And if we could turn to Pages 11
10 and 12 of DX-201.

11 BY MS. PITZEL CRUZ:

12 Q. Can you describe what information is provided here?

13 A. This is the monograph for light mineral oil in that
14 handbook.

15 MS. PITZEL CRUZ: And if we could look at the lower
16 -- or the upper corner of 448, Section 7.

17 BY MS. PITZEL CRUZ:

18 Q. Can you describe what this portion of the *Handbook of*
19 *Pharmaceutical Excipients* entry describes?

20 A. So we see in the upper portion, I guess it's the second
21 sentence, it's used primarily as an excipient in topical
22 pharmaceutical formulation. It's a well-known emollient.

23 And we see in the Table 1, at the bottom, some
24 recommended concentrations, even, for topical emulsions -- of
25 course, of interest in this case -- topical lotions as well as

1 topical ointments.

2 Q. And, Dr. Michniak-Kohn did you also address Claim 4 of
3 the '502 patent?

4 A. Yes, I did.

5 THE WITNESS: If I can have the next slide.

6 And here is Claim 4. And again, the claim
7 limitations are, again, four. And the obvious rationale on
8 the right-hand side.

9 We'll start off with the claim limitation Number 1:
10 A pharmaceutical composition for topical application to the
11 skin of an individual comprising: a liquid oil component
12 comprising diethyl sebacate and a corticosteroid selected from
13 the group consisting of halobetasol propionate, clobetasol
14 propionate, betamethasone dipropionate, diflorasone diacetate,
15 and fluocinonide at a concentration less than 0.05 percent.

16 And a POSA would have been motivated to use
17 halobetasol topical formulations with halobetasol less than
18 0.05. Blum, '295, '566 and JP '228. And Blum, of course,
19 discloses the 0.02 halobetasol propionate formulations.

20 And the POSA would have been motivated to use liquid
21 oil component comprising one or more dicarboxylic acid esters.
22 Again, that's in the '295, '566 and JP '228.

23 And the '295, '566 and JP '228 all disclose
24 dicarboxylic acid esters to dissolve and deliver
25 corticosteroids.

1 Claim limitation Number 2: an aqueous component
2 comprising water.

3 We know that the '295, '566 and JP '228 all teach
4 compositions comprising a liquid oil component as well as an
5 aqueous component.

6 Claim limitation Number 3: Wherein the composition
7 is free of white petrolatum.

8 It's obvious to exclude white petrolatum, and we
9 discussed that, because it's greasy and undesirable, and it's
10 certainly not liked by patients.

11 The '295 patent discloses examples free of white
12 petrolatum.

13 The '566 teaches the advantages of excluding white
14 petrolatum.

15 And JP '228, in fact, doesn't teach at all the use of
16 white petrolatum.

17 Claim limitation Number 4: wherein the
18 corticosteroid is halobetasol propionate and the concentration
19 of the halobetasol propionate is 0.01 or less.

20 The POSA would have been motivated to use halobetasol
21 topical formulations with halobetasol propionate at
22 0.01 percent from Blum.

23 And the JP '228 Publication and JP '228 steroid is
24 present in a range from 0.01 to 0.5. This is DTX-005 at 1,
25 Claim 1, pages 2 to 4.

1 BY MS. PITZEL CRUZ:

2 Q. Dr. Michniak-Kohn, can you describe any conclusions that
3 you made regarding the asserted claims of the halobetasol
4 patents?

5 THE WITNESS: Can I have the next slide, please?

6 So this is high-level conclusions now that one
7 skilled in the art would have been motivated to combine with a
8 reasonable expectation of success:

9 Number 1, Blum and the '295 patent.

10 Secondly, Blum and the '295 and '566 patents.

11 And, Number 3, Blum and the '295 and JP '228.

12 In conclusion, the Claims 13, 16 and 20 of the '307
13 patent, and Claim 4 of the '502 would have been obvious to one
14 of skill in the art over the combination of, firstly, Blum and
15 the '295; secondly, Blum, the '295 and the '566 patents; Blum,
16 the '295 and JP '228 Publication.

17 BY MS. PITZEL CRUZ:

18 Q. And did you also address Claim 16 of the '502 patent?

19 A. I did. And here we have a chart for Claim 16 of the
20 '502.

21 And, again, we see the claim limitations on the
22 left-hand side. There are two of them this time.

23 And I read claim limitation Number 1. It is: A
24 method of treating a disorder of the skin that's amenable to
25 treatment with a topical corticosteroid, the method comprising

1 applying the pharmaceutical composition of Claim 1 to the skin
2 of an individual having the disorder in an amount that's
3 effective in ameliorating the signs and symptoms of the
4 disorder.

5 We can see '502 patent Claim 4 analysis above.

6 And we know that Blum discloses a method of treating
7 psoriasis at a concentration of 0.02, less than 0.05 percent,
8 for 21 days that was effective in treating the signs and
9 symptoms of psoriasis.

10 And we also know that the Temovate® Label teaches the
11 use of a corticosteroid for the treatment of psoriasis for
12 four weeks.

13 Claim limitation Number 2 of Claim 16 of the '502, we
14 read: wherein the method comprises applying the
15 pharmaceutical composition over a period of treatment longer
16 than two weeks.

17 We see '502 patent Claim 16, 1, analysis above.

18 Q. And, Dr. Michniak-Kohn, you mentioned the Temovate®
19 Label. Can we -- what does the Temovate® Label disclose with
20 respect to duration of treatment?

21 A. If we can bring up the Temovate® Label.

22 Thank you.

23 So here we see the Temovate® product information.
24 Temovate E® is a clobetasol propionate emollient cream at a
25 concentration of 0.05 percent.

1 MS. PITZEL CRUZ: And if we could turn to the next
2 slide. I believe it's Slide 39.

3 THE WITNESS: So here are the highlights from the
4 Temovate® Label.

5 First of all, it's from July of 2000, which makes it
6 prior art.

7 It teaches, as I've already mentioned, this topical
8 emollient cream formulation that has clobetasol propionate at
9 0.05 percent. It's DX-006.

10 And the disclosed formulations can be used for up to
11 four consecutive weeks when the application is limited to less
12 than 10 percent of the body surface area.

13 And we read: In the treatment of moderate to severe
14 plaque-type psoriasis, Temovate E® emollient applied to
15 5 percent to 10 percent of body surface area can be used up to
16 four consecutive weeks. The total dosage should not exceed
17 50 grams per week.

18 That's DX-006 at 1, Indications and Usage.

19 And also in a controlled clinical trial involving
20 patients with moderate to severe plaque-type psoriasis,
21 Temovate E® emollient applied to 5 percent to 10 percent of
22 body surface area resulted in additional benefits in the
23 treatment of patients for four consecutive weeks.

24 That's DX-006 at 1 in the Precautions section.

25 BY MS. PITZEL CRUZ:

1 Q. Dr. Michniak-Kohn, did you consider any secondary
2 considerations of non-obviousness?

3 A. I certainly considered them and found none. In fact,
4 none of the secondary considerations that Bausch has raised
5 overcome the strong case of obviousness of the asserted claims
6 of the halobetasol patents. There were no unexpected results.
7 Formulating an effective lower dose halobetasol was expected.

8 And I reserve the right to rebut anything Bausch may
9 raise in response to my opinions.

10 Q. And, Dr. Michniak-Kohn, I'm actually just turning back to
11 Claim 16 of the '502 patent.

12 MS. PITZEL CRUZ: If we could turn to Slide 41.

13 BY MS. PITZEL CRUZ:

14 Q. Can you describe to us your conclusions regarding
15 Claim 16 of the '502 patent as they relate to the prior art?

16 A. Yes, I can.

17 We see on the second half of the slide that Claim 16
18 of the '502 patent would have been obvious to one of skill in
19 the art over the combination of number one, Blum and the '295
20 patent; secondly, Blum and the '295 and '566 patents; Blum,
21 the '295 and the Temovate® Label.

22 Q. Dr. Michniak-Kohn, did you consider any other invalidity
23 bases regarding the halobetasol patents?

24 A. Yes, I did.

25 So again, I relied on my legal counsel for the legal

1 standards. And I quote here that the patent claim must
2 particularly point out and distinctly claim subject matter of
3 the invention.

4 The claim is indefinite if the claim language fails
5 to inform the POSA of the bounds of the invention with
6 reasonable certainty.

7 And thirdly, a claim is indefinite if a POSA would
8 understand the claim language to have multiple meanings or no
9 informed and confident choices available among those meanings.

10 Q. Dr. Michniak-Kohn, can you describe your indefiniteness
11 analysis with respect to the halobetasol patents?

12 A. Yes, I can. And we'll start off first looking at
13 construction of claim terms.

14 The liquid oil component that's mentioned in the '307
15 patent and the '502, the Court's construction, which is
16 actually identical to the '307 language in Column 4, the
17 liquid oil component includes "all ingredients of the
18 formulation that are practically insoluble or insoluble in
19 water and which are liquid at room temperature of 22° degrees
20 C." That is the Court's construction which I used and a
21 person of ordinary skill in the art would use for the
22 analysis.

23 And we will see that the term, this particular term,
24 the liquid oil component, is indefinite. And I'll present why
25 that is the case.

1 THE WITNESS: If I can have the next slide, please.

2 So what do the '307 and '502 patents say about this
3 term "liquid oil component" and "light mineral oil" in the
4 patent itself?

5 And we look first at the '307 patent at Column 4,
6 Lines 17 to 34, and we read, underlined in red, "The liquid
7 oil component may contain additional components, such as
8 hydrocarbons, like mineral oil, light mineral oil," et cetera.

9 And down below, we see Claim 19 from the '307 patent.
10 And I read: The pharmaceutical composition of Claim 1,
11 wherein the liquid oil component further comprises light
12 mineral oil.

13 BY MS. PITZEL CRUZ:

14 Q. Are there any other portions of the specification that
15 address the liquid oil component?

16 A. Yes, there were.

17 Now, the liquid oil component, we have to still bear
18 that in mind from the other two slides with the claim
19 construction and now we move further in with more detail. And
20 we see there's going to be a mention of an emulsifier called
21 sorbitan monooleate.

22 So let's have a look at the quote that comes first
23 from the '502 patent.

24 Claim 8, it reads: The pharmaceutical composition of
25 Claim 1, wherein the liquid oil component further comprises an

1 emulsifying agent.

2 And then we see from the '307 patent in the middle,
3 from Column 6, Lines 40 to 51, that such emulsifying agents,
4 otherwise known as emulsifiers, include, among others,
5 sorbitan monooleate.

6 Now, what is sorbitan monooleate? Well, a person of
7 ordinary skill in the art already knows about emulsifiers,
8 knows that sorbitan monooleate is an example, but we can also
9 check the textbook that we've already mentioned, DX-201,
10 *Handbook of Pharmaceutical Excipients*, at 676, that tells us
11 that sorbitan monooleate is liquid at room temperature of 22°
12 degrees Centigrade and is practically insoluble or insoluble
13 in water.

14 Thus, conclusion is that sorbitan monooleate falls
15 within the scope of the term "liquid oil component."

16 Let's, perhaps, turn to the *Handbook of*
17 *Pharmaceutical Excipients* and have a look whether we can get
18 any more information.

19 MS. PITZEL CRUZ: If we can pull up DX-201, please,
20 at 15.

21 THE WITNESS: So we, first of all, see under this
22 monograph -- and the monograph actually gives the class under
23 which sorbitan monooleate fits -- Table 5 mentions:
24 Appearance of selected sorbitan esters.

25 And we look down and we see the fact that this is --

1 sorbitan monooleate is the third one down, and we see that its
2 appearance is a yellow viscous liquid.

3 So we confirm what we had suspected, that it is a
4 liquid.

5 Let's move on to the next portion.

6 MS. PITZEL CRUZ: I think if we look at the lower
7 right-hand corner of the document.

8 THE WITNESS: So under the section "Typical
9 Properties," we see right at the bottom some information about
10 solubility. And it says that: Sorbitan esters are generally
11 soluble or dispersible in oils; they are also soluble in most
12 organic solvents. And in water, although insoluble, they are
13 generally dispersible.

14 So that confirms the information that I had, I guess,
15 in the previous slide.

16 BY MS. PITZEL CRUZ:

17 Q. And were there any other portions of the '307
18 specification that discuss the liquid oil component?

19 A. Yes, there were.

20 THE WITNESS: If I could have the next slide, please.

21 So what we see is Table 1 and Table 2.

22 So Table 1 is the '307 patent, Column 9, 26 to 51.
23 And Table 2 is the '307 patent at 10, Lines 11 to 22.

24 So the person of ordinary skill in the art sees in
25 Table 1 the various formulations that were prepared, the

1 concentration of the steroid being at 0.035, but they're
2 interested more in the vehicle that this steroid is dissolved
3 in.

4 And we see highlighted on the left the diethyl
5 sebacate and the isopropyl myristate. We see light mineral
6 oil and sorbitol monooleate that we just learned is oily,
7 should be part of the liquid oil component.

8 They read on and go to Table 2 of the '307 patent,
9 and here the formulations are again listed, the same ones as
10 in Table 1, A to D. And a calculation was being made for the
11 concentration of liquid oil component as a percentage weight
12 and weight. And we see four numbers there.

13 And the POSA says, well, where did these numbers come
14 from? How did they calculate this? And, in fact, the
15 explanation is in the box below, that the way this was
16 calculated was that only the diethyl sebacate for each
17 formulation, diethyl sebacate for Formulation A and light
18 mineral oil was added from the formulation in Table 1 to get
19 the 4.0 percent. And that was repeated for the rest of the
20 formulations.

21 But the POSA says, well, I know that sorbitan
22 monooleate is part of the liquid oil component as well. So
23 these numbers don't quite make sense. It looks as though that
24 was missed out.

25 So there's a little bit of confusion here as to what

1 the '307 patent teaches because the numbers should have been
2 different there in Table 2 if the sorbitan monooleate had been
3 included or any other component that belonged to this class of
4 emulsifiers.

5 BY MS. PITZEL CRUZ:

6 Q. And did you include any other information or consider any
7 other information with respect to your indefiniteness
8 analysis?

9 THE WITNESS: If I can have the next slide.

10 This is Dr. Lane's declaration from the opening claim
11 construction at Paragraph 60. And highlighted in yellow we
12 read, Table 2, which by the way is the one from the last
13 slide, expressly excludes sorbitan monooleate from the
14 calculation.

15 And she concludes that a POSA would not be able to
16 reconcile Perrigo's proposed construction of the term liquid
17 oil component with the specification and claims of the
18 Bryhali® patents. Bryhali® patents being the '307 and the
19 '502.

20 So it seems as though Dr. Lane basically agrees with
21 the POSA, that there's a discrepancy, an inconsistency within
22 the patent information that's given.

23 BY MS. PITZEL CRUZ:

24 Q. Dr. Michniak-Kohn, what conclusions did you reach from
25 your indefiniteness analysis?

1 A. The slide is already up.

2 Sorbitan monooleate falls within the liquid oil
3 component as construed.

4 Table 2 excludes sorbitol monooleate from the liquid
5 oil component section term. Because of this inconsistency,
6 the person of ordinary skill in the art cannot tell you with
7 reasonable certainty what the scope of that term "liquid oil
8 component" would be, making that term indefinite.

9 Q. Dr. Michniak-Kohn I'd like to switch gears now and talk
10 about the combination patents or, as plaintiffs have called
11 them, the Duobrii® patents?

12 MS. PITZEL CRUZ: Can we pull up JTX-002, please?

13 BY MS. PITZEL CRUZ:

14 Q. Do you recognize this document, Dr. Michniak-Kohn?

15 A. Yes, I do. This is the '895 patent, dated April 9, 2019.

16 MS. PITZEL CRUZ: If we can pull up JTX-003, please.

17 BY MS. PITZEL CRUZ:

18 Q. What is this document, Dr. Michniak-Kohn?

19 A. This is the '787 patent, dated October 1, 2019.

20 Q. Dr. Michniak-Kohn, can you describe generally what's
21 disclosed in the combination patents?

22 THE WITNESS: Yes, if I can have the next slide,
23 please.

24 So we see the two patents up here, the '895 and the
25 '787. And we see also that the provision application was

1 filed on June 18, 2015, making it prior art.

2 Combination of -- on the right-hand side, sorry --
3 combination of 0.01 percent halobetasol and 0.045 tazarotene
4 are disclosed for the treatment of psoriasis.

5 Claims contain formulation limitations as well as
6 claims of synergy.

7 Opinion as to the formulation limitations.

8 And the patents refer to the combination product as
9 IDP-118.

10 And I need to correct myself. We're talking about
11 the '787 patent, not prior art. Excuse me.

12 BY MS. PITZEL CRUZ:

13 Q. And just to clarify another point that you mentioned,
14 Dr. Michniak-Kohn, with respect to your opinion on the '895
15 and '787 patents, can you explain what opinion you were asked
16 to provide with respect to the claim limitations?

17 A. Excuse me, I couldn't hear the last portion, sorry.

18 Q. Just to clarify, what were you asked to look at with
19 respect to the claim limitations of the combination patents?

20 THE WITNESS: If I can have the next slide, please.

21 So, again, this is high level summary of the asserted
22 claims of these two patents.

23 We start with the '895 patent, Claims 3 and 6.

24 Those mention halobetasol propionate at 0.01 percent
25 and tazarotene at 0.045 percent.

1 They mention a dermatologically acceptable carrier
2 comprising an oil-in-water emulsion that is a lotion; a liquid
3 oil component of diethyl sebacate and light mineral oil.

4 They also mention carbomer homopolymer type A and
5 carbomer copolymer type B and some synergy limitations.

6 The '787 patent, Claims 4, 5 and 7 mention, again,
7 halobetasol propionate 0.01 percent and tazarotene at 0.045
8 dissolved in a component of the liquid oil of the oil-in-water
9 emulsion; a liquid oil comprising diethyl sebacate and light
10 mineral oil; an aqueous dermatologically acceptable carrier
11 comprising carbomer homopolymer type A and carbomer copolymer
12 type B.

13 It mentioned some synergy limitations and a method of
14 treating that provides relief after eight weeks of treatment.

15 MS. PITZEL CRUZ: If we look at the next slide.

16 BY MS. PITZEL CRUZ:

17 Q. Can you describe which claims are the asserted claims of
18 the '895 patent?

19 A. So here we have the '895 patent and the asserted claims
20 are 3 and 6. And again, as in my previous slides of this
21 presentation, I have underlined the highlights that I just
22 went over here with red.

23 MS. PITZEL CRUZ: If we could turn to the next slide.

24 BY MS. PITZEL CRUZ:

25 Q. Can you describe the asserted claims of the '787 patent?

1 A. And, again, for the '787, the asserted claims are
2 Claims 4, 5 and 7. And in the same way, I've underlined the
3 highlights in red on this slide that I've just gone over a
4 couple slides ago.

5 Q. And, Dr. Michniak-Kohn, how did you assess the
6 obviousness for the asserted claims of the combination
7 patents?

8 A. Again, a person of ordinary skill in the art, the same as
9 for the halobetasol patents in the relevant time period now of
10 June 2015 or before.

11 Q. And were there any claim constructions that you applied
12 in your analysis of the asserted claims of the combination
13 patents?

14 A. There was.

15 THE WITNESS: If I can have the next slide.

16 So the claim term, and we see on the left-hand side,
17 reads: Wherein the liquid oil component consists of diethyl
18 sebacate and light mineral oil. That's in the '895 patent.

19 And the agreed to construction on the right: The
20 parties agree that "consists of" renders "liquid oil
21 component" a closed claim element that excludes additional,
22 unrecited components, such that "consists of diethyl sebacate
23 and light mineral oil" means "includes only diethyl sebacate
24 and light mineral oil."

25 BY MS. PITZEL CRUZ:

1 Q. Did you review any prior art relevant to the formulation
2 limitations of the combinations patents?

3 A. Yes, I did.

4 MS. PITZEL CRUZ: If we could pull up DX-142, please.

5 BY MS. PITZEL CRUZ:

6 Q. Dr. Michniak-Kohn, do you recognize DX-142?

7 A. Yes, I do. It is the '824 patent, publication date
8 May 12th -- sorry, May 24, 2012.

9 Q. Can you tell us what the '824 publication, please?

10 THE WITNESS: If I could have the next slide, please.

11 So this '824 Publication is the publication of the
12 '307 patent. It was published May 24, 2012, as we just saw,
13 making it prior art.

14 BY MS. PITZEL CRUZ:

15 Q. Dr. Michniak-Kohn, can you provide us with some
16 information regarding what the '824 Publication discloses to
17 one of skill in the art?

18 THE WITNESS: If I could have the next slide, please.

19 So we see Paragraphs 12 on the left hand and
20 Paragraph 16 from the '824 Publication on the right-hand side.

21 And these teach a corticosteroid in a formulation
22 with a liquid oil component that includes a dicarboxylic acid
23 ester. And that, in fact, is in and underlined in red in
24 Paragraph 12.

25 It also teaches that the liquid oil component

1 dissolves the corticosteroid. And that's Paragraph 16 on the
2 right-hand side. Again, the relevant portion is underlined in
3 red.

4 BY MS. PITZEL CRUZ:

5 Q. Is there any additional information in the '824
6 Publication relevant to one of skill in the art?

7 A. Yes, there is.

8 The slides are arranged the same way. We have
9 Paragraph 14 on the left and 22 and 26 on the right.

10 It teaches the addition of light mineral oil and the
11 liquid oil component. And that's mentioned in Paragraphs 14
12 and 26, again, highlighted in red.

13 And teaches that the composition may be a lotion,
14 including an oil-in-water emulsion. That's in Paragraph 22,
15 and we see the relevant portions underlined.

16 Q. Is there any other additional information in the '824
17 Publication that's relevant to one of skill in the art?

18 THE WITNESS: If I can have the next slide, please.

19 And so what we see here in the '824, and we recognize
20 some of this, we see in the middle Table 1 of certain
21 formulations that were prepared from -- labelled A to D, with
22 the halobetasol propionate.

23 We have various concentrations listed there that are
24 in the red box. And we see point 0.035, 0.025, 0.01, and D
25 had a variant, again, with the same concentration of 0.035.

1 We also see at Table 3 with the same Formulations A
2 to D. We've seen this before, by the way, with the
3 vasoconstrictor assay scores. Then we see in the middle the
4 halobetasol concentrations that I've just gone through.

5 And we also see in Paragraph 40, highlighted in red,
6 that: Formulations A to D of the present invention provide a
7 VCA score similar to that of the prior art formulation
8 Ultravate®, that we've already discussed in the presentation.

9 This high level of VCA score, which is indicative of
10 the local desired response of the corticosteroid, was obtained
11 even though the level of the corticosteroid in the
12 formulations of the inventions are markedly lower than that of
13 the prior art formulations.

14 Of course going to the middle, we confirm that. And
15 that all of these are much lower than the 0.05 percent
16 Ultravate®, and it includes the 0.035, 0.025 and the
17 0.01 percentages of halobetasol.

18 BY MS. PITZEL CRUZ:

19 Q. Is there any other information in the '824 Publication
20 relevant to one of skill in the art?

21 A. Yes, there is. There's a Table 4 in the '824
22 Publication, and it looks at lotion formulations.

23 We see Paragraphs 41, 42, 43 and 45 from the '824.
24 And on the left-hand side, we see Table 4 for two
25 formulations, Formula 4A and 4B.

1 This was particularly interesting to the person of
2 ordinary skill in the art because not only was the
3 concentration lower than 0.05 percent, it was 0.01 and 0.025,
4 but we also have a way of making or compounding or
5 manufacturing this particular lotion formulation.

6 And we read in the paragraphs on the right-hand side,
7 as I mentioned in Paragraph 41, "lotion formulations," which
8 is underlined -- there's a color code here, as lotion
9 formulations in green.

10 We go on to Paragraph 42, and we start reading about
11 an "aqueous phase" and "purified water." And I particularly
12 chose blue to emphasize and underline the aqueous phase or the
13 hydrophilic watery phase, which is portion of the emulsion
14 that the lotion is going to be made of.

15 We read further that with continuous propeller
16 agitation Carbopol 981 and Pemulen TR-1 are added. So we are
17 still in the aqueous phase.

18 And if we look across on Table 4, the aqueous
19 phase -- and I'll follow the color selection there by sticking
20 to the blue for the aqueous -- we see the box of all the
21 excipients in that formulation that belong to the aqueous
22 phase.

23 We also see the reference to this Carbopol 981 and
24 Pemulen TR-1. These are basically brand names for the
25 carbomers. And the POSA knows that TR-1 is actually carbomer

1 copolymer type B and Carbopol at 981, carbomer homopolymer
2 type A.

3 We read on, on Paragraph 43, that the POSA sees a
4 mention of an "oil phase." We're given that oil phase and
5 things to do with it red underlining and a red box in the
6 formula.

7 So that oil phase has diethyl sebacate and the
8 halobetasol propionate are combined. Again, not surprising,
9 we've mentioned that halobetasol propionate is a
10 corticosteroid. It has to dissolve in an oily component.
11 That's already been established.

12 And the mixture is agitated until a solution is
13 achieved. Then to this mixture, light mineral oil and
14 sorbitan monooleate are also added, and we've discussed both
15 of those. And they belong in the oily or lipophilic class.

16 And then mixing is continued until a solution is
17 obtained.

18 If we move to Table 4 we see a red box and we see
19 those three excipients in there, as well as the drug,
20 belonging to the oily phase of the lotion emulsion.

21 And in Paragraph 45, underlined in green, we see that
22 the final product or the final formulation after this
23 procedure is followed, a homogeneous, which means uniformly
24 disbursed, emulsion is obtained.

25 Q. Dr. Michniak-Kohn, did you form any conclusions regarding

1 the asserted claims of the combination patents in light of the
2 '824 Publication?

3 A. Yes, I did. And here is the summary.

4 So first of all, let's just summarize what is in '895
5 patent and the '787 to makes things easier. We know that we
6 need the solubilization of halobetasol propionate and the
7 tazarotene in the liquid oil component.

8 The '895 patent, Claim 2, reads: Wherein the
9 halobetasol propionate and the tazarotene are dissolved in the
10 liquid oil component of the emulsion.

11 In the '787, Claim 4, the asserted claim, a method of
12 Claim 3, wherein the said halobetasol propionate and the said
13 tazarotene are dissolved in a component of said liquid oil of
14 the oil-in-water emulsion.

15 The POSA would know, of course, that incorporating
16 tazarotene into, for example, the formulation that we
17 discussed, 4A, would have been routine optimization. And the
18 reason is it's routine to assess the solubility of actives in
19 vehicles.

20 It's actually relatively easy to do. You know the
21 drug's physical chemical properties. You know how highly or
22 less highly lipophilic it is and which vehicles are likely to
23 completely dissolve that particular drug or active.

24 So solubility takes not too long. And I will briefly
25 describe it to you.

1 You take your drug, you dissolve it in a series of
2 vehicles in small test tubes that are put in a heat block that
3 are kept at a certain temperature. You oversaturate, in other
4 words, you put excess into the vehicle. You then filter it
5 off. You only keep it for 48 hours for typical solubility
6 data.

7 You then clean it up from excess solid, and you then
8 inject it into an equipment that's called an HPLC, a
9 chromatograph, that measures what amounts you have of the drug
10 there that's dissolved.

11 And of course, the POSA also knows that they have to
12 dissolve the drug. That's the crucial thing for the drug to
13 penetrate skin or any other membrane in the body.

14 They also know that they have a combination here of
15 tazarotene and halobetasol. And again, it's routine. If
16 you're mixing drugs, even if you're mixing excipients, that
17 you would test and be on the lookout for any interactions.

18 There's certainly nothing in the literature that says
19 you cannot mix a steroid and a retinoid together, that, you
20 know, anything would explode or major problems.

21 So that would involve just routine optimization in
22 the lab.

23 So a POSA would have had a reasonable expectation
24 that tazarotene could be dissolved in a liquid oil portion of
25 a formulation like 4A given tazarotene's physical chemical

1 properties and the known solubility in lipophilic vehicles.

2 Another example is provided in DX-203, which is the
3 '716 patent at Example 1, which we'll have a look at right
4 now.

5 Q. Dr. Michniak-Kohn, do you recognize DX-203?

6 A. Yes, this is what I just mentioned, the '716 patent, and
7 it's dated August 19, 2014.

8 Q. Can you tell us what the '716 patent?

9 THE WITNESS: Yes, if I can have the next slide.

10 Yes, as we mentioned this issued August 19, 2014, so
11 it's prior art. And if we look at Example 1, it is covering,
12 from the title, a method of preparing an emulsion -- foam
13 formulation but an emulsion, same principles -- of tazarotene.

14 And we see underlined under Phase 2, the active
15 phase, it says: Tazarotene dissolved in diisopropyl adipate.

16 And then we follow down to the red underlined Number
17 1: Dissolve tazarotene in diisopropyl adipate in a suitable
18 stainless steel container at ambient temperature.

19 Here is information already for the POSA that you can
20 dissolve tazarotene in the similar vehicles that we've been
21 discussing this morning and that it will dissolve.

22 BY MS. PITZEL CRUZ:

23 Q. Dr. Michniak-Kohn, did you review any documents from
24 plaintiffs relevant to the use of 0.045 percent tazarotene?

25 A. Yes, I did.

1 THE WITNESS: If I can have the next slide.

2 So here is information from some meeting background
3 materials for an Investigational New Drug. There was a
4 meeting with the FDA over IDP-118, which is the halobetasol
5 propionate and tazarotene lotion at 0.01 percent and
6 0.045 percent for the tazarotene.

7 And we read, in yellow highlight, the concentration
8 of tazarotene in IDP-118 Lotion is similar to or lower than
9 the reference Tazorac® cream that has 0.045 -- well, it's not
10 -- Tazorac® cream is 0.05, but, of course, the lotion was
11 0.045 percent versus the 0.05 percent of the Tazorac® cream
12 and 0.1, respectively.

13 This concentration offers the potential for efficacy
14 in the treatment of psoriasis similar to that of Tazorac®
15 cream, 0.05 percent.

16 BY MS. PITZEL CRUZ:

17 Q. Dr. Michniak-Kohn, did you form any conclusion regarding
18 the asserted claims of the combination patents?

19 A. Yes, I did. And, in fact, all formulation limitations of
20 the asserted Claims 3 and 6 are obvious over the '824
21 Publication.

22 And again, what we see on the left-hand side is
23 Claim 1, Claim 2 and the asserted Claim 3 and Claim 5, but I
24 was asked to look at, specifically, the formulation
25 limitations of these claims. And to make things easier for

1 everyone, they're highlighted in red.

2 And I read, for Claim 1, Limitation B: A
3 dermatologically acceptable carrier; wherein the composition
4 is an oil-in-water emulsion; wherein an oil phase in the
5 oil-in-water emulsion comprises a liquid oil component;
6 wherein the liquid oil component is liquid at 22° degrees
7 Centigrade and consists of diethyl sebacate and light mineral
8 oil.

9 In the '824 Publication, see, for example, Table 4,
10 Example 4, Paragraphs 41 to 44.

11 Claim 2, we read: Wherein the halobetasol propionate
12 and the tazarotene are dissolved in the liquid oil component
13 of the emulsion.

14 And in the '824, we see, for example, 4, Paragraph 43
15 for halobetasol, and then routine experimentation in light of
16 the known physical chemical properties and solubility of
17 tazarotene.

18 Claim 3 is the asserted claim. Wherein the emulsion
19 is a lotion. That was addressed for Claim 1.

20 And for Claim 5, Wherein an aqueous phase of the
21 emulsion comprise a carbomer copolymer type B and a carbomer
22 homopolymer type A. That was addressed for Claim 1.

23 Q. Dr. Michniak-Kohn, did you form any conclusions regarding
24 the asserted claims of the '895 patent Claim 6?

25 A. Yes, I did. And this is the '895 patent, asserted

1 Claims 3 and 6.

2 And of course, all formulation limitations disclosed
3 and are obvious over the '824.

4 What we read here in Claim 6, that's the asserted
5 claim, and, again, for ease of reference underlined in red,
6 and I read: Wherein the diethyl sebacate is present at a
7 concentration of 2.5 to 3.5 percent by weight of the
8 composition, the light mineral oil is present at a
9 concentration of 7.5 to 8.5 percent by weight of the
10 composition, the carbomer copolymer type B is present at a
11 concentration of 0.3 to 0.5 percent by weight of the
12 composition, and the carbomer homopolymer type A is present at
13 a concentration of 0.5 to 0.7 percent by weight of the
14 composition.

15 And what I did with all of this information is I put
16 it in tabular form, which we see below. You see Claim 6,
17 percentage by weight of composition. We have those values and
18 the ranges put in for each of the drug and the tazarotene and
19 the other excipients.

20 And then what I did in the far end portion of this, I
21 put formulation 4A from the '824 Publication and compared the
22 values there to those of Claim 6.

23 So we see for halobetasol propionate, formulation 4A
24 happens to be 0.01 percent. That's exactly what is mentioned
25 in Claim 6.

1 Tazarotene, of course, in Claim 6 is 0.045, and
2 that's very close, by the way, as we established, to the
3 already existing and marketed formulation Tazorac® which is at
4 0.05. It's slightly less -- when we would have added, as a
5 person of ordinary skill in the art or the team that's there,
6 would have added the tazarotene, we would have probably looked
7 at various concentrations of the tazarotene, and routine
8 optimization would have included something as similar to the
9 original tazarotene concentration as 0.045.

10 We see with the diethyl sebacate that in formulation
11 4A we have 2.97 percent. It is within the range for Claim 6.

12 We now look at light mineral oil. It's listed as
13 8.03 in formulation 4A which again is within the range that's
14 mentioned in Claim 6.

15 The carbomer copolymer type B that's a portion of the
16 aqueous phase of the emulsion, in formulation 4A is at
17 0.40 percent, which, again, is within the range claimed by
18 Claim 6.

19 And, finally, the carbomer homopolymer type A, again,
20 portion of the aqueous phase of the emulsion of the
21 formulation, the formulation 4A lists it as 0.60 and, again,
22 that's within the range for Claim 6.

23 Q. And did you form any conclusions regarding the asserted
24 claims of the '787 patent?

25 A. Yes, I did. And I stuck to the same kind of presentation

1 mode.

2 Now, for the '787, the asserted of Claims 4, 5 and 7,
3 and I, again, was involved with the formulation limitations,
4 and I disclosed them bolded in red.

5 So for Claim 1, we see a pharmaceutical composition
6 wherein the composition comprised an aqueous
7 dermatologically-acceptable carrier comprising carbomer
8 copolymer type B, carbomer homopolymer type A and a liquid oil
9 comprising diethyl sebacate and light mineral oil.

10 So we see in the '824 Publication, for example, the
11 example 4, Table 4 we discussed, paragraphs 41 to 44.

12 There's also a Claim 2.

13 Claim 3 has a formulation portion, and I read:
14 Composition is an oil in water emulsion. That was addressed
15 for Claim 1.

16 The asserted Claim 4: Wherein said halobetasol
17 propionate and said tazarotene are dissolved in a component of
18 said liquid oil of the oil-in-water emulsion, that was also
19 addressed for Claim 1.

20 Claim 5 it's asserted: Wherein said emulsion is a
21 lotion, that was also addressed for Claim 1.

22 And then Claim 7 asserted did not have any
23 formulation limitations.

24 Q. And, Dr. Michniak-Kohn, did you consider any secondary
25 considerations of nonobviousness in your analysis of the

1 asserted claims of the combination patents?

2 A. I did, and there were no secondary considerations. None
3 of the secondary considerations that Bausch has raised
4 overcome the strong case of obviousness of the asserted claims
5 of the combination patents.

6 And I reserve the right to rebut anything Bausch may
7 raise in response to my opinions.

8 Q. And can you summarize your conclusions with respect to
9 the combination patents?

10 A. Yes, I can.

11 So this is the conclusion for the combination
12 patents.

13 One of skill in the art would have been motivated to
14 combine tazarotene with the teachings of the '824 Publication
15 and would have a reasonable expectation of success in
16 achieving an effective formulation.

17 The formulation limitations of the combination
18 patents would have been obvious to one skilled in the art
19 prior to 2015 in view of the '824 Publication.

20 MS. PITZEL CRUZ: And, Your Honor, I just would like
21 to note for the record that several of the exhibits that we
22 mentioned today were actually admitted into evidence by
23 stipulation and order. That was Document 207, and I was asked
24 to include these in the transcript.

25 That they are DX-002, DX-003, DX-004, DX-005, DX-006,

1 DX-009, DX-010, DX-140, DX-141 and DX-142.

2 (Exhibit Number DX-002 is received in evidence.)

3 (Exhibit Number DX-003 is received in evidence.)

4 (Exhibit Number DX-004 is received in evidence.)

5 (Exhibit Number DX-005 is received in evidence.)

6 (Exhibit Number DX-006 is received in evidence.)

7 (Exhibit Number DX-009 is received in evidence.)

8 (Exhibit Number DX-010 is received in evidence.)

9 (Exhibit Number DX-140 is received in evidence.)

10 (Exhibit Number DX-141 is received in evidence.)

11 (Exhibit Number DX-142 is received in evidence.)

12 THE COURT: They are all admitted into evidence.

13 MS. PITZEL CRUZ: Thank you, Your Honor.

14 And with that, I would pass the witness.

15 THE COURT: Thank you.

16 MR. STEINDLER: It's quarter to 1:00 one. Shall we
17 take a lunch break?

18 THE COURT: We'll break for lunch. Okay? Everybody
19 have a great lunch. I'm sure you'll all be working through
20 lunch.

21 THE COURTROOM DEPUTY: All rise.

22 (Lunch recess taken at 12:47 p.m.)

23 AFTERNOON SESSION

24 (In open court at 2:03 p.m.)

25 (Parties present.)

1 THE COURT: Ready to proceed.

2 MR. STEINDLER: Thank you, Your Honor.

3 CROSS-EXAMINATION

4 BY MR. STEINDLER:

5 Q. Good afternoon. I'm Thomas Steindler. I'm here to ask
6 you a few questions.

7 A. Good afternoon.

8 Q. Now, you're a formulator, right?

9 A. Yes, I am.

10 Q. And you agree that formulations play an enormous role in
11 the delivery of any drug, right?

12 A. That would be a correct statement, yes.

13 Q. In fact, it's your view that the formulation makes all
14 the difference in the delivery of a drug, right?

15 A. Well, certainly the active is important, the drug, but
16 the formulation is important in its delivery, yes.

17 MR. STEINDLER: Can we just pull up some
18 deposition --

19 BY MR. STEINDLER:

20 Q. You recall you were deposed in this case, right?

21 A. Of course.

22 MR. STEINDLER: And let me play some tape and see
23 whether you agree with the answer that you gave.

24 At 107, Lines 12 to 22.

25 (Video played.)

1 "QUESTION: And different types of formulations may
2 have different potencies.

3 "ANSWER: Well, it would depend, again, on the
4 steroids, because some steroids are much more potent from
5 their chemical structure than others. But, again, the
6 formulation makes all the difference in the delivery of the
7 drug."

8 (Video stopped.)

9 MR. STEINDLER: Thank you.

10 BY MR. STEINDLER:

11 Q. You agree the formulation makes all the difference in the
12 delivery of the drug, correct?

13 A. Yes. I just said that, yes.

14 Q. Now, and that's true of the topical formulations we're
15 talking about in this case.

16 Isn't that correct?

17 A. That is correct.

18 Q. As of 2010, a POSA would have known how important a
19 formulation is for a topical corticosteroid product, correct?

20 A. Correct.

21 Q. And at the time, and today, there was an extensive
22 literature available to a POSA describing ingredients in
23 different formulations that could be used in topical products,
24 correct?

25 A. There is a literature available, yes. Of course.

1 Q. But, in fact, there is extensive literature available to
2 a POSA describing ingredients and different formulations that
3 could be used in topical corticosteroids.

4 Isn't that true?

5 A. Correct.

6 Q. All right. Now, I think you've described this as a whole
7 world of combinations a POSA would have known about and was
8 able to select from in developing a formulation, correct?

9 A. Could you repeat the question?

10 Q. So you've described this as a whole world of combinations
11 that a POSA would have known about and was able to select from
12 in developing a formulation, correct?

13 A. Well, the formulator would know at some stage what
14 they're trying to prepare. So that narrows down the wealth of
15 literature on topical formulations down to a certain focus.

16 MR. STEINDLER: Can we go back to -- play the
17 deposition transcript at lines -- strike that.

18 Go back and play the deposition transcript at
19 Page 54, Lines 17 through 55, Line 6, please.

20 (Video played.)

21 "QUESTION: Do you agree that there were no
22 formulations of superpotent corticosteroids treating psoriasis
23 marketed before 2010 that were lotions?

24 "ANSWER: Again, if we're narrowing it down to just
25 marketed, I believe that's correct. But, again, the POSA

1 knows how important a formulation is, so that is only one of
2 the considerations that they would give when they think of
3 formulations. There's a whole world of combinations that are
4 available that the POSA obviously knows about and is able to
5 select from and also will consider, obviously, what is
6 marketed."

7 (Video stopped.)

8 MS. PITZEL CRUZ: Your Honor, I would just like to
9 object that that was improper impeachment. The question that
10 was asked was not --

11 THE COURT: I'm sorry. Say that again, please.

12 MS. PITZEL CRUZ: I would just like to object as
13 improper impeachment. It didn't appear that the question that
14 was asked matched what was in the transcription.

15 And I would also like to note, the witness doesn't
16 have a copy of her transcript to review.

17 MR. STEINDLER: Why don't we just move on. Maybe
18 that would be the best thing.

19 BY MR. STEINDLER:

20 Q. A POSA would have to consider a number of different
21 interactions when developing formulations for a topical
22 product, correct?

23 A. Could you define what you mean by "interactions"?

24 Q. Well, a POSA would have to consider interactions between
25 the vehicle and the active, right?

1 A. Correct.

2 Q. The POSA would have to consider interactions between the
3 vehicle and the skin, correct?

4 A. Yes.

5 Q. The POSA would have to consider interactions between the
6 active and the skin, correct?

7 A. I think you would have to define what you mean by
8 "interactions."

9 Q. Well, let's move on.

10 When formulating a topical fixed-dose combination
11 product, you have to consider drug-to-drug interactions,
12 right?

13 A. When formulating, is that your question?

14 Q. Let me repeat it.

15 When formulating a topical fixed-dose combination
16 product, you have to consider drug-to-drug interactions,
17 correct?

18 A. Correct.

19 Q. You also have to look at the chemistry of both agents to
20 see how they interact, right?

21 A. Correct, and depending on the drug --

22 Q. That's all I need. Thank you.

23 Now, you agree that the potency of a corticosteroid's
24 formulation is influenced by numerous factors, right?

25 A. "Numerous" is a relative term. I don't know what I would

1 be agreeing or disagreeing to, unfortunately. It's too
2 general.

3 MR. STEINDLER: All right. Can you please pull up
4 the deposition transcript at Page 95 -- excuse me, at Page 98,
5 lines 5 to 8.

6 (Video played.)

7 "QUESTION: Do you agree that a corticosteroid
8 formulation's potency is influenced by numerous factors?

9 "ANSWER: Yes, it is.

10 (Video stopped.)

11 BY MR. STEINDLER:

12 Q. That is the exact question verbatim that I just asked
13 you, right? And the answer is yes.

14 Wouldn't you agree?

15 A. Yes, that there are numerous considerations, yes. I
16 don't know what context that particular question was in,
17 though.

18 Q. So one of the factors that would affect the potency of a
19 corticosteroid formulation is the concentration of the active
20 ingredient, right?

21 A. Yes, it would be.

22 Q. Another is the type of formulation, right?

23 A. Correct.

24 Q. Another is the specific ingredients used in the vehicle,
25 correct?

1 A. Correct.

2 Q. And another is the concentration of the ingredients used
3 in the vehicle, correct?

4 A. Correct.

5 Q. So I'd like to now turn to what you contend is a POSA's
6 motivation to select the particular combinations of
7 ingredients in the Bryhali® patents. Okay?

8 Are you with me?

9 A. Okay.

10 Q. Let's take them one by one first.

11 MR. STEINDLER: I'd like to start with the selection
12 of halobetasol, and I'd like to put up your DDX-3.33.

13 BY MR. STEINDLER:

14 Q. Now, you say a POSA would have been motivated to use HP
15 topical formulations with HP at 0.4 percent or less based on
16 Blum, the '295 patent, the '566 patent, and JP '228, right?

17 A. Correct.

18 MR. STEINDLER: Now, let's turn to your
19 Slide DX-3.36.

20 BY MR. STEINDLER:

21 Q. And for Claim 4 of the '502 patent, you say a POSA would
22 have been motivated to use HP -- topical formulations with HP
23 with less than 0.05 percent citing those same four references,
24 right?

25 A. Correct.

1 MR. STEINDLER: Let's turn to Exhibit JTX-001, which
2 is the '307 patent.

3 And if you could go to Table 1, Column 1 and blow
4 that up, please.

5 BY MR. STEINDLER:

6 Q. You see that there are five Class 1 superpotent
7 corticosteroids that are listed in the table, right?

8 A. I see that.

9 Q. One of them is clobetasol 0.05 percent, correct?

10 A. Correct.

11 Q. And as I believe we've established here, that was sold
12 commercially under the brand name Temovate®, correct?

13 A. Correct.

14 Q. Temovate® was sold at 0.05 percent concentration, right?

15 A. Correct.

16 Q. And it was indicated for the treatment of psoriasis as of
17 2010, correct?

18 A. Correct.

19 Q. Halobetasol 0.05 is also on the list, right?

20 A. Correct.

21 Q. And as we know, halobetasol 0.05 percent was under the
22 brand name Ultravate®, correct?

23 A. Correct.

24 Q. And it was also being used for the treatment of psoriasis
25 prior to 2010, right?

1 A. Yes, it was.

2 Q. Now, it's your opinion that a POSA would have been
3 motivated to pick one of the commercially available
4 corticosteroids to work with, right?

5 A. Well, Ultravate® was being used and that was a
6 halobetasol propionate formulation at 0.05 already on the
7 market with issues.

8 Q. So -- but Temovate® was also available and on the market,
9 correct?

10 A. Yes, it was.

11 Q. And there is no specific reason for a POSA to have picked
12 halobetasol rather than clobetasol, correct?

13 A. Well, they would have known that corticosteroids in
14 general have a problem, and one of the marketed products
15 happens to be halobetasol.

16 Q. Let me try my question again.

17 There was no specific reason for a POSA to have
18 picked halobetasol rather than clobetasol, correct?

19 A. It's possible that another POSA would have taken the
20 other drug for the same reason.

21 THE COURT: Doctor, please answer the question as
22 asked.

23 THE WITNESS: Okay.

24 Could you repeat the question?

25 BY MR. STEINDLER:

1 Q. Sure.

2 There was no specific reason for a POSA to have
3 picked halobetasol rather than clobetasol, correct?

4 A. They could have picked either.

5 MR. STEINDLER: Let's turn to diethyl sebacate, and
6 I'd like to pull up your Slide DX-3.36.

7 BY MR. STEINDLER:

8 Q. Now, Claim 4 of the '502 patent requires diethyl
9 sebacate, right?

10 A. Correct.

11 Q. And you say in your chart here that a POSA would have
12 been motivated to use liquid oil component comprising one or
13 more dicarboxylic acid esters. And you cite to '295 patent,
14 '566 patent, and JP '228, correct?

15 A. Correct.

16 Q. And you go on to state that '295 patent, the '566 patent,
17 and JP '228 all disclose dicarboxylic acid esters to dissolve
18 and deliver corticosteroids, right?

19 A. Correct.

20 Q. But for clarity, the claim isn't directed to a liquid oil
21 component comprising one or more dicarboxylic acid esters.

22 Isn't that correct?

23 A. When it comprises of one of these class of compounds.

24 Q. So, again, for clarity, the claim isn't directed to a
25 liquid oil component comprising one or more dicarboxylic acid

1 esters, as you write in your Slide DX-3.36, correct?

2 A. Correct, in that it --

3 Q. That's all I need. Thank you very much.

4 Now, in fact, it specifically requires diethyl
5 sebacate, correct?

6 A. Correct.

7 Q. Now, as of 2010, there were no commercial formulations
8 for corticosteroids for treating psoriasis that contained
9 diethyl sebacate, correct?

10 A. I believe that's correct.

11 Q. So your obviousness analysis still requires a POSA to
12 select diethyl sebacate from among the class of dicarboxylic
13 acid esters to arrive at this claim, right?

14 A. Correct. They have the prior art.

15 Q. Right.

16 Now, you say a POSA would have chosen diethyl
17 sebacate as a solvent because it is oily or oleaginous, right?

18 A. Correct.

19 Q. But there were other oily or oleaginous solvents that
20 were potential candidates for a POSA to choose from as of
21 2010, correct?

22 A. There were.

23 Q. And, in fact, you don't know how many oily solvents
24 existed before 2010 that a POSA could have chosen from, right?

25 A. They could have, but they would have gone to the

1 literature to look.

2 THE COURT: Doctor, the question was: You don't know
3 how many there were.

4 Is that correct?

5 THE WITNESS: Yes, that is correct.

6 THE COURT: Good. Please listen to the question,
7 answer the question.

8 THE WITNESS: Yes, Your Honor.

9 BY MR. STEINDLER:

10 Q. Now, if a POSA had identified diethyl sebacate as one of
11 the solvents to test, there's nothing in the prior art that
12 would have established that diethyl sebacate would have been
13 the one that they'd have picked, right?

14 A. I disagree.

15 Q. All right. There's no evidence in the prior art that
16 shows that diethyl sebacate is better at dissolving
17 halobetasol than any other of the oleaginous solvents, right?

18 A. I disagree.

19 I have a reason, but...

20 Q. There's no experimental evidence in the prior art that
21 shows that diethyl sebacate is better at dissolving
22 halobetasol than any of the other oleaginous solvents,
23 correct?

24 A. Experimental evidence? Are you saying data?

25 Q. Do you want me to repeat my question?

1 A. Please.

2 Q. There is no experimental evidence in the prior art that
3 shows diethyl sebacate is better at dissolving halobetasol
4 than any of the other oleaginous solvents, correct?

5 A. Correct.

6 Q. And you don't offer any data to support the contention
7 that a POSA would have picked diethyl sebacate rather than a
8 different oleaginous solvent.

9 Isn't that true?

10 A. I don't provide any data, but publications --

11 Q. I just want you to answer my question, please.

12 You don't provide any data to support the contention
13 that a POSA would have picked diethyl sebacate rather than a
14 different oleaginous solvent, correct?

15 A. I disagree.

16 Q. Now, in fact, we know that Ultravate®, the prior art
17 halobetasol product, doesn't use diethyl sebacate, right?

18 A. That's correct.

19 Q. Now, you would assume that when Bristol-Myers Squibb
20 developed Ultravate®, they went through the process of trying
21 to pick the best solvent for halobetasol, correct?

22 A. Of the ones they tested, yes.

23 Q. And they didn't pick diethyl sebacate, right?

24 A. No, they did not.

25 Q. But diethyl sebacate was already out there in the art as

1 a potential oleaginous solvent at the time BMS was developing
2 Ultravate®, correct?

3 A. Correct.

4 Q. So what actually happened in the real world teaches us
5 that a formulation team working on a halobetasol product would
6 not have selected diethyl sebacate as a solvent, correct?

7 A. I disagree.

8 Q. And you disagree with that despite the fact that the
9 development team at BMS that developed Ultravate® did not pick
10 diethyl sebacate as a solvent, correct?

11 A. I still disagree, yes.

12 Q. All right.

13 MR. STEINDLER: Let's talk about light mineral oil
14 and turn to DX-3.35.

15 BY MR. STEINDLER:

16 Q. Now, you see at the bottom that Claim 20 of the '307
17 patent requires light mineral oil in the formulation, correct?

18 A. Correct.

19 Q. Now, you say it would have been obvious to add light
20 mineral oil to the liquid oil component because it was a
21 well-known excipient, and you cite the handbook of
22 pharmaceutical excipients, right?

23 A. Correct.

24 Q. I've actually brought a copy of the *Handbook of*
25 *Pharmaceutical Excipients*.

1 You're familiar with this, correct?

2 A. Very.

3 Q. There are thousands of excipients that are disclosed in
4 this handbook.

5 Isn't that true?

6 A. Yes, but they are very different from each other.

7 Q. Now, just to be clear, you didn't cite the *Handbook of*
8 *Pharmaceutical Excipients* as one of the references in your
9 obviousness combinations, right?

10 A. Correct.

11 Q. Now, you also say that JP '228 discloses use of a liquid
12 oil component that includes light mineral oil, right?

13 A. Correct.

14 Q. And you further cite to that same proposition to the '295
15 point, the '566 patent, and JP '228, right?

16 A. Correct.

17 Q. Now, you're aware that, again, the Ultravate® product,
18 the commercial halobetasol product, does not have light
19 mineral oil, right?

20 A. That is correct.

21 Q. So, again, the team at BMS that developed Ultravate® was
22 not motivated to include light mineral oil in their
23 halobetasol formulation, right.

24 A. No, they decided on another formulation.

25 Q. And, in fact, light mineral oil was not in any of the

1 other commercially available topical products for treatment of
2 psoriasis as of 2010.

3 Isn't that correct?

4 A. I believe that's correct.

5 Q. So, again -- strike that.

6 Temovate® is the commercial clobetasol product.

7 Correct?

8 A. That is correct.

9 Q. It does not have light mineral oil, correct?

10 A. I believe it does not.

11 Q. So again, the real world teaches us that formulators
12 would not have been motivated to include light mineral oil in
13 a halobetasol formulation.

14 Isn't that correct?

15 A. That is not correct.

16 I disagree.

17 Q. But, in fact, nobody did it for more than 20 years.

18 Isn't that correct?

19 A. For more than 20 years nobody in the industry happened to
20 have done it, but...

21 Q. I don't need any further explanation. Thank you. You've
22 answered my question.

23 MR. STEINDLER: Let's turn to petrolatum to your
24 DDX-3.36.

25 BY MR. STEINDLER:

1 Q. Claim 4 of the '502 patent requires the composition is
2 free of white petrolatum, right?

3 A. Correct.

4 Q. And you say it would have been obvious to exclude white
5 petrolatum because it's greasy and undesirable, right?

6 A. That is correct.

7 Q. And you say that the '295 patent discloses examples free
8 of white petrolatum, the '566 patent teaches advantages of
9 excluding white petrolatum, and JP '228 does not teach the use
10 of white petrolatum, correct?

11 A. Correct.

12 Q. But there is white petrolatum in the Ultravate® ointment.

13 Isn't that true?

14 A. That is correct. It's an old formulation.

15 Q. So again, what happened in the real world is different
16 from what you're saying in court here today, right?

17 A. I disagree.

18 MR. STEINDLER: Now let's turn to the combinations
19 that you assert in DDX-3.17.

20 BY MR. STEINDLER:

21 Q. So for the Bryhali® patents, you contend the asserted
22 claims would have been obvious based on four combinations of,
23 in total, five prior art references, right?

24 A. Correct.

25 Q. And those references are the '295 patent, Blum, JP '228,

1 the '566 patent, and the Temovate® Label, correct?

2 A. Correct.

3 MR. STEINDLER: If you turn now to your

4 Slide DDX-3.25.

5 BY MR. STEINDLER:

6 Q. In your first bullet, you say there was a motivation to
7 formulate a lower concentration of halobetasol to minimize the
8 risk of known adverse events while still maintaining efficacy,
9 right?

10 A. Correct.

11 Q. And that risk of adverse events was known well before
12 Ultravate® came out, right?

13 A. Correct.

14 Q. Ultravate® was approved in 1990, as we've said, right?

15 A. Correct.

16 Q. And it came out at a 0.05 percent concentration, not a
17 lower concentration, right?

18 A. When it came out as 0.05.

19 MR. STEINDLER: So let's go back to DDX-3.17.

20 BY MR. STEINDLER:

21 Q. Now, you cite these five references that you say would
22 have rendered the invention obvious to a POSA as of 2010. And
23 by "the invention" here, I'm referring to the Bryhali®
24 patents, right?

25 A. Correct.

1 Q. And just so the record is clear, the '295 patent issued
2 in 1990, right?

3 A. I believe so.

4 Q. Blum was published in 1986, right?

5 A. I believe so.

6 Q. The '566 patent issued in 1994, correct?

7 A. Correct.

8 Q. JP '228 published in 1988, correct?

9 A. I believe so.

10 Q. The Temovate® Label that we are working with here was
11 from 2000, right?

12 A. That is correct.

13 Q. I'm being advised that I may have misspoken.

14 For clarity, the '295 patent issued in 1980, correct?

15 A. Well, I had also forgotten exactly and assumed you were
16 correct.

17 So I agree.

18 Q. Right. Just so the record is clear, the '295 patent
19 issued in 1980, correct?

20 A. Correct.

21 Q. Now, you're aware that Temovate E® was actually approved
22 by the FDA in 1996, right?

23 A. I believe so.

24 Q. So the '295 patent is 1980, Blum is 1986, JP '228 is
25 1988, the '566 patent is 1994, and the Temovate E® Label is

1 1996, right?

2 A. Correct.

3 Q. And you contend that the Bryhali® patents would have been
4 obvious to a POSA in 2010 based on these references, correct?

5 A. Correct.

6 Q. But you agree that nobody ever made this invention during
7 all those years until Bausch did it in 2010, right?

8 A. Well, that's what happened in industry.

9 Q. All right. Well, let's take each of these references in
10 turn.

11 MR. STEINDLER: Start with the '295 patent.

12 Turn to DDX-3.21.

13 BY MR. STEINDLER:

14 Q. Now, in your direct you presented a series on slides of
15 the '295 patent, right?

16 A. Correct.

17 Q. I'd like to look at it in a little more detail at this
18 patent.

19 Now, at the bottom of your slide you reference that
20 the '295 patent is DX-003, correct?

21 A. Correct.

22 MR. STEINDLER: So let's go to DX-003, please.

23 BY MR. STEINDLER:

24 Q. And if you could just repeat, the issue date here is
25 November 11, 1980, right?

1 A. Correct.

2 Q. And that's 30 years before the priority date of the
3 Bryhali® patents, right?

4 A. Correct.

5 MR. STEINDLER: Let's go to Column 1, Lines 5 to 10,
6 please.

7 BY MR. STEINDLER:

8 Q. It states: The present invention relates to
9 pharmaceutical formulations which include a dialkyl sebacate,
10 such as dibutyl sebacate or diisopropyl sebacate as a vehicle
11 for the pharmaceutical, right?

12 A. That's what it says.

13 Q. So the '295 patent discloses a class of compounds called
14 "dialkyl sebacates" to use in formulations with
15 corticosteroids, right?

16 A. Correct.

17 Q. And the patent doesn't limit the utility of its invention
18 to superpotent steroids, right?

19 A. That's correct.

20 Q. The '295 patent does not specifically disclose
21 halobetasol, correct?

22 A. It doesn't.

23 Q. And it certainly doesn't disclose halobetasol at a
24 concentration of less than 0.05 percent, correct?

25 A. Correct.

1 MR. STEINDLER: Could we go to Column 1, Lines 45 to
2 50.

3 BY MR. STEINDLER:

4 Q. And I think you went through some of this in direct.

5 The '295 patent discloses a broad range of steroid
6 concentrations from 0.001 percent to 3 percent, right?

7 A. Correct.

8 Q. And the top end of that range is 3,000 times larger than
9 the bottom end, right?

10 A. Correct.

11 Q. Nothing in the '295 patent explains how to determine the
12 appropriate amount of corticosteroid to include in any
13 formulation suggested by the '295 patent, right?

14 A. Standing alone, correct.

15 MR. STEINDLER: Let's turn to your Slide DX-3.36.

16 BY MR. STEINDLER:

17 Q. Now, you cite the '295 patent for the proposition that a
18 POSA would have been motivated to use HP at less than
19 0.05 percent, correct?

20 A. Correct.

21 Q. But the '295 patent doesn't specifically disclose
22 halobetasol at any concentration, correct?

23 A. Correct. It discloses others.

24 Q. And just so that we're all clear, the word "halobetasol"
25 doesn't appear in the '295 patent, right?

1 A. Correct.

2 MR. STEINDLER: All right. Let's go back to the
3 DX-003, the '295 patent.

4 I'd like you to turn to the description of the
5 invention in Column 1.

6 BY MR. STEINDLER:

7 Q. Now, the '295 patent discloses formulations that, as we
8 said, include a dialkyl sebacate, right?

9 A. Correct.

10 Q. Dialkyl sebacates are a class of compounds, right?

11 A. Correct.

12 Q. There are multiple different species of dialkyl
13 sebacates, correct?

14 A. Correct.

15 Q. The '295 patent specifically discloses only two species
16 of sebacates, dibutyl sebacate and diisopropyl sebacate,
17 correct?

18 A. Correct.

19 Q. And all of the sebacates in the examples in the '295
20 patent are limited to these two compounds, right?

21 A. Correct.

22 Q. And again, to be clear, the '295 patent does not
23 specifically disclose diethyl sebacate as claimed in the
24 Bryhali® patents, correct?

25 A. Specifically, no.

1 Q. None of the examples in the '295 patent use diethyl
2 sebacate, correct?

3 A. Correct.

4 Q. Now, as we've said before, in the 30 years after the '295
5 patent was published, diethyl sebacate was never used in any
6 formulation for a halobetasol product, correct?

7 A. Not a marketed one, no.

8 Q. But your contention is that a POSA would have relied on
9 the generic disclosure of sebacates in the '295 patent to pick
10 out the specific diethyl sebacate that's claimed in the
11 Bryhali® patents.

12 Is that right?

13 A. Correct. It's part of the prior art.

14 Q. Now, the '295 patent also teaches a POSA that white
15 petrolatum can be used as part of the invention, correct?

16 A. Correct.

17 Q. The '295 -- strike that.

18 The '295 patent does not teach a POSA that use of
19 white petrolatum would be prohibited, correct?

20 A. It doesn't have that language, no.

21 Q. But again, for clarity, the use of white petrolatum is
22 specifically prohibited in Claims 4 and 16 of the '502 patent,
23 right?

24 A. Correct.

25 MR. STEINDLER: Let's turn to Blum and go to your

1 Slide DDX-3.18, please.

2 BY MR. STEINDLER:

3 Q. So you've got a series of slides that you've presented in
4 your direct testimony on the Blum, right?

5 A. Correct.

6 MR. STEINDLER: I'd like to actually look at that
7 article, DX-002. So could you please go -- well, strike that.

8 BY MR. STEINDLER:

9 Q. The Blum -- strike that.

10 Blum is an article that was published in the *Chinese*
11 *Journal of Dermatology*, right?

12 A. Correct.

13 Q. If we go to the next page, we see it was published in
14 1986, right?

15 A. I believe so, yes.

16 Q. Now, that's almost two and a half decades before the
17 priority date of the Bryhali® patents, right?

18 A. Correct.

19 Q. Now, Blum -- strike that.

20 Blum was originally published in Chinese, correct?

21 A. Correct.

22 Q. You don't know if Blum was publicly available in English
23 prior to 2010, right?

24 A. No, I do not know.

25 Q. You don't know whether Blum was publicly available in the

1 United States prior to 2010, correct?

2 A. No, I don't. But it could have been translated easily.

3 Q. I'm sorry. I didn't ask that question.

4 All I asked was: You don't know whether Blum was
5 available in the United States prior to 2010, correct?

6 A. Correct.

7 Q. Now, Blum disclosed his clinical trials with 0.05 percent
8 and 0.02 percent halobetasol, correct?

9 A. Correct.

10 Q. It doesn't disclose anything about the formulations that
11 were used other than that they were ointments, correct?

12 A. Correct.

13 Q. Now, Blum looked at both the 0.2 percent -- strike that.

14 Blum looked at both the 0.02 percent halobetasol
15 concentration and the 0.05 percent concentration and
16 recommends the 0.05 percent concentration, correct?

17 A. There's a recommendation, yes.

18 Q. For clarity, Blum recommends -- let me ask again.

19 Blum looked at both the 0.02 percent halobetasol
20 concentration and the 0.05 percent concentration and
21 recommends the higher 0.05 percent concentration, correct?

22 A. There is one sentence there recommending that, yes.

23 MR. STEINDLER: Well, let's take a look at this.

24 Could you please go to the page that's Bates-marked
25 ending 20220, please.

1 And can you blow up the sentence in the top of the
2 left column.

3 BY MR. STEINDLER:

4 Q. Blum states there that the 0.05 percent halobetasol
5 ointment would be a favorite treatment weapon, right?

6 A. That's what it says.

7 Q. And then it goes on to say the lower concentration would
8 be less effective, correct?

9 A. Correct.

10 MR. STEINDLER: Let's go to the abstract, please,
11 last line.

12 BY MR. STEINDLER:

13 Q. In the abstract in Blum, it states again that the
14 0.05 percent halobetasol ointment would be a welcome addition
15 to the therapeutic armamentarium for chronic, localized,
16 severe, or recalcitrant dermatoses, right?

17 A. That's what that sentence says.

18 Q. Blum doesn't say either of these things about the
19 0.02 percent halobetasol formulation, correct?

20 A. Not in that sentence, no.

21 Q. Blum doesn't say anything anywhere in this article that
22 describes the 0.02 percent concentration as either a welcome
23 addition or a favorite treatment weapon.

24 Isn't that true?

25 A. I disagree.

1 Q. You will agree to me -- strike that.

2 You will agree with me that Blum looked at both the
3 0.02 percent concentration and the 0.05 percent concentration
4 and recommends the 0.05 percent concentration, right?

5 A. Correct.

6 Q. And your contention is that even though Blum looked at
7 both the 0.02 and 0.05 percent concentration and recommends
8 the higher concentration, that a POSA would ignore Blum's
9 recommendation and rely on the Blum article as a motivation to
10 pick a lower concentration.

11 Is that your testimony?

12 A. Yes, it is.

13 MR. STEINDLER: Let's turn to JP '228, please.

14 And I want to specifically look at your Slide
15 DDX-3.30.

16 BY MR. STEINDLER:

17 Q. Now, as you know in your -- strike that.

18 As you note in the top of your Slide JP '228 was
19 published in October 21, 1988, correct?

20 A. Correct.

21 Q. That was more than two decades before the priority date
22 for the Bryhali® patents, right?

23 A. Yes. It's definitely prior art, yes.

24 Q. Again, I'm asking you just to answer my question. I
25 didn't ask about whether it was prior art.

1 I just asked you that it was published more than two
2 decades before the priority date for the Bryhali® patents.

3 Isn't that correct?

4 A. Correct.

5 MR. STEINDLER: Turn to JTX-4 which is JP '228,
6 please.

7 Strike that. Strike that.

8 BY MR. STEINDLER:

9 Q. I'm going to take you now to JTX-4, which is one of the
10 Bryhali® patents, the '502 patent, right?

11 You're familiar with the '502 patent, right?

12 A. Yes. Of course, I am.

13 Q. Right.

14 A. Yes.

15 MR. STEINDLER: And can you just blow up the portion
16 -- strike that.

17 BY MR. STEINDLER:

18 Q. You see that JP '228 was before the examiner during
19 prosecution of the Bryhali® patents, right?

20 A. Correct.

21 MR. STEINDLER: All right. Let's go back to DX- --
22 strike that.

23 Let's go to DX-005, please, which is JP '228, and go
24 to the page Bates number ending in 20451.

25 BY MR. STEINDLER:

1 Q. So let's take a look at this patent application
2 publication.

3 Now, the invention of JP '228 relates to a steroid
4 cream preparation where the steroid is represented by the
5 general expression of Formula 1, right?

6 A. Correct.

7 Q. And we see that generic Formula 1 there on the left-hand
8 side. It's blown up on the screen, right?

9 A. Correct.

10 Q. That generic structure is shared by most steroids, right?

11 A. And my answer is yes.

12 Q. So JP '228 is disclosing a cream preparation that it says
13 can be used with essentially any steroid, right?

14 A. Correct.

15 Q. There are quite a number of steroids that have this
16 generic chemical structure, right?

17 A. Yes, there are.

18 MR. STEINDLER: So let's go to the page ending in
19 20453, please.

20 I'd like you to blow up the first full paragraph on
21 the left-hand side at the bottom.

22 BY MR. STEINDLER:

23 Q. Now, you see it says, for the steroids, any known
24 steroids represented by the aforesaid general expression may
25 be used, correct?

1 A. Correct.

2 Q. It gives some specific examples of steroids, right?

3 A. Correct.

4 Q. The ones that are mentioned are all variations of
5 methylprednisolone, right?

6 A. Correct.

7 Q. Halobetasol is not mentioned, correct?

8 A. It is not.

9 Q. Halobeta -- strike that.

10 Halobetasol is not mentioned anywhere in JP '228,
11 correct?

12 A. Correct.

13 MR. STEINDLER: So go to the top of right-hand column
14 on that same page.

15 BY MR. STEINDLER:

16 Q. And the patent discloses three different solvents:
17 diisopropyl adipate, diethyl sebacate, and triacetin.

18 Correct?

19 A. That's correct.

20 Q. There's no data in JP '228 which shows that diethyl
21 sebacate is preferable to the other two solvents, correct?

22 A. Correct.

23 MR. STEINDLER: Go to the page Bates number ending in
24 20455, please. And you can go through the blow-ups that we
25 have, please.

1 BY MR. STEINDLER:

2 Q. You see at the bottom of this left-hand column there's a
3 header entitled "Embodiment Examples."

4 Do you see that?

5 A. I do.

6 Q. And as you'll read through, there's a description of
7 three embodiment examples, Examples 1, 2 and 3, right?

8 A. Correct.

9 Q. Example 1 uses diisopropyl adipate as it's solvent,
10 right?

11 A. Yes, it does.

12 Q. And in Example 2, that solvent is replaced with
13 triacetin, correct?

14 A. Correct.

15 Q. And at the bottom of the page, Example 3 swaps that out
16 and uses diethyl sebacate as the solvent, correct?

17 A. Correct.

18 Q. Now, those embodiment examples weren't the ones that were
19 actually tested as reported in JP '228, correct?

20 A. Correct.

21 Q. The patent discloses human vasoconstriction action tests,
22 or VCA tests, for five different cream preparations, right?

23 A. Correct.

24 MR. STEINDLER: Let's go to the page ending in
25 020456, please.

1 BY MR. STEINDLER:

2 Q. The patent discloses those five cream preparations as A,
3 B, C, D, and E, right?

4 A. Correct.

5 Q. All five of the cream preparations that were actually
6 tested have diisopropyl adipate as the solvent except for B,
7 which has propylene glycol as the solvent, right?

8 A. Correct.

9 Q. None of the samples they tested had diethyl sebacate,
10 right?

11 A. Correct.

12 MR. STEINDLER: Let's go to page Bates number ending
13 20457, please.

14 BY MR. STEINDLER:

15 Q. Now, here it says that VCA tests were -- for these five
16 -- strike that.

17 Here it says that VCA tests for these five cream
18 preparations were run on 10 healthy adult test subjects,
19 right?

20 A. Correct.

21 Q. Then it goes on to say that the results of the VCA
22 studies are reported in Table 3 here on the bottom of that
23 page, right?

24 A. Correct.

25 Q. So again, when the inventors tested their invention and

1 reported these results, they chose cream preparations with
2 diisopropyl adipate or polypropylene glycol and not diethyl
3 sebacate, right?

4 A. Correct.

5 Q. Now, again, as we've said, JP '228 issued in 1998, right?

6 A. Correct.

7 Q. And in the 22 years between 1998 and the Bryhali®
8 invention date of 2010, no one ever used any of the solvents
9 disclosed in JP '228 to make a preparation for a topical
10 corticosteroid, correct?

11 A. For a marketed product, no.

12 MR. STEINDLER: Let's turn to DDX-3.27, please.

13 BY MR. STEINDLER:

14 Q. Now, in your slides you discussed the '566 patent, right?

15 A. Correct.

16 Q. It issued in 1994, correct?

17 A. Yes.

18 Q. And again, that's 16 years before the priority date of
19 the Bryhali® patents, correct?

20 A. Correct.

21 MR. STEINDLER: Let's go to JTX-004 again, which is
22 one of the Bryhali® patents.

23 Go to the face page.

24 BY MR. STEINDLER:

25 Q. And you can see that the '566 patent was before the

1 examiner during prosecution of the Bryhali® patents, right?

2 A. Yes, it was.

3 Q. And, in fact, the '566 patent is specifically discussed
4 in the specification of the Bryhali® patents, right?

5 A. Correct.

6 MR. STEINDLER: So can we go back to Slide DDX-3.27,
7 please.

8 BY MR. STEINDLER:

9 Q. You say that '566 patent teaches that by optimizing the
10 vehicle of a topical formulation to increase absorption, drug
11 concentration can be reduced without a significant, if any,
12 reduction in potency, right?

13 A. Correct.

14 Q. And just to be clear, optimizing the vehicle to increase
15 absorption would lead to an increase in systemic side effects,
16 right?

17 A. I disagree.

18 MR. STEINDLER: Let's go to DDX-3.29.

19 BY MR. STEINDLER:

20 Q. Now, in your top bullet, you say that the '566 patent has
21 numerous example formulations containing halobetasol, right?

22 A. Correct.

23 Q. And that's what you told the Court in your direct, right?

24 A. Correct.

25 Q. But, in fact, what you didn't tell the Court is that each

1 and every one of the example formulations in the '566 patent
2 uses the 0.05 percent concentration of halobetasol, right?

3 A. That's correct.

4 Q. The '566 patent doesn't contain any reference to a
5 halobetasol formulation with a concentration of less than
6 0.05 percent, right?

7 A. That is correct, too.

8 MR. STEINDLER: Let's go to DDX-3.33.

9 BY MR. STEINDLER:

10 Q. Now, this, again, is one of your claim charts for
11 Claim 13 of the '307 patent.

12 You cite the '566 patent for the proposition that a
13 POSA would be motivated to use HP topical formulations with HP
14 at 0.04 percent or less, right?

15 A. Correct.

16 Q. But there's nothing in the '566 patent that would
17 motivate a POSA would use HP at 0.04 percent or less, correct?

18 A. Correct.

19 MR. STEINDLER: Let's go to DDX-3.33. I guess we're
20 still there.

21 Go down to the right-hand box.

22 BY MR. STEINDLER:

23 Q. In your Claim 3 here, you also cite the '566 patent for
24 motivation to use halobetasol specifically at less than
25 0.025 percent, correct?

1 A. Correct.

2 Q. And there's nothing in the '566 patent that directs a
3 POSA to use halobetasol at less than 0.025 percent, correct?

4 A. Correct.

5 MR. STEINDLER: Let's go to DDX-3.36, please.

6 BY MR. STEINDLER:

7 Q. Now, you cite -- let me just move on.

8 Now, as of 2010, there was no commercially available
9 superpotent corticosteroid for the treatment of psoriasis that
10 uses the vehicle described in the '566 patent, right?

11 A. Correct.

12 Q. And to be clear, the Bryhali® patents don't use the
13 vehicle disclosed in the '566 patent, correct?

14 A. The specific one, no.

15 MR. STEINDLER: Let's go to DX-4, please.

16 BY MR. STEINDLER:

17 Q. Again, we're in the '566 patent. And in the abstract, it
18 says, The present invention relates the composition and
19 methods for enhancing or controlling epidermal, dermal, and
20 transdermal penetration of topically active -- strike that.

21 The abstracts states that the present invention
22 relates to compositions and methods for enhancing and/or
23 controlling epidermal, dermal, and transdermal penetration of
24 topically applied pharmacologically active agents by use of
25 dibutyl adipate or a mixture of dibutyl adipate and isopropyl

1 myristate.

2 Right?

3 A. That's what it states, correct.

4 Q. The '566 patent is then directed to the use of dibutyl
5 adipate, either alone or in combination with isopropyl
6 myristate, to enhance or control penetration of the active,
7 correct?

8 A. Correct.

9 Q. Now, the '566 patent doesn't mention diethyl sebacate
10 anywhere, correct?

11 A. That's correct.

12 Q. The '566 patent mentions dibutyl adipate, right?

13 A. Correct.

14 Q. Dibutyl adipate is not a sebacate, right?

15 A. It's not a sebacate, no.

16 Q. As we've discussed, sebacates were the class of compounds
17 disclosed in the '295, right?

18 A. Correct.

19 Q. Now, the '566 patent also discloses isopropyl myristate,
20 right?

21 A. It does.

22 Q. And isopropyl myristate is also not a sebacate, correct?

23 A. Correct.

24 MR. STEINDLER: Let's turn to DDX-3.33.

25 BY MR. STEINDLER:

1 Q. In the bottom right-hand box, you say a POSA would have
2 been motivated to use a liquid oil component comprising
3 diethyl sebacate. And you cite the '566 patent in support for
4 that proposition, right?

5 A. That's correct.

6 Q. So despite the fact that the '566 patent discloses the
7 use of dibutyl adipate and isopropyl myristate and doesn't
8 disclose diethyl sebacate, you cite the '566 patent as
9 motivation for a POSA to use diethyl sebacate, correct?

10 A. Correct, because it's not standing alone.

11 Q. Now, as we said, the '566 patent discloses use of
12 isopropyl myristate, right?

13 A. Correct.

14 Q. Isopropyl myristate was a well-known penetration
15 enhancer, right?

16 A. Right.

17 Q. One of the objects of the invention of the '566 patent
18 was to enhance delivery of the active ingredient systemically,
19 correct?

20 A. Could you repeat the question?

21 Q. Yes. One of the objects of the invention of the '566
22 patent was to enhance delivery of the active ingredient
23 systemically, correct?

24 A. I disagree.

25 MR. STEINDLER: Could we go to deposition transcript

1 at Page 179, Lines 20, through Page 180, Line 2?

2 "QUESTION: You would agree that one object of the
3 invention, though, would be to enhance delivery of the active
4 ingredient systemically, right?

5 "ANSWER: That is mentioned here by the inventors.
6 That's why probably, most likely, they included isopropyl
7 myristate."

8 BY MR. STEINDLER:

9 Q. Let's move on from the '566 patent and talk about the
10 Temovate® Label.

11 MR. STEINDLER: Could you go to DX-3.28, please.
12 Thank you.

13 BY MR. STEINDLER:

14 Q. Now, you say the Temovate® Label teaches the use of
15 corticosteroid for treatment of psoriasis for four weeks,
16 right?

17 A. Correct.

18 Q. The Temovate® Label does not disclose the use of a
19 concentration of corticosteroid less than 0.05 percent for
20 longer than four weeks, correct?

21 A. Correct.

22 Q. Temovate® is the commercial clobetasol product, right?

23 A. Correct.

24 Q. As we've said, the commercial halobetasol product was
25 Ultravate®, right?

1 A. Correct.

2 Q. There's no similar four-week exception for Ultravate®,
3 right?

4 A. Correct.

5 MR. STEINDLER: Could you go to, now, DDX-3.43?

6 BY MR. STEINDLER:

7 Q. I'd like to switch gears and talk about your
8 indefiniteness contention.

9 Now, the Court as construed the term "liquid oil
10 component," correct?

11 A. Correct.

12 Q. And the construction is, "The liquid oil component
13 includes all ingredients of the formulation that are
14 practically insoluble or insoluble in water and which are
15 liquid at room temperature of 22° degrees C," correct?

16 A. Correct.

17 Q. Now, a person of ordinary skill would reasonably
18 understand what it means for an ingredient to be practically
19 insoluble or insoluble in water, correct?

20 A. Correct.

21 Q. And a person of ordinary skill would reasonably
22 understand what it means for an ingredient, which is -- strike
23 that.

24 A person of ordinary skill would reasonably
25 understand what it means for an ingredient to be liquid at

1 room temperature of 22° degrees C, correct?

2 A. Correct.

3 Q. I'd like to now turn to the Duobrii® patents and your
4 arguments about the Duobrii® patents.

5 Now, I believe the only art that you're relying on
6 for your analysis for the Duobrii® patents is the '824
7 Publication, right?

8 A. Correct.

9 MR. STEINDLER: Let's turn to the '824 Publication
10 which is DX-142, please.

11 Now, can you just blow up the top of it.

12 BY MR. STEINDLER:

13 Q. I believe in your direct that you referred to the '824
14 patent -- strike that.

15 I believe in your direct you referred to the '824
16 Publication as a published patent, right?

17 A. That may have been a slip of the tongue, and I apologize.
18 It's a publication.

19 Q. Not only is it a publication, it is a publication of a
20 patent application, correct?

21 A. Correct.

22 Q. It is a published patent application which later became
23 the Bryhali® patents, right?

24 A. Correct.

25 Q. And the '824 Publication is the sole reference you rely

1 on to conclude that the formulation limitations of the
2 Duobrii® patents would have been obvious, right?

3 A. Correct.

4 Q. Now, I want to know exactly what you're contending based
5 on the '824 Publication.

6 Are you contending that a POSA would have been
7 motivated to arrive specifically at the IDP-118 composition
8 based on the '824 Publication?

9 A. Correct.

10 Q. You're not contending that a POSA would have been
11 motivated to arrive at all of the compositions of the asserted
12 claims of the Duobrii® patents, correct?

13 A. Correct.

14 Q. All right. Now, we've established that the '824
15 Publication is a patent application, right?

16 A. Yes, correct.

17 Q. Not an issued patent, right?

18 A. Correct.

19 Q. Doesn't disclose any clinical data, correct?

20 A. Correct.

21 Q. You agree that the '824 Publication does not stand out
22 from the overall literature available to a POSA as of 2015,
23 right?

24 A. It would be part of the literature.

25 Q. You agree that the '824 Publication does not stand out

1 from the overall literature available to a POSA as of 2015,
2 right?

3 A. Correct, it's part of the literature.

4 Q. That's all I need. Thank you very much.

5 Now, the '824 Publication contains a broad disclosure
6 of ingredients and concentrations that can be used, correct?

7 A. Correct.

8 Q. And most of the ingredients and concentrations disclosed
9 in the '824 Publication don't fall within the scope of the
10 claims of the Duobrii® patents, right?

11 A. Correct.

12 MR. STEINDLER: I'd like to turn to Paragraph 17 and
13 18 of the '824 Publication, which you now have before you on
14 the slide.

15 BY MR. STEINDLER:

16 Q. In Paragraph 17, the application discloses a series of
17 examples of superpotent corticosteroids that can be used,
18 right?

19 A. Correct.

20 Q. These include clobetasol, halobetasol, and a whole series
21 of others, right?

22 A. Correct.

23 Q. It also says that potent corticosteroids can be used, and
24 it gives a list of examples, correct?

25 A. Correct.

1 Q. And then in Paragraph 18, it states that steroids other
2 than superpotent or potent steroid can be used, correct?

3 A. Correct.

4 Q. Again, the only steroid in IDP is halobetasol and not any
5 of the other steroids in this long lists, right?

6 A. Correct.

7 MR. STEINDLER: Let's go to Paragraphs 19 and 20.

8 BY MR. STEINDLER:

9 Q. Now, in Paragraph 19, the '824 Publication also discloses
10 that dicarboxylic acid esters can be used, right?

11 A. Correct.

12 Q. It identifies diethyl sebacate as preferred and typical
13 of this class of compounds, but it includes a long list of
14 other examples, right?

15 A. Correct.

16 Q. And IDP-118, as we know, the only dicarboxylic acid ester
17 is diethyl sebacate, right?

18 A. Correct.

19 MR. STEINDLER: Let's go to Paragraph 23.

20 BY MR. STEINDLER:

21 Q. In Paragraph 23, the '824 Publication describes various
22 thickening agents that can be added so that the formulation
23 may be provided in the form of a lotion, gel, cream, or
24 ointment, right?

25 A. That's correct.

1 Q. IDP-118 is a lotion, right?

2 A. Correct.

3 Q. And in Claim 3 of the '895 patent and Claim 5 of the '787
4 patent, the composition must be -- strike that question.

5 Let's move on.

6 MR. STEINDLER: Let's go to Paragraph 26, please.

7 BY MR. STEINDLER:

8 Q. In Paragraph 26, the '824 Publication discloses that the
9 formulations may include other lipophilic liquids and sets out
10 a series of examples, including lanolin oil, mineral oil,
11 light mineral oil, and a series of others, right?

12 A. Correct.

13 Q. IDP-118 has only light mineral oil, right?

14 A. Correct.

15 MR. STEINDLER: Let's go to Example 1, Table 1.

16 BY MR. STEINDLER:

17 Q. You addressed some of this in your direct testimony.

18 The '824 Publication also sets out a series of
19 example formulations in Example 1, Table 1, which are listed
20 as Formulations A, B, C, D, and E, correct?

21 A. Correct.

22 Q. And it says that Formulation E is outside the scope of
23 the invention, right?

24 A. Correct.

25 Q. Now, Formulations A, B, and C each have different

1 concentrations of halobetasol, right?

2 A. Correct.

3 Q. Formulation A has 0.035 percent halobetasol, Formulation
4 B has 0.025 percent halobetasol, and Formulation C has
5 0.01 percent halobetasol, correct?

6 A. Correct.

7 Q. And IDP just has 0.01 percent halobetasol, right?

8 A. Correct.

9 Q. Now, Table 3 sets out the results using a VCA test for
10 these different halobetasol concentrations, right?

11 A. Correct.

12 Q. And as I think you explained, VCA is a test for potency,
13 correct?

14 A. Correct.

15 Q. And Paragraph 40 states that each of the formulations, A
16 through D, provided a VCA score similar to that of the prior
17 art formulation of Ultravate®, right?

18 A. Correct.

19 Q. And that includes the 0.035 percent formulation, the
20 0.025 percent formulation and the 0.01 percent formulation,
21 correct?

22 A. Correct.

23 Q. It does not state that any one of these concentrations is
24 a preferred or particularly preferred embodiment of the
25 invention, right?

1 A. Correct.

2 Q. It says that all three of them had VCA scores that were
3 similar to the commercial product, right?

4 A. Correct.

5 Q. Now, there's stability testing that's described in
6 Example 5, right?

7 A. I believe so, yes.

8 Q. Now, in Example 5, the inventors actually made an example
9 lotion and tested it to see whether it met the FDA stability
10 requirements, right?

11 A. Correct.

12 MR. STEINDLER: Now, if you go to the last line.

13 BY MR. STEINDLER:

14 Q. You see the inventors actually set out the stability
15 specifications for a halobetasol lotion that would be required
16 for a commercial product, right?

17 A. Correct.

18 Q. And those FDA requirements are then set out below in
19 Table 6, correct?

20 A. Correct.

21 MR. STEINDLER: Now, if you go to the next page.

22 BY MR. STEINDLER:

23 Q. The inventors set out the stability test results for this
24 example lotion in Table 7, correct?

25 A. Correct.

1 Q. And in Paragraph 49, the inventors stated that this
2 lotion would meet the FDA's stability requirements, right?

3 A. Correct.

4 Q. So this is the lotion -- strike that.

5 This is the formulation the inventors chose to test
6 to see whether it would meet the FDA requirements for a
7 commercial product, right?

8 A. For that purpose, yes.

9 Q. And it shows the inventors had a particular preference
10 for this formulation, correct?

11 A. Correct, the stability studies.

12 Q. And it was the only formulation that the inventors chose
13 to test to see if it met FDA standards, right?

14 A. As reported in the patent -- or the application, yes.

15 MR. STEINDLER: Now, let's go back to Paragraph 46 on
16 the previous page.

17 BY MR. STEINDLER:

18 Q. In Table 5, it sets out the formulation for this example
19 that they tested to see whether it met FDA commercial
20 standards, right?

21 A. Correct.

22 Q. And that formulation has halobetasol at 0.025 percent,
23 correct?

24 A. Yes, it does.

25 Q. It is not a 0.01 percent halobetasol formulation,

1 correct?

2 A. For the stability data, no.

3 Q. Now, if you go to Table 4, which you were describing in
4 your direct testimony, there are two lotion formulations,
5 right?

6 A. Correct.

7 Q. There's no test data disclosed in the '824 Publication
8 for either example 4A or 4B, right?

9 A. Test data stability or any data?

10 Q. There is no test data of any kind disclosed in the '824
11 Publication for the Formulations 4A or 4B.

12 Isn't that correct?

13 A. That is correct.

14 Q. And, in fact, the formulation in Table 5 that they
15 actually tested is different than either of these two
16 formulations, right?

17 A. For the stability testing, correct.

18 Q. Just so that the record is clear, the formulation that
19 was tested for stability testing, as disclosed in the '824
20 Publication, is different from either of the formulations for
21 4A or 4B in Table 4, right?

22 A. That is correct.

23 MR. STEINDLER: Now, if you go to your Slide
24 DDX-3.59.

25 BY MR. STEINDLER:

1 Q. You testified in your direct testimony that there was
2 directions that were given in the '824 patent for how to make
3 the Formulations 4A and 4B, right?

4 A. Correct.

5 Q. And if you go -- that same direction was used to make the
6 formulation that was tested for stability testing in Table 5,
7 right?

8 A. I believe so.

9 Q. So the '824 Publication discloses test data on formulas
10 A, B, C, and D, as well as the formulations from Table 5,
11 right?

12 A. I believe so.

13 Q. So the '824 Publication discloses five different formulas
14 with test data, right?

15 A. Correct.

16 Q. So a POSA reading the '824 Publication would be presented
17 with five different formulas with test data before they would
18 even get to Formulas 4A and 4B, right?

19 A. I disagree, because it would be looked as a whole piece
20 of evidence.

21 Q. There's no reason for a POSA to have picked Formula 4A,
22 which you use in your explanation, which has no test data
23 reported in the patent over the five formulas disclosed in the
24 '824 Publication that do have test data.

25 Isn't that correct?

1 A. The POSA would have considered all of them, I agree.

2 Q. Now, you're aware that the '824 application was submitted
3 with a series of claims that are included in the back, right?

4 A. Correct.

5 MR. STEINDLER: Let's turn to them, please.

6 BY MR. STEINDLER:

7 Q. These are hard to see yet, but these are the claims that
8 were submitted with the '824 application, right?

9 A. Correct.

10 Q. There is no claim in the '824 Publication that specifies
11 a 0.01 percent concentration of halobetasol, correct?

12 A. I believe there isn't.

13 Q. Isn't it true that by testing the formulation in Table 5
14 to determine whether it met FDA requirements, the inventors
15 were expressing a preference for that 0.025 percent
16 halobetasol formulation in the '824 Publication?

17 A. I disagree.

18 Q. So it's your view that when the '824 Publication only
19 tests one formulation to see whether it met FDA requirements
20 for a commercial product, that is not a preference for that
21 concentration?

22 A. I believe not.

23 Q. All right.

24 Now, you say the '824 -- strike that.

25 You would agree that the '824 Publication doesn't

1 disclose tazarotene, correct?

2 A. That's correct.

3 Q. And nothing in the '824 Publication discloses the utility
4 of the claimed invention in a single fixed-dose combination
5 drug, correct?

6 A. Correct.

7 Q. Nothing in the '824 Publication describes any benefits of
8 combining a corticosteroid and a retinoid in a fixed-dose
9 combination?

10 A. I believe it doesn't.

11 Q. Nothing in the prior art provided any information on the
12 compatibility of tazarotene with any of the formulations
13 disclosed in the '824 Publication, right?

14 A. I disagree.

15 MR. STEINDLER: Now, can we go to your Slide DX-3.63,
16 please? 63.

17 BY MR. STEINDLER:

18 Q. In your direct examination you said you were only
19 addressing the formulation limitations of the Duobrii® patent
20 claims which you highlighted in red, right?

21 A. Correct.

22 Q. And therefore, you are not rendering an opinion on the
23 limitation in Claim 1 that recites: Tazarotene at a
24 concentration of 0.045 percent by weight of the composition,
25 correct?

1 A. I think that should have maybe been highlighted in red.

2 Q. Well, it's not. And you testified on direct that you
3 were not rendering an opinion on any claim limitation that
4 wasn't highlighted in red and that's one of them, right?

5 A. Correct.

6 Q. So help us out here.

7 Are you or are you not rendering an opinion on
8 tazarotene at a concentration of 0.045 percent by weight of
9 the composition?

10 A. I did offer an opinion, as was in my report.

11 Q. Right. So notwithstanding the fact that you said you
12 weren't offering an opinion, you actually did offer an
13 opinion.

14 Is that your contention?

15 A. Correct.

16 Q. You understand my confusion based on these slides, right?

17 A. I understand there should have been a red line.

18 Q. And in fact, the same thing is repeated at 3.65, right?

19 Again, in 3.65, when you are addressing the claims in
20 the '787 patent, you don't indicate that you're giving an
21 opinion on the tazarotene at a concentration of 0.045 percent,
22 right?

23 A. I should have left that in red because it was a
24 pharmaceutical composition and the formulation included it.

25 MR. STEINDLER: Now, let's go to DDX-3.64.

1 BY MR. STEINDLER:

2 Q. You say that, in fact, it would have been a matter of
3 routine experimentation to arrive at 0.045 percent
4 concentration of tazarotene, right?

5 A. Correct.

6 Q. Now, you don't have any actual evidence that routine
7 experimentation would have arrived at 0.045 percent tazarotene
8 and not some other concentration, right?

9 A. Could you clarify what you mean by "evidence"?

10 Q. You don't have any experimental evidence that would
11 establish that the optimal concentration of tazarotene in the
12 formulations described in the '824 publication is
13 0.045 percent.

14 Isn't that correct?

15 A. I disagree because we had Tazorac® out there marketed.

16 Q. But Tazorac® is not at 0.045 percent, right?

17 A. Correct, but it's close.

18 Q. Tazorac® is not in the concentration -- strike that.

19 Tazorac® is not included in the formulations
20 disclosed in the '824 Publication, correct?

21 A. Correct.

22 Q. You don't have any experimental evidence to establish
23 that the optimal concentration of tazarotene in the
24 formulations of the '824 patent would have been 0.045 rather
25 than 0.040 percent or 0.035 percent or even 0.01 percent,

1 right?

2 A. Correct.

3 Q. You've got no way of knowing whether what you call
4 routine experimentation would have arrived at the
5 0.045 percent concentration, correct?

6 A. I absolutely disagree.

7 Q. But you didn't do any optimization testing yourself,
8 correct?

9 A. Correct.

10 Q. And as far as you know, Padagis didn't do any
11 optimization testing to try to establish that 0.045 percent
12 concentration is the optimal concentration in this
13 formulation, right?

14 A. Correct.

15 MR. STEINDLER: Pass the witness.

16 THE COURTROOM DEPUTY: Judge, you want to take the
17 break?

18 THE COURT: We'll take the break.

19 THE COURTROOM DEPUTY: All rise.

20 (Recess taken from 2:41 p.m. to 3:00 p.m.)

21 THE COURTROOM DEPUTY: All rise.

22 THE COURT: Be seated.

23 You may proceed.

24 MS. PITZEL CRUZ: We have no redirect for
25 Dr. Michniak-Kohn.

1 THE WITNESS: Thank you very much.

2 Thank you, Your Honor.

3 MS. PITZEL CRUZ: We'd like to call -- our next
4 witness will be by video deposition.

5 THE COURT: Okay.

6 MS. PITZEL CRUZ: Binu Alexander.

7 THE COURT: Thank you, you're excused. Thank you
8 very much.

9 (Witness is excused.)

10 THE COURTROOM DEPUTY: This is the deposition
11 testimony that we're going to be playing for the record on
12 behalf of the defendant. That's what we're doing.

13 (Video played.)

14 BINU ALEXANDER, DEFENSE WITNESS,
15 having been duly sworn, testifies
16 through his videotaped deposition as follows:

17 DIRECT EXAMINATION

18 "QUESTION: Please state your full name for the
19 record.

20 "ANSWER: My name is Binu Jacob Alexander.

21 "QUESTION: Are you concurrently employed?

22 "ANSWER: I am.

23 "QUESTION: By whom?

24 "ANSWER: I'm currently employed by Bausch + Lomb.

25 "QUESTION: And what is your current title?

1 "ANSWER: My current title is executive director
2 pharmacovigilance.

3 "QUESTION: Do you understand that you are under oath
4 today and that you must testify truthfully, accurately and
5 completely, the same as if you were in court?

6 "ANSWER: Yes, I do.

7 "QUESTION: Is there any reason that you cannot
8 testify truthfully, accurately and completely here today?

9 "ANSWER: No.

10 "QUESTION: Okay. And, you know, to the extent I
11 have specific questions, I will direct you to the, you know,
12 particular pages of interest. But just as an initial matter,
13 is it your understanding that you've been designated to
14 testify on behalf of Plaintiff Bausch Health Ireland Limited,
15 Bausch Health Americas, Incorporated, and Bausch Health U.S.
16 LLC on certain topics that are discussed in Exhibit 1?

17 "ANSWER: My understanding is that I was to speak on
18 behalf of topic 12.

19 "QUESTION: Okay. All right. As far as providing
20 testimony on behalf of Plaintiff Bausch Health Ireland
21 Limited, Bausch Health America, Incorporated, Bausch Health
22 U.S. LLC, is it your understanding that your testimony is on
23 their behalf?

24 "ANSWER: Correct.

25 "QUESTION: Is it your understanding that you've been

1 designated to testify about Bausch's general practices and
2 procedures regarding the submission, updating or removal of
3 information from or to ClinicalTrials.gov?

4 "ANSWER: Yes.

5 "QUESTION: Are you prepared to testify on this
6 subject?

7 "ANSWER: Yes.

8 "QUESTION: And is it your understanding that you
9 have been designated to testify about whether Bausch's general
10 practices and procedures regarding a submission, updating or
11 removal of information from or to ClinicalTrials.gov were
12 followed in relation to the posting of such information with
13 regards to study number NCT 02045277?

14 "ANSWER: Yes.

15 "QUESTION: And are you prepared to testify on this
16 subject?

17 "ANSWER: Yes.

18 "QUESTION: So as we've discussed, you have been
19 designated to testify regarding Bausch's general practices and
20 procedures regarding the submission, updating or removal of
21 information from or to ClinicalTrials.gov.

22 "Is that correct?

23 "ANSWER: That's correct.

24 "QUESTION: What is ClinicalTrials.gov?

25 "ANSWER: It's a public repository of clinical trials

1 that are being conducted.

2 "QUESTION: Does Bausch submit any information about
3 its clinical trials to ClinicalTrials.gov?

4 "ANSWER: Yes.

5 "QUESTION: What kinds of information does Bausch
6 submit to ClinicalTrials.gov regarding these clinical trials?

7 "ANSWER: So the trial information, as required by
8 ClinicalTrial.gov, is entered into a system.

9 "QUESTION: What do you mean by a 'trial
10 information'?

11 "ANSWER: So in general the trial title, what phase
12 it is, what proposed criteria is within the protocol. Once
13 results are available, they should be included, locations
14 where sites might be available. Essentially, it's a way for
15 the public to understand if there are clinical trials going
16 on, which may pertain, to help them with their health issues.

17 "QUESTION: Are you aware of any written policies
18 that Bausch has that concern what information is submitted to
19 ClinicalTrials.gov?

20 "ANSWER: As I recall, there were SOPs put into
21 place, and I believe it was in 2017.

22 "QUESTION: And when you refer to 'SOPs,' are you
23 referring to standard operating procedures?

24 "ANSWER: That's correct.

25 "QUESTION: Is there a written document that reflects

1 that standard operating procedure?

2 "ANSWER: Yes, that's what SOP CLN-029 is.

3 "QUESTION: Between 2014 and 2017, who at Bausch was
4 involved in the submission of information to
5 ClinicalTrials.gov for Bausch's dermatology clinical studies?

6 "ANSWER: Yeah, I can't speak to all of the
7 dermatology profile. Like for the Duobrii® trials that you're
8 stating, I was responsible.

9 "QUESTION: And what was your role with respect to
10 submitting information to ClinicalTrials.gov for the Duobrii®
11 clinical studies?

12 "ANSWER: So it was to provide the information to
13 CT.gov.

14 "QUESTION: Do you recognize Exhibit 3?

15 "ANSWER: Yup.

16 "QUESTION: And what do you recognize Exhibit 3 to
17 be?

18 "ANSWER: I recognize it to be the listing in CT.gov
19 for the NCT number in question.

20 "QUESTION: Okay. And just to provide a little more
21 detail, I'll represent to you that Exhibit 3 is a printout of
22 the study details portion of the study record for study number
23 NCT 02045277 on ClinicalTrials.gov as of January 10th, 2022.

24 "At the top of Page 1 of Exhibit 3, there's a title
25 that says, 'Safety and efficacy of IDP-118 in the treatment of

1 plaque psoriasis.'

2 "Is that correct?

3 "ANSWER: Yes, that's correct.

4 "QUESTION: Okay. And if you can turn to Page 4, for
5 a moment and let me know when you're there.

6 "ANSWER: Okay.

7 "QUESTION: On Page 4 of Exhibit 3, do you see the
8 heading 'More Information'?

9 "ANSWER: Yes.

10 "QUESTION: And that under this heading, Exhibit 3
11 identifies another ID number for NCT 02045277, that is number
12 V01-118A-201.

13 "Is that correct?

14 "ANSWER: That is correct.

15 "QUESTION: And right above the heading 'More
16 Information,' do you see your name on the page identified as
17 the study director for study number NCT 02045277?

18 "ANSWER: Yes.

19 "QUESTION: Did you -- were you the one who initially
20 registered the study at ClinicalTrials.gov?

21 "ANSWER: So I initiated the process.

22 "QUESTION: And by 'the process,' are you referring
23 to the process of registering the study on ClinicalTrials.gov?

24 "ANSWER: Yes.

25 "QUESTION: Okay. And what did initiating the

1 registration process entail?

2 "ANSWER: So I don't remember exactly what was done,
3 but I, you know, the information such as study title. So
4 these headings are here: Study description, study design,
5 arms and interventions, outcome measures, eligibility
6 criteria, and contacts and locations.

7 "QUESTION: So were you responsible for determining
8 what information about the study to submit to CT.gov in order
9 to comply with those guidelines?

10 "ANSWER: So I was responsible for providing
11 information that was then subject to review by our executive
12 director of clinical operations, which was there by -- subject
13 to review by PRS at CT.gov to make ensure we're meeting the
14 requirements.

15 "QUESTION: With respect to study number NCT
16 02045277, did you ever update the information on
17 ClinicalTrials.gov regarding the concentration of the active
18 ingredients in IDP-118?

19 "ANSWER: Yes, I did.

20 "QUESTION: Did anyone ask you to update the
21 information on ClinicalTrials.gov regarding the concentration
22 of the active ingredients in IDP-118?

23 "ANSWER: Yeah, I, I recall we had discussions
24 around, you know, proprietary information that was disclosed
25 that did not need to be disclosed; and in the next update,

1 those were reflected to still meet the requirements of CT.gov.

2 "QUESTION: So under that line there are a few dates.
3 There is a first posted date of January 24, 2014; a results
4 first posted date of August 20, 2020; and a last update posted
5 of August 20, 2020.

6 "Is that accurate?

7 "ANSWER: Yes.

8 "QUESTION: Do you have an understanding of the
9 difference between the first posted date and the results first
10 posted date?

11 "ANSWER: Yes.

12 "QUESTION: And what is that understanding?

13 "ANSWER: So first posted is when the CT.gov listing
14 is first made public. Results first posted is when the
15 results were first posted and made public.

16 "QUESTION: If you can turn to Page 2 of Exhibit 3.

17 "Can you see that heading 'Arms and Interventions'?

18 "ANSWER: Yes.

19 "QUESTION: This section identifies four study arms.

20 "Is that correct?

21 "ANSWER: That is correct.

22 "QUESTION: And the experimental arm is identified as
23 IDP-118 lotion.

24 "Is that correct?

25 "ANSWER: That is correct.

1 "QUESTION: And the Arms and Intervention section of
2 Exhibit 3 describes IDP-118 lotion as containing halobetasol
3 propionate and tazarotene.

4 "Is that correct?

5 "ANSWER: That's correct.

6 "QUESTION: The Arms and Intervention section of
7 Exhibit 3 does not disclose the concentration of either active
8 ingredient in that IDP-118 lotion.

9 "Is that correct?

10 "ANSWER: That is correct.

11 "QUESTION: So as we discussed earlier, the
12 information regarding study number NCT 02045277 was first
13 posted on ClinicalTrials.gov on January 24th, 2014.

14 "Is that correct?

15 "ANSWER: That's correct.

16 "QUESTION: And when the study information for study
17 number NCT 02045277 was first posted on ClinicalTrials.gov, is
18 it your understanding that the Arms and Intervention section
19 identified the concentration of the active ingredient in
20 IDP-118 lotion?

21 "ANSWER: That is correct.

22 "QUESTION: Do you recognize Exhibit 4?

23 "ANSWER: Yes.

24 "QUESTION: And what do you recognize Exhibit 4 to
25 be?

1 "ANSWER: This is the initial public display of the
2 submission and registration of the trial.

3 "QUESTION: And when you say 'the trial,' are you
4 referring to study number NCT 02045277 on ClinicalTrials.gov?

5 "ANSWER: That's correct.

6 "QUESTION: In the middle of Page 1 of Exhibit 4,
7 there is a box with a heading 'Study Record Versions' that
8 lists seven versions of the study record for study number NCT
9 02045277.

10 "Is that correct.

11 "ANSWER: That's correct.

12 "QUESTION: And Exhibit 4 identifies version 1 as
13 having a submitted date of January 22, 2014.

14 "Is that correct?

15 "ANSWER: That's correct.

16 "QUESTION: And Exhibit 4 identifies version 2 of the
17 study record as having a submitted date of February 19th,
18 2014.

19 "Is that correct?

20 "ANSWER: That's correct.

21 "QUESTION: And Exhibit 4 identifies version 3 of the
22 study record as having a submitted date of April 30th, 2014.

23 "Is that correct?

24 "ANSWER: That's correct.

25 "QUESTION: And Exhibit 4 identifies version 4 of the

1 study record as having a submitted date of December 8th, 2014.

2 "Is that correct?

3 "ANSWER: That's correct.

4 "QUESTION: Exhibit 4 identifies version 5 of the
5 study record as having a submitted date of August 15th, 2016;
6 is that correct?

7 "ANSWER: That's correct.

8 "QUESTION: And Exhibit 4 identifies version 6 as
9 having a submitted date of December 13th, 2017.

10 "Is that correct?

11 "ANSWER: That's correct.

12 "QUESTION: And Exhibit 4 identifies version 7 of the
13 study record as having a submitted date of August 8th, 2020.

14 "Is that correct?

15 "ANSWER: That's correct.

16 "QUESTION: Do you understand the submitted date to
17 refer to the date that each version of the study record was
18 submitted to ClinicalTrials.gov by Bausch?

19 "ANSWER: That's my understanding.

20 "QUESTION: In the study record version box of
21 Exhibit 4, version 1 of study number NCT 02045277 is selected.

22 "Is that correct?

23 "ANSWER: Yes, that's correct.

24 "QUESTION: And so do you understand Exhibit 4 to
25 depict version 1 of the study record for study number

1 NCT 02045277 that was submitted to ClinicalTrials.gov on
2 January 22nd, 2014?

3 "ANSWER: That's correct.

4 "QUESTION: And if you look at the bottom of Page 1
5 of Exhibit 4, do you see the section titled 'Study Status'?

6 "ANSWER: On what page again?

7 "QUESTION: The same page, Page 1.

8 "ANSWER: I see 'overall status.'

9 "QUESTION: Oh, so the heading above that for that
10 second box at the bottom of the page, the first box, the study
11 identification, the second is study status.

12 "Do you see that?

13 "ANSWER: Oh, yes.

14 "QUESTION: Okay. And in the study status box, do
15 you see the first posted date at the very bottom of that page?

16 "ANSWER: Yes, I do.

17 "QUESTION: And the first posted date is identified
18 as January 24, 2014.

19 "Is that correct?

20 "ANSWER: That's correct.

21 "QUESTION: Do you understand this to mean that
22 version 1 of the study record for study number NCT 02045277
23 was first posted on ClinicalTrials.gov's website around
24 January 24th, 2014?

25 "ANSWER: Yes.

1 "QUESTION: If can you turn to Page 2 of Exhibit 4,
2 please.

3 "ANSWER: Okay.

4 "QUESTION: Do you see the section titled 'Arms
5 Intervention'?

6 "ANSWER: Yes.

7 "QUESTION: And again, the experimental arm in
8 Exhibit 4 is identified as IDP-118 lotion.

9 "Is that correct?

10 "ANSWER: That's correct.

11 "QUESTION: And the Arms and Intervention section of
12 Exhibit 4 discloses the concentration of halobetasol
13 propionate in IDP-118 lotion as 0.01 percent.

14 "Is that correct?

15 "ANSWER: That's correct.

16 "QUESTION: The Arms and Intervention section of
17 Exhibit 4 discloses the concentration of tazarotene in IDP-118
18 lotion as 0.045 percent.

19 "Is that correct?

20 "ANSWER: That's correct.

21 "QUESTION: So do you agree that version 1 of the
22 study record for study number NCT 02045277 that on
23 ClinicalTrials.gov included the concentrations of halobetasol
24 propionate and tazarotene in IDP-118 lotion?

25 "ANSWER: Yes.

1 "QUESTION: So as we discussed earlier with respect
2 to Exhibit 3, the current study record, or the study record
3 that was current as of January 10th, 2022 or study record
4 NCT 02045277 does not identify the concentration of the active
5 ingredients in IDP-118 lotion.

6 "Is that correct?

7 "ANSWER: Yes.

8 "QUESTION: And you previously testified that you
9 removed the concentration information from the study record
10 for study number NCT 02045277 on ClinicalTrials.gov.

11 "Is that correct?

12 "ANSWER: Yes.

13 "QUESTION: Do you recognize Exhibit 6?

14 "ANSWER: It looks like the fifth version of the NCT
15 study description.

16 "QUESTION: And so in the study records version box
17 of Exhibit 6, version 5 of study number NCT 02045277 is
18 selected.

19 "Is that correct?

20 "ANSWER: That's correct.

21 "QUESTION: The study record of version box of
22 Exhibit 6 identifies August 15th, 2016, as the date that
23 version 5 of the study record was submitted to
24 ClinicalTrials.gov.

25 "Is that correct?

1 "ANSWER: That's correct.

2 "QUESTION: Can you please turn to Page 2 of
3 Exhibit 6?

4 "ANSWER: Okay.

5 "QUESTION: And can you look at the section titled
6 'Arms and Interventions?

7 "ANSWER: Okay.

8 "QUESTION: The Arms and Interventions section of
9 Exhibit 6 does not disclose the concentration of halobetasol
10 propionate in IDP-118 lotion.

11 "Is that correct?

12 "ANSWER: That's correct.

13 "QUESTION: The Arms and Interventions section of
14 Exhibit 6 does not disclose the concentration of tazarotene in
15 IDP-118 lotion.

16 "Is that correct?

17 "ANSWER: That's correct.

18 "QUESTION: Do you agree that version 5 of the study
19 record for study number NCT 02045277 on ClinicalTrials.gov
20 does not disclose the concentrations of halobetasol propionate
21 and tazarotene in IDP-118 lotion?

22 "ANSWER: That's correct.

23 "QUESTION: Do you agree that when the study record
24 was updated for study number NCT 02045277 from version 4 to
25 version 5, information about the concentration of the active

1 ingredients in IDP-118 lotion was removed from the study
2 record?

3 "ANSWER: It looks like that was one of the things
4 that was updated, along with some other descriptions as well.

5 "QUESTION: So, Dr. Alexander, earlier we were
6 discussing the update of the information for study number
7 NCT 02045277 on ClinicalTrials.gov to remove information about
8 the concentration of the active ingredient. And you mentioned
9 that the information was removed based on discussions that you
10 had with Johnson Varughese around proprietary information that
11 was disclosed that did not need to be disclosed.

12 "Is that correct?

13 "ANSWER: Yes. And so to clarify, again, information
14 is never removed from CT.gov. It's always present within the
15 audit history.

16 "I don't recall if I made this change or if my
17 subordinate at that time had made the change, but, but we were
18 involved in those conversations and this was proprietary
19 information that did not need to be disclosed in a public
20 site.

21 "QUESTION: And so you mentioned that in your
22 conversations with Johnson Varughese, you -- it was discussed
23 that this was proprietary information. So is it your
24 understanding that the concentration of halobetasol and
25 tazarotene in IDP-118 lotion is proprietary information?

1 "ANSWER: It's my opinion that any concentration for
2 any molecule that's being investigated is proprietary to that
3 company.

4 "QUESTION: And what is your understanding of the
5 meaning of 'proprietary information'?

6 "ANSWER: Well, it's confidential. It's to our
7 investigation, and it's specific to our company.

8 "QUESTION: Was is your understanding that it was
9 important to maintain the confidentiality of the concentration
10 of the active ingredients in IDP-118 lotion?

11 "ANSWER: Yeah. So in my opinion, any concentration
12 of any formulation is not required to be publicly disclosed.

13 "QUESTION: So apart from your understanding that
14 there is no requirement to disclose this information, is there
15 a reason that Bausch would want to avoid disclosing the
16 concentration of the active ingredients in an experimental
17 drug?

18 "ANSWER: So, again, being a public front-facing
19 information, it could be subject to any other competitor,
20 especially in this competitive space. So because of that,
21 that would be my understanding."

22 (Video stops.)

23 THE COURT: Okay, thank you.

24 What's next?

25 MS. PITZEL CRUZ: Your Honor, we have one more short

1 fact witness by video deposition, Sean Humphrey, one of
2 Bausch's 30(b)(6) representatives.

3 THE COURT: Okay. Let's proceed.

4 THE COURTROOM DEPUTY: This is live? This is live.
5 Is it deposition or is it live testimony --

6 MS. PITZEL CRUZ: Deposition.

7 SEAN HUMPHREY, DEFENSE WITNESS,
8 having been duly sworn, testifies
9 through his videotaped deposition as follows:

10 DIRECT EXAMINATION:

11 "QUESTION: Can you state your full name for the
12 record.

13 "ANSWER: Sure. Sean Humphrey.

14 "QUESTION: And are you currently employed?

15 "ANSWER: Yes, I am.

16 "QUESTION: And by whom are you employed.

17 "ANSWER: Bausch Health.

18 "QUESTION: And what is the address of your place of
19 employment?

20 "ANSWER: The address here at the office is 1330
21 Redwood Way, Petaluma, California 94954.

22 "QUESTION: Thank you. And what is your current
23 title at Bausch?

24 "ANSWER: Director of regulatory affairs.

25 "QUESTION: And do you understand that you're under

1 oath today?

2 "ANSWER: I do understand I'm under oath.

3 "QUESTION: Do you understand that you must testify
4 truthfully, accurately and completely, the same as if you were
5 in court?

6 "ANSWER: I do understand.

7 "QUESTION: Is there any reason that you cannot
8 testify truthfully, accurately or completely today?

9 "ANSWER: No. No reason.

10 "QUESTION: Mr. Humphrey, do you have Exhibit 6 in
11 front of you?

12 "ANSWER: Yes, I do have Exhibit 6 in front of me.

13 "QUESTION: Do you recognize Exhibit 6?

14 "ANSWER: I recognize that it is a cover letter for
15 an IND.

16 "QUESTION: And what is the IND number associated
17 with Exhibit 6?

18 "ANSWER: IND 111218.

19 "QUESTION: Can we agree to refer to IND
20 number 111218 as the 'Duobrii® IND'?

21 "ANSWER: Yes, we can.

22 "QUESTION: Was Exhibit 6 submitted to the FDA?

23 "ANSWER: It appears as though it would have been
24 part of the original IND, yes.

25 "QUESTION: Do you recall when the Duobrii® IND was

1 first submitted to the FDA?

2 "ANSWER: I do not have -- I do not recall the exact
3 date that the Duobrii® IND was submitted to the FDA.

4 "QUESTION: Do you recall roughly when it was first
5 submitted to the FDA?

6 "ANSWER: If I had to, I would assume that it was
7 submitted October 2011.

8 "QUESTION: Do you recognize Exhibit 8?

9 "ANSWER: Yes, I do.

10 "QUESTION: What is Exhibit 8?

11 "ANSWER: Exhibit 8 appears to be the Section 2.5,
12 Clinical Overview, that was submitted with the Duobrii® IND.

13 "QUESTION: Do you know whether Exhibit 8 was
14 submitted with the Duobrii® IND?

15 "ANSWER: It appears as though, yes, it was.

16 "QUESTION: Do you know when it was submitted to the
17 FDA as part of the Duobrii® IND?

18 "ANSWER: The 2.5, clinical overview, would have been
19 submitted with the original IND submission.

20 "QUESTION: And what is the purpose of the clinical
21 overview?

22 "ANSWER: To provide FDA background on the disease
23 that is intended to be studied and as well as any information
24 that might be out there on an already-marketed product as well
25 as to provide a general understanding of the safety of the

1 product you're intended to study.

2 "MR. BARNES: And, for the record, Exhibit 9 is a
3 document bearing Bates Number BAU00013654.

4 "QUESTION: Do you recognize Exhibit 9, Mr. Humphrey?

5 "ANSWER: I recognize that it is meeting background
6 materials.

7 "QUESTION: Do you know whether Exhibit 9 was
8 submitted to the FDA as part of the Duobrii® IND?

9 "ANSWER: I'm going to search through the document
10 here to --

11 "QUESTION: Yeah. Feel free to turn to any page of
12 the document that you need to to answer the question.

13 "(Witness peruses the exhibit.)

14 "ANSWER: Yes, this document was submitted to the
15 Duobrii® IND -- or, sorry, to the FDA in the Duobrii® IND.
16 Sorry.

17 "MR. BARNES: And, for the record, Exhibit 11 is a
18 document bearing Bates Number BAU00053099.

19 "QUESTION: Do you recognize Exhibit 11?

20 "ANSWER: Yes, I do.

21 "QUESTION: And what is Exhibit 11?

22 "ANSWER: Exhibit 11 is the cover letter that was
23 submitted with the original Duobrii® NDA.

24 "QUESTION: And the NDA number identified on
25 Exhibit 11 is 209354.

1 "Is that correct?

2 "ANSWER: That is correct.

3 "QUESTION: Can we agree to refer to NDA Number
4 209354 as the Duobrii® NDA?

5 "ANSWER: Yes, we can agree that.

6 "MR. BARNES: And for the record, Exhibit 20 is a
7 document bearing Bates Number BAU00232725.

8 "QUESTION: Do you recognize Exhibit 20?

9 "ANSWER: Yes, I do.

10 "QUESTION: What is Exhibit 20?

11 "ANSWER: Exhibit 20 is the cover letter that
12 accompanied the original NDA for Bryhali®.

13 "QUESTION: And Exhibit 20 identifies the NDA number
14 as 209355.

15 "Is that correct?

16 "ANSWER: That is correct.

17 "QUESTION: And can we agree to refer to NDA number
18 209355 as the Bryhali® NDA?

19 "ANSWER: Yes, we can.

20 "QUESTION: Is it Bausch's understanding that all of
21 the statements submitted to the FDA regarding Duobrii® were
22 accurate at the time that they were submitted?

23 "ANSWER: Yes.

24 "QUESTION: Is it Bausch's understanding that all of
25 the statements regarding Bryhali® submitted to the FDA were

1 accurate at the time they were submitted?

2 "ANSWER: Yes.

3 "MR. BARNES: For the record, Exhibit 33 is a
4 document bearing Bates Number BAU00006434.

5 "QUESTION: Do you recognize Exhibit 33?

6 "ANSWER: Yes, I do.

7 "QUESTION: What is Exhibit 33?

8 "ANSWER: This is FDA Form 3674 that accompanies IND
9 submissions.

10 "QUESTION: Is it correct that Exhibit 33 is a
11 certification of compliance?

12 "ANSWER: It does state 'certification of compliance'
13 at the top of the form, yes.

14 "QUESTION: Do you see on Page 1 of Exhibit 33 there
15 is a heading labelled 'Product Information'?

16 "ANSWER: Yes, I see this.

17 "QUESTION: And underneath that heading, do you see
18 IDP-118 lotion listed there?

19 "ANSWER: Yes, I do.

20 "QUESTION: Is it your understanding that Exhibit 33
21 was submitted to the FDA in connection to the Duobrii® IND?

22 "ANSWER: Yes.

23 "QUESTION: If you go to Page 2 of Exhibit 33.

24 "ANSWER: Okay.

25 "QUESTION: Is it correct that you electronically

1 signed Exhibit 33?

2 "ANSWER: That is correct.

3 "QUESTION: And at the top of Page 2 of Exhibit 33,
4 there's a heading labelled 'Certification
5 Statement-Information.

6 "Do you see that?

7 "ANSWER: Yes, I do.

8 "QUESTION: And do you see, under that heading, there
9 is a NCT number listed?

10 "ANSWER: Yes, I see that.

11 "QUESTION: And is it correct that Exhibit 33 lists
12 NCT 02045277?

13 "ANSWER: That is correct. That's what I see on the
14 form as well.

15 "QUESTION: Do you have an understanding of what that
16 refers to?

17 "ANSWER: So, yes. I understand, that NCT number
18 refers to a clinical study that is listed on
19 ClinicalTrials.gov.

20 "QUESTION: If we go back to Exhibit 33. At the
21 bottom of the first page of Exhibit 33, there is a heading
22 titled 'Certification Statement.'

23 "Do you see that?

24 "ANSWER: Yes, I do.

25 "QUESTION: And do you see that the third box from

1 the top has been crossed out?

2 "ANSWER: Yeah. I see that, yeah, C has been
3 checked, yes.

4 "QUESTION: And Box C is associated with the
5 statement: I certify that the requirements of 42 U.S.C.,
6 Section 282(j), Section 402(j) of the Public Health Service
7 Act apply to one or more of the clinical trials referenced in
8 the application-submission which this certification
9 accompanies and that those requirements have been met.

10 "Do you see that?

11 "ANSWER: Yes, I do.

12 "QUESTION: Do you have an understanding of what the
13 requirements referred to in that statement are?

14 "ANSWER: Yes, I do understand.

15 "QUESTION: And what is that understanding?

16 "ANSWER: That if this form is accompanying
17 information about a clinical study, that needs to be uploaded
18 to ClinicalTrials.gov that it has been uploaded there.

19 "QUESTION: So is it fair to say that you certified
20 to the FDA that information regarding Study V01-118A-201 was
21 submitted to ClinicalTrials.gov?

22 "ANSWER: That would be correct.

23 "QUESTION: How did you determine that the
24 information regarding Clinical Study V01-118A-201 had been
25 uploaded to ClinicalTrials.gov?

1 "ANSWER: By taking this NCT number that was provided
2 and searching in ClinicalTrials.gov."

3 (Video concluded.)

4 MS. PITZEL CRUZ: Your Honor, we would respectfully
5 ask to admit three of the exhibits that were played during the
6 deposition testimony: DX-063, DX-066 and DX-115.

7 MR. STEINDLER: No objection.

8 THE COURT: They're admitted into evidence.

9 (Exhibit Number DX-063 is received in evidence.)

10 (Exhibit Number DX-066 is received in evidence.)

11 (Exhibit Number DX-115 is received in evidence.)

12 MS. PITZEL CRUZ: Thank you.

13 And with that, defendants rest their invalidity case
14 in chief.

15 THE COURT: Very good.

16 All right. Is Bausch ready to proceed?

17 MR. STEINDLER: Yes, Your Honor.

18 But before we do, I'd like to make a Rule 52(c)
19 motion for --

20 THE COURT: Okay.

21 MR. STEINDLER: -- partial judgment. If you'll --
22 with your permission, I'll -- it'll take two minutes to
23 explain. It's very simple.

24 You have the command here, sir?

25 So in Dr. Michniak's -- strike that. Let me start

1 over from the beginning.

2 The motion that we're making pertains to just the
3 Bryhali® patents. And the argument is that the defendants
4 have failed to prove invalidity of the Bryhali® patents.

5 You just heard testimony from Dr. Michniak-Kohn about
6 the formulation limitations of the Bryhali® patents, and she
7 said the formulation limitations of the Bryhali® patents would
8 be obvious based on these four combinations of the prior art.

9 But when she went into her actual analysis of the
10 individual claims, she didn't apply any of those combinations.

11 What she supplied was, if you can see on the
12 left-hand side, those are the four combinations that she said
13 she was going to assert. But on the right-hand side, she's
14 got a whole jungle of different combinations that she
15 presented.

16 She never presented an analysis of the claims based
17 on the combinations of the patents that she said she was going
18 to rely on.

19 And for that reason there's a failure -- an entire
20 failure of proof. She hasn't presented the analysis she said
21 she was going to present and upon which she bases her
22 conclusions.

23 That's our motion, Judge.

24 THE COURT: Okay. Thank you.

25 Decision reserved. I'm sure you're surprised.

1 MR. STEINDLER: No, understood.

2 MS. WEISBRUCH: Your Honor, before Bausch calls its
3 first witness on rebuttal, we have a fairly long list of
4 exhibits that I am told there are no objections to. But I
5 need to read them into the -- or read them out with the
6 Court's permission.

7 THE COURT: Don't be offended if I close my eyes.

8 MS. WEISBRUCH: No offense will be taken.

9 And I will try to read these slowly so as not to
10 inundate the poor court reporter.

11 The list of exhibits is JTX-5-2, JTX-6-4, JTX-11-4,
12 JTX-12-2, JTX-12-6, JTX-12-12, PTX-43, PTX-44, PTX-54, PTX-73,
13 PTX-85, PTX-86, PTX-87, PTX-104, PTX-122, PTX-138, PTX-143,
14 PTX-212, PTX-216, PTX-219, PTX-222, PTX-223, PTX-224, PTX-307,
15 PTX-333, PTX-354, PTX-356, PTX-358, PTX-363, PTX-367, PTX-368,
16 PTX-372, PTX-376, PTX-383, PTX-396, PTX-447, DX-8, DX-64,
17 DX-127, DX-139, DX-150, DX-196, DX-505, DX-506, DX-507.

18 THE COURTROOM DEPUTY: All in evidence?

19 THE COURT: All admitted into evidence.

20 (Exhibit Number JTX-5-2 is received in evidence.)

21 (Exhibit Number JTX-6-4 is received in evidence.)

22 (Exhibit Number JTX-11-4 is received in evidence.)

23 (Exhibit Number JTX-12-2 is received in evidence.)

24 (Exhibit Number JTX-12-6 is received in evidence.)

25 (Exhibit Number JTX-12-12 is received in evidence.)

1 (Exhibit Number PTX-43 is received in evidence.)
2 (Exhibit Number PTX-44 is received in evidence.)
3 (Exhibit Number PTX-54 is received in evidence.)
4 (Exhibit Number PTX-73 is received in evidence.)
5 (Exhibit Number PTX-85 is received in evidence.)
6 (Exhibit Number PTX-86 is received in evidence.)
7 (Exhibit Number PTX-87 is received in evidence.)
8 (Exhibit Number PTX-104 is received in evidence.)
9 (Exhibit Number PTX-122 is received in evidence.)
10 (Exhibit Number PTX-138 is received in evidence.)
11 (Exhibit Number PTX-143 is received in evidence.)
12 (Exhibit Number PTX-212 is received in evidence.)
13 (Exhibit Number PTX-216 is received in evidence.)
14 (Exhibit Number PTX-219 is received in evidence.)
15 (Exhibit Number PTX-222 is received in evidence.)
16 (Exhibit Number PTX-223 is received in evidence.)
17 (Exhibit Number PTX-224 is received in evidence.)
18 (Exhibit Number PTX-307 is received in evidence.)
19 (Exhibit Number PTX-333 is received in evidence.)
20 (Exhibit Number PTX-354 is received in evidence.)
21 (Exhibit Number PTX-356 is received in evidence.)
22 (Exhibit Number PTX-358 is received in evidence.)
23 (Exhibit Number PTX-363 is received in evidence.)
24 (Exhibit Number PTX-367 is received in evidence.)
25 (Exhibit Number PTX-368 is received in evidence.)

1 (Exhibit Number PTX-372 is received in evidence.)

2 (Exhibit Number PTX-376 is received in evidence.)

3 (Exhibit Number PTX-383 is received in evidence.)

4 (Exhibit Number PTX-396 is received in evidence.)

5 (Exhibit Number PTX-447 is received in evidence.)

6 (Exhibit Number DX-8 is received in evidence.)

7 (Exhibit Number DX-64 is received in evidence.)

8 (Exhibit Number DX-127 is received in evidence.)

9 (Exhibit Number DX-139 is received in evidence.)

10 (Exhibit Number DX-150 is received in evidence.)

11 (Exhibit Number DX-196 is received in evidence.)

12 (Exhibit Number DX-505 is received in evidence.)

13 (Exhibit Number DX-506 is received in evidence.)

14 (Exhibit Number DX-507 is received in evidence.)

15 MS. WEISBRUCH: With that, Bausch calls Dr. Majella

16 Lane.

17 DR. MAJELLA LANE, PLAINTIFF'S WITNESS,

18 having been duly sworn, testifies as follows:

19 THE COURTROOM DEPUTY: Please state your full name
20 for the record.

21 THE WITNESS: Majella Eileen Lane.

22 THE COURTROOM DEPUTY: Please spell your first,
23 middle and last name.

24 THE WITNESS: First one is Majella, M-A-J-E-L-L-A.
25 Second one, Eileen, E-I-L-E-E-N. And my surname, L-A-N-E.

1 THE COURTROOM DEPUTY: Thank you.

2 DIRECT EXAMINATION

3 BY MS. WEISBRUCH:

4 Q. Good afternoon, Dr. Lane.

5 A. Good afternoon.

6 Q. Could you please introduce yourself to the Court?

7 A. Yes. So I've just told you I am Majella Lane. And I'm
8 associate professor at University College London and I'm also
9 the director of the skin research group at University College
10 London.

11 Q. Why are you here today, Dr. Lane?

12 A. So I'm here today to respond to the opinions that
13 Dr. Michniak-Kohn has offered in relation to validity of the
14 asserted claims of the patents that we are here to discuss.

15 Q. How long have you worked as an associate professor and
16 director of the skin research group at the University College
17 in London?

18 A. 17 years.

19 Q. And what are your responsibilities in those positions?

20 A. So, as an associate professor, I have to conduct
21 teaching, I have to conduct research, and I have to take on a
22 certain amount of administration. But I try to focus on
23 research.

24 Q. What type of research do you focus on?

25 A. So my research is focused on topical formulations, and

1 specifically with reference to the skin, the nails and other
2 mucous membranes.

3 So the goal of my research is to develop safe and
4 effective medicines for treatment of diseases of the skin, the
5 nails and other mucous membranes.

6 Q. Could you please describe your educational background for
7 the Court?

8 A. Sure. So I have a bachelor's degree in pharmaceutical
9 science, as you see here, and a Ph.D. also in pharmaceutical
10 science from Trinity College Dublin in Ireland.

11 Q. And throughout your career, have you ever had occasion to
12 work for or with any pharmaceutical companies as a consultant?

13 A. Yes. Some of the companies would be familiar to the
14 Court, like GlaxoSmithKline, Pfizer, AstraZeneca.

15 But there are also smaller companies that the Court
16 might not be so familiar with that are focused on topical
17 formulation.

18 THE COURT: Okay. Now, we have her CV. Let's mark
19 it for identification and then go into the evidence.

20 MS. WEISBRUCH: Yes, Your Honor.

21 THE COURT: Okay. What are you offering the doctor
22 as an expert on?

23 MS. WEISBRUCH: Dr. Lane is offered as an expert in
24 the field of topical pharmaceutical formulations including
25 development and testing of topical pharmaceutical

1 formulations.

2 THE COURT: Okay. Are there any objections to her
3 being deemed an expert in this area?

4 MS. PITZEL CRUZ: No objections, Your Honor.

5 THE COURT: Doctor, I am certain that you are an
6 exalted, esteemed expert in this field. You're deemed an
7 expert just like every other expert in this case has been
8 deemed an expert.

9 THE WITNESS: Thank you, Your Honor.

10 THE COURT: Now let's move to the testimony.

11 MS. WEISBRUCH: Yes, Your Honor. And I will just
12 make one note for the record that Dr. Lane's CV is in evidence
13 as PTX-85.

14 BY MS. WEISBRUCH:

15 Q. What's your role in this case, Dr. Lane?

16 A. So I understand that my role is to respond to specific
17 arguments that Dr. Michniak-Kohn has made about the validity
18 of the claims that are at issue in this case.

19 Q. And were you asked to evaluate two sets of patents?

20 A. Yes. The patents that I was asked to evaluate fall into
21 two sets. The first group are the '307 patent and the '502
22 patent, which we are calling the Bryhali® patents.

23 And the second set of patents are the '895 patent and
24 the '787 patent, which we're calling the Duobrii® patents.

25 Q. And if I could just make it easier for us to discuss

1 today, the '307 patent is JTX-1, the '502 patent is JTX-4, the
2 '895 patent is JTX-2, and the '787 patent is JTX-3.

3 Dr. Lane, at a high level, could you please describe
4 the subject matter of the Bryhali® patents?

5 A. Sure. So the Bryhali® patents describe topical
6 formulations of a superpotent corticosteroid. It's formulated
7 at a low concentration, but it still is as effective as other
8 topical corticosteroid formulations that contain higher
9 concentrations of the same drug.

10 Q. And at a high level, could you describe the subject
11 matter of the Duobrii® patents, please?

12 A. Yes. So turning to the Duobrii® patents, these are
13 combination products.

14 So combination products contain two drugs, generally.
15 And the Duobrii® patents contain a topical corticosteroid but
16 also a retinoid. And again, this is for the treatment of
17 psoriasis.

18 Q. In rendering your opinions on these patents, what
19 materials did you consider?

20 A. So I looked at the patents, the specification to the
21 patents, the prosecution history, the claims. I carefully
22 reviewed Dr. Michniak-Kohn's report and all the references
23 that she cited in her report.

24 And I also had other references that I use either in
25 my teaching or as part of my work.

1 And, finally, I rely on my own experience as a
2 formulator.

3 Q. Could you please summarize your opinions relating to the
4 validity of the Bryhali® patents?

5 A. Sure. I have a slide to help us with that.

6 So here I show you the summary of my opinions in
7 relation to the Bryhali® patents.

8 So it's my opinion that the asserted claims of the
9 Bryhali® patents would not have been obvious to a person of
10 skill in the art.

11 I considered that Dr. Michniak-Kohn's analysis that
12 involves picking and choosing from old references.

13 I don't believe that a person of skill in the art
14 would actually have been motivated to select and combine these
15 prior art references to arrive at the formulations of the
16 asserted claims of the Bryhali® patents.

17 I also consider that a person of skill in the art
18 would not have a reasonable expectation of success in
19 combining the prior art references to arrive at the claimed
20 invention.

21 And, finally, it is my opinion that the term "liquid
22 oil component" is not indefinite.

23 Q. What claims of the '307 patent did you consider in
24 rendering your analysis?

25 A. So if we can look at the slide I have prepared here.

1 The asserted claims of the '307 patent that we are
2 considering include the highlighted claims, Claims 13, 16 and
3 20.

4 Q. And what is the priority date of the '307 patent?

5 A. So we see here that the priority date of the patent is
6 November 22nd, 2010.

7 Q. What claims of the '502 patent did you consider in your
8 analysis?

9 A. So again, we have a slide to help us with that.

10 And so here I show you that the asserted claims I'm
11 considering are Claims 4 and 16 in relation to the '502
12 patent.

13 Q. What is the priority date of the '502 patent?

14 A. The priority date is November 22nd, 2010.

15 Q. Are there any differences between the '307 and the '502
16 patents?

17 A. The claims of each patent are different, but they share a
18 common specification.

19 Q. At a high level, could you please summarize your opinions
20 relating to the validity of the Duobrii® patents?

21 A. Yes. And again, we see my opinions on this slide.

22 So I analyzed the formulation limitations of the
23 Duobrii® claims. And it is my opinion that the formulations
24 of the asserted claims of the Duobrii® patents would not have
25 been obvious to a person of skill in the art. And I've

1 highlighted the formulation limitations in blue.

2 Q. What claims of the '895 patent did you consider in your
3 analysis of the Duobrii® patents?

4 A. Let's take a look at the next slide, please.

5 So the claims of the '895 patent that I considered in
6 my analysis are shown here, Claims 3 and 6.

7 Q. What is the priority date of the '895 patent?

8 A. June 18, 2015.

9 Q. What claims of the '787 patent did you consider in your
10 analysis?

11 A. So we can see those claims on my next slide.

12 So here I have highlighted the claims, Claims 4, 5
13 and 7.

14 Q. What is the priority date of the '787 patent?

15 A. June 18, 2015.

16 Q. Are there any differences between the '895 and '787
17 patents?

18 A. So the patents share a common specification but have
19 different claims.

20 Q. Dr. Lane, in rendering your opinions in this case, did
21 you apply a definition of a person of skill in the art?

22 A. Yes, I did.

23 Q. What definition of person of skill in the art did you
24 apply?

25 A. So I show that on my next slide.

1 So my definition of a person of skill in the art is
2 shown here with Bausch.

3 So I believe it's a person with several years of
4 experience working in the design and evaluation of
5 formulations for a topical treatment of diseases of the skin.

6 And I believe that person would have an advanced
7 degree, such as a Ph.D. or an M.D., and at least two to three
8 years of postgraduate experience studying and treating skin
9 diseases in dermatology or a related field.

10 But the person of skill in the art could also have a
11 bachelor's degree in a suitable field, such as chemistry,
12 pharmaceutical chemistry, pharmacy; and they would have more
13 years of experience in designing, developing, evaluating and
14 testing pharmaceutical formulations for the treatment of skin
15 diseases.

16 Q. What definition of a person of skill in the art do you
17 understand Dr. Michniak-Kohn to be applying in this case?

18 A. So I have shown Dr. Michniak-Kohn's definition here
19 alongside my definition. And it does differ from my
20 definition because it considers that the person of skill in
21 the art would have worked as part of a multidisciplinary team.
22 I would have included persons with different expertise in
23 different disciplines.

24 Q. Would any of your opinions that you've offered in this
25 case change under Dr. Michniak-Kohn's definition of a person

1 of skill in the art?

2 A. I don't believe there would have been any difference in
3 my opinions if I had adopted Dr. Michniak-Kohn's definition.

4 Q. You stated just a few minutes ago that it was your
5 understanding Bryhali® patents each have a priority date of
6 November 22nd, 2010, right?

7 A. Yes.

8 Q. So in your analysis of the validity of the Bryhali®
9 patents, did you consider references that were available prior
10 to that date?

11 A. Yes. I considered references before that date in my
12 analysis.

13 Q. And before we go to the specific references that
14 Dr. Michniak-Kohn was talking about, let's talk a little bit
15 about formulation science more generally.

16 What types of challenges does a formulation scientist
17 face when developing a new topical pharmaceutical formulation?

18 A. So formulation science is very challenging anyway. But
19 when it comes to the skin, I'm afraid we have a much bigger
20 problem because the skin evolved to keep things out, not to
21 let things in.

22 And as I've tried to explain here, a formulation of a
23 topical product can greatly impact drug delivery.

24 And as we see here, the formulation makes all the
25 difference in the delivery of the drug.

1 So formulation science is unpredictable. It's
2 rigorous. It requires trial and error experimentation. There
3 are no predictable outcomes in this field.

4 Another part of the problem is the vehicle itself can
5 affect the skin. So with no drug in the vehicle, it can still
6 have some effects on the skin that you may not want.

7 And here, again, I'm trying to explain that there are
8 a number of interactions that you have to think about when
9 you're a topical formulator.

10 So what are those interactions?

11 So the interaction with the drug and the vehicle has
12 to be considered. So the vehicle is the carrier. So the
13 interaction with the vehicle and the skin has to be
14 considered.

15 And we know that the drug and the skin can have
16 issues as well that may need to be tested.

17 And, finally, there's the vehicle/drug/skin interplay
18 that you also have to consider when you're trying to develop
19 an effective and safe topical formulation.

20 Q. Just to be clear, for those of us who are not formulation
21 scientists, when you refer to a "vehicle," what do you mean by
22 that?

23 A. When we make a medicine, we don't just give the drug. So
24 the vehicle is everything we add to the drug to make it
25 suitable to the patient.

1 So today, we're here to talk about halobetasol, a
2 corticosteroid, but, obviously, we can't put that drug
3 directly on the skin. So to make it suitable for application
4 and to make it safe and effective, we build an appropriate
5 vehicle around it.

6 Q. And just speaking generally, how would a person of skill
7 in the art come to discover how effective any -- strike that.

8 Speaking generally, how would a POSA come to discover
9 how effective any particular vehicle is at delivering drug to
10 the skin?

11 A. So as I have stated, it is an unpredictable field,
12 requiring testing at every stage. And so as I've stated on my
13 slide, these four interactions that I've just discussed are
14 unpredictable, and they do require testing at every stage to
15 determine how a particular combination of active ingredients
16 or drugs and the vehicle and the components of the vehicle
17 will work together.

18 Q. How would a POSA go about selecting ingredients for a
19 vehicle?

20 A. So it's true to say that there are many ingredients
21 available to a person of skill in the art and I think I've got
22 a slide to help you with that.

23 Okay. So there are many ingredients, and I hope the
24 *Handbook of Pharmaceutical Excipients* is still somewhere
25 around, because that's just one textbook that describes

1 hundreds of excipients.

2 So that means that we have lots of options available
3 to us, but there's no direct pathway to tell us which
4 ingredient or excipient to select.

5 So not just the textbook we saw earlier today in
6 court, there are a huge range of textbooks, reference sources,
7 databases that we can consult.

8 But even having all that information at your disposal
9 doesn't mean that you have a guideline or framework to take
10 you to a particular formulation. And so, of course,
11 formulation development almost always involves working with
12 excipients we know and testing them. So they may have been
13 around for a long time, but that doesn't mean we have an
14 expectation that we can assemble them to make an effective and
15 safe medicine.

16 Q. Is there any such thing as a universal vehicle that can
17 be used to deliver any active to the skin?

18 A. So, again, I have another slide to help you with that.

19 So this is a table from one of the textbooks I use in
20 my teaching of undergraduate students back in London, and it's
21 really trying to explain why the formulation of topical
22 formulations for application to the skin is actually an
23 unpredictable art.

24 So there are a number of criteria that the
25 formulation scientists has to think about when you're actually

1 developing a formulation, and sometimes those criteria are not
2 working together. They pose competing challenges for the
3 formulation scientist.

4 So we can start by thinking about the drug stability,
5 the stability of the excipients and other properties of our
6 formulation.

7 And then we have to think about our patient. You
8 know, we do want them to use our formulation because if they
9 don't use it, we won't have a good treatment outcome.

10 But, fundamentally, we must get the drug to the site
11 of action. So that's what I'm trying to explain in the last
12 caption there, Biopharmaceutical Criteria for Topical
13 Vehicles.

14 Our formulation must deliver enough of the drug at
15 the right rate to achieve therapeutic outcome for our patient.

16 Q. And the table that you've identified on the slide here,
17 you said that came from a textbook?

18 A. Yes. And the textbook was authored by Professor Howard
19 Maibach and Robert Bronaugh, and this is a book chapter taken
20 from the textbook and the author is Dr. Eric Smith.

21 MS. WEISBRUCH: I'll just note for the record that
22 it's noted on Dr. Lane's slide as PTX-307.

23 BY MS. WEISBRUCH:

24 Q. Dr. Lane, in your view, is Dr. Smith's list at Table 2
25 complete?

1 A. Well, Dr. Smith put this table together some years ago.
2 And in the intervening years, I believe I've identified, and
3 other researchers, have identified other factors that we need
4 to think about when developing a topical formulation.

5 Q. Do you have an example?

6 A. Sure.

7 So for many years, we understood that even if you
8 apply formulation on the skin, some of the drug gets stuck on
9 the skin; so it crystalizes on the skin. So for the last five
10 years or so, we have found methods to show that the drug
11 actually gets stuck in the skin or it crystallizes out in the
12 skin as well. So that's a pretty new development.

13 And then, of course, what you apply on the skin, what
14 you squeeze out of the tube and you rub it in, that is very
15 different as it dries down and evaporates. So we've also
16 developed methods to try and study how that influences the
17 performance of our vehicle.

18 Q. Did Dr. Smith have anything else to say about the factors
19 a formulator takes into account when designing a formulation
20 vehicle?

21 A. Sure. And, again, I've tried to explain that on my next
22 slide.

23 So what Dr. Smith is telling us here is it's not just
24 science. Topical formulation development is actually an art
25 that is gleaned by your own personal experience as a

1 formulator. And he's gone on to explain his views on that in
2 the conclusion to this same chapter we're talking about.

3 So really, the important point I think I would make
4 is the sentence: Due to this complexity, no uniform and
5 comprehensive recommendations and guidelines are available for
6 the development and the use of semisolid formulations.

7 THE WITNESS: If we could go to the next box. I
8 mean, this really, for me, encapsulates the problems we face
9 and the unpredictability of the field.

10 Although we might wish to have a universal vehicle,
11 there is no one-size-fits-all approach. So each drug at each
12 concentration requires a unique vehicle.

13 BY MS. WEISBRUCH:

14 Q. Dr. Lane, do you agree with Dr. Smith's characterization
15 dermatological vehicle treatment as more art than science?

16 A. That's certainly been my experience in the field over the
17 last 25 years.

18 Q. Now, let's shift gears a little bit and talk about the
19 state of the art for superpotent corticosteroid treatments for
20 psoriasis as of 2010.

21 At that time, were there any commercially available
22 superpotent corticosteroid treatments for psoriasis?

23 A. Yes. And we see a number of superpotent corticosteroid
24 preparations that were available for topical psoriasis prior
25 to 2010 on this slide.

1 We've heard today, and on the first day of trial,
2 about Ultravate®. So we see that product, Ultravate® Cream,
3 Ultravate® Ointment, and that is halobetasol propionate at a
4 concentration of 0.05 percent.

5 And we also heard about Temovate® Cream, and that's a
6 different superpotent corticosteroid. And, again, in
7 Temovate® Cream, it's present at a concentration of
8 0.05 percent.

9 Q. Do you know of any commercially available options for
10 superpotent corticosteroid treatments for psoriasis available
11 prior to -- in or before 2010 that contained a concentration
12 of 0.05 percent -- strike that whole question.

13 Did any of the commercial options that were available
14 in 2010 for superpotent corticosteroid treatment of psoriasis
15 contain a concentration of steroid that was less than
16 0.05 percent?

17 A. So as I've explained on the slide, none of these
18 commercial options that were available in 2010 contained
19 concentrations of corticosteroid at less than 0.05 percent, as
20 described in the Bryhali® patent.

21 Q. So you mentioned Ultravate®. Let's talk about Ultravate®
22 for a minute.

23 What is Ultravate®?

24 A. So we were just looking at Ultravate® ointment and cream.
25 So it contains a superpotent corticosteroid, halobetasol

1 propionate, at a concentration of 0.05 percent.

2 It was regarded as the gold standard halobetasol
3 product. However, the use of Ultravate® was limited to two
4 weeks, and the vehicle is different from the carrier that is
5 described in the Bryhali® patent.

6 Q. On that last point, does Ultravate® use a dicarboxylic
7 acid ester vehicle?

8 A. It does not.

9 Q. You also mention that Ultravate® was the gold standard.
10 Can you explain what you mean by that?

11 A. Yes.

12 So Ultravate® had an acceptable balance of safety,
13 efficacy and side effects, and it was accepted by physicians
14 for treatment of their patients. Clearly, it had been
15 approved by the FDA, and it had been tested in clinical trials
16 here in the United States.

17 Q. You also said on your slide that Ultravate®'s use was
18 limited to two weeks. And you've identified a statement to
19 this effect from PTX-87, which is the Ultravate® Label.

20 Why was Ultravate®'s use limited to two weeks?

21 A. Because the superpotent corticosteroids have a side
22 effect that if they are absorbed all the way through the skin
23 into the blood supply, they can cause this problem of
24 hypothalamic-pituitary-adrenal axis suppression. So that
25 actually means it's disrupting the patient's ability to

1 produce their own cortisol, and it can trigger a whole load
2 of --

3 (Reporter clarification.)

4 THE WITNESS: It can disrupt the patient's own
5 cortisol production.

6 BY MS. WEISBRUCH:

7 Q. Why was this a problem for the treatment of psoriasis?

8 A. Because if you know any patients with psoriasis, it's a
9 very serious disease that has a powerful effect on the quality
10 of life of patients. Skin diseases really bother patients.
11 But psoriasis does not just last for two weeks; it lasts for
12 longer. And even if you clear it, it will come back.

13 Q. I think you also mentioned Temovate E® earlier.

14 Is that right?

15 A. Yes.

16 Q. What is Temovate E®?

17 A. So as we mentioned a few slides back, Temovate E® is also
18 a formulation that contains a superpotent topical
19 corticosteroid. In this case, it's clobetasol propionate;
20 again, at a concentration of 0.05 percent. It was available
21 since 2000, and its use was limited to two weeks, but the
22 two-week limitation could be extended to four weeks if the
23 patient was careful to restrict how much of the body surface
24 area they applied the formulation to.

25 Q. What was the purpose of restricting the body surface

1 area?

2 A. If you restrict body surface area you are, in effect,
3 restricting the exposure of the patient to the problem of the
4 drug getting all the way into systemic circulation in a
5 suitable concentration to cause this HPA axis disruption.

6 So it's a way of trying to manage the side effect
7 profile of the superpotent corticosteroids.

8 Q. And in addition to halobetasol and clobetasol, which
9 we've now talked about, are there other superpotent
10 corticosteroids?

11 A. Yes, there are.

12 So we can see them on this table. There were five
13 superpotent corticosteroids listed. And this is the
14 background in the Bryhali® patent, and it shows you that there
15 are five superpotent corticosteroids. I won't read out all
16 the names as they're shown here on the table.

17 Q. Just for the record, you're referring to Table 1 of the
18 '307 patent, which is JTX-1.

19 Is that right?

20 A. Yes.

21 Q. So for these 0.05 percent superpotent corticosteroid
22 formulations, their use was limited to two weeks for all of
23 these. Is that right?

24 A. Correct.

25 Q. In your opinion, would a person of skill in the art in

1 2010 have thought to experiment with a lower concentration of
2 corticosteroid in order to reduce the side effects that were
3 associated with those high concentration formulations?

4 A. Yes. So the common wisdom at the time was if you
5 decrease the concentration of a drug in a formulation, you
6 would compromise the efficacy. So you would be worried that
7 this would not be as effective as the formulation with the
8 higher dose concentration. So if you decrease concentration,
9 you decrease efficacy.

10 And because of that, I do not believe that a person
11 of skill in the art, in 2010, would have been motivated to
12 decrease the concentration because we want our medicines to
13 work. We do not want to decrease their efficacy.

14 Q. What support do you have for the premise that decreasing
15 the concentration will generally correspond with a decrease in
16 efficacy?

17 A. Yes. So on this slide, this is taken from the background
18 to the '307 patent. And it's a table that shows you the
19 potency of different types of corticosteroids.

20 So if we start at the top with the superpotent
21 corticosteroids, we have a drug called fluocinonide, and
22 that's there at a concentration of 0.1 percent. So that's the
23 most potent, the superpotent.

24 Now let's look at the same drug, fluocinonide, in the
25 next class, which are the potent corticosteroids. So not as

1 powerful as the superpotent corticosteroids. And now you see
2 we are at a concentration of 0.05 percent. So that has moved
3 this drug into a less potent category.

4 And, again, moving into a lower potency category,
5 upper mid strength, here the formulation means that this,
6 again, the same drug, is now less effective. It's less potent
7 even though it's at a concentration of 0.05 percent.

8 And the last box I'm showing you is the mild category
9 of corticosteroids. So we see a tenfold drop in concentration
10 compared to where we started with a superpotent
11 corticosteroids.

12 So that tenfold drop in concentration has moved this
13 drug all the way down from being a superpotent corticosteroid
14 to what is classified as a mild corticosteroid.

15 Q. What other support do you have for the idea that
16 decreasing the concentration will generally correspond with a
17 decrease in efficacy?

18 A. So, again, if we take a look at my slide here, this is
19 the Blum study, and it shows that 0.02 percent halobetasol
20 ointment is less effective than 0.05 percent halobetasol
21 ointment, and this is the statement that the clinicians who
22 ran the study made towards the end of their study.

23 In the treatment of severe chronic psoriasis
24 vulgaris, the ointment with the lower concentration,
25 0.02 percent, and that's halobetasol, that code name, was less

1 effective than that with a concentration of 0.05 percent, and
2 it was also less effective than the commercial clobetasol
3 ointment available at the time.

4 Q. Did you hear Dr. Michniak-Kohn's testimony earlier today
5 about the Gao paper?

6 A. I did, yes.

7 MS. WEISBRUCH: And I'll just note for the record
8 that you've identified Gao as DX-196 on your slide.

9 BY MS. WEISBRUCH:

10 Q. Dr. Michniak-Kohn's opinion of Gao is that different
11 concentrations of the same steroid can exhibit a similar
12 pharmacodynamic response.

13 (Reporter clarification.)

14 Q. Dr. Michniak-Kohn says that the Gao paper shows different
15 concentrations of the same corticosteroid may exhibit a
16 similar pharmacodynamic response.

17 Is that your understanding of Dr. Michniak-Kohn's
18 position on the Gao paper?

19 A. No. I mean, first of all, I think we have to realize
20 this is an old paper in the field of topical formulation. So
21 that's important. And I will go on to explain why that's the
22 case.

23 But what are the findings of this paper?

24 In fact, Gao notes that when you lower the
25 concentration, there is a trend towards lesser activity. So

1 Gao reflects the expectation that a POSA would have: a
2 reduction in concentration will cause a decrease in efficacy.

3 And the authors actually tells us the intuitive
4 expectation is that dilution will reduce the activity or the
5 efficacy of the corticosteroid formulation.

6 But very tellingly, Gao tells us their own data is
7 not reliable. And part of the problem is the study design.

8 So what's the problem?

9 The need to occlude for several hours means that
10 blanching at the early time points was not measurable. In any
11 case, the early results tended to be erratic. The sustained
12 activity of the steroids makes volunteer trials difficult to
13 arrange.

14 So that's a major problem in how these authors
15 conducted the study. And, of course, it has a very important
16 bearing on the results reported.

17 So we can't take this paper as telling us anything
18 really about saying less -- you know, that you can lower the
19 concentration and still maintain activity. That is not the
20 teaching of this paper.

21 Q. And what steroid was tested in Gao?

22 A. Fluocinolone.

23 Q. Is fluocinolone a superpotent corticosteroid?

24 A. It is not.

25 Q. As of 2010, what methods were being used to improve

1 topical corticosteroid treatments?

2 A. So here I show you some of the common approaches to
3 improve formulations of topical corticosteroids that would
4 have been available to a person of skill in the art in 2010.

5 So several of the references that were cited by
6 Dr. Michniak-Kohn, including the '295 patent, the '566 patent,
7 and the JP '228 patent application that was unpublished,
8 are -- sorry, unexamined -- are addressed to formulations
9 which are penetration enhancers for the topical
10 corticosteroids.

11 So if we start with the '566 patent, this teaches the
12 use of dibutyl adipate with isopropyl myristate or dibutyl
13 adipate alone as penetration-enhancing agents.

14 And the inventor explains that he will achieve the
15 objective of the invention by employing an effective amount of
16 dibutyl adipate or a mixture of dibutyl adipate and isopropyl
17 myristate as the penetration-enhancing agent.

18 We also see in the '295 patent that there is an
19 effort to develop formulations for percutaneous delivery, so
20 delivery all the way through the skin.

21 And throughout the JP '228 Publication, the inventors
22 tell us that they need to solve the problem of prior topical
23 formulations of corticosteroids because the problem was these
24 formulations showed inadequate transdermal absorption. So
25 transdermal, all the way through the skin.

1 Q. Why are -- strike that.

2 Given the risk of systemic absorption and side
3 effects that can result from sustained use of corticosteroids,
4 why are these references trying to push more steroid through
5 the skin and into systemic circulation?

6 A. So we have to come back to the fact that these are old
7 references.

8 Now, one reference was 1980, I think one of them was
9 1988 and the other was 1994. So that reflected the
10 understanding in the field that the way to succeed with your
11 formulation is to push it all the way through the skin.

12 But science moves on, especially the field of topical
13 formulation.

14 So since those 1980s and 1990s references, we
15 understand that our goal is actually more subtle than that.

16 To treat a skin disease, we have to try and localize
17 the drug in the skin. We do not want to push it all the way
18 through the skin.

19 So the inventors of the Bryhali® patents have
20 explained they want to achieve localized delivery. So to the
21 skin, not through the skin.

22 Q. And can you explain how the Bryhali® patents achieve that
23 goal?

24 A. Yes.

25 We have a slide to help us with that.

1 So as I said, the inventors of the Bryhali® patents
2 understood the need for localized delivery of the topical
3 corticosteroid. So they solved the problems of the prior art
4 in a different way.

5 So how do they do that?

6 So the formulation, the vehicle that carries the drug
7 into the skin, deliver the drug preferentially into the skin
8 rather than through the skin and into the systemic circulation
9 of the blood supply. We don't want our drug to go all the way
10 through the skin into the systemic circulation.

11 So these novel formulations allowed the inventors to
12 use a lower concentration of these superpotent
13 corticosteroids, such as halobetasol propionate, with the same
14 efficacy of the Ultravate® product. And remember, that had
15 0.05 percent halobetasol. And so that meant you could use the
16 formulations of the invention for a period longer than two
17 weeks.

18 MS. WEISBRUCH: If we could bring up Table 3 of the
19 '307 patent, please.

20 THE COURT: Can I interrupt for a second?

21 So am I correct in understanding your testimony being
22 that the traditional penetration enhancers that existed in the
23 art in the '80s and '90s would, in fact, have been
24 dysfunctional for the use of HP because they would tend to, in
25 fact, increase systemic absorption of HP?

1 THE WITNESS: So that's a really good question
2 because, you know, when people use the term "penetration
3 enhancers," right, sometimes they're not penetration enhancers
4 and sometimes they are. So that's one problem.

5 But as I said, back then, the field and scientists in
6 the field thought if we push it all through, then we are
7 making a super effective formulation. But that misses for
8 skin disease like eczema, psoriasis, rosacea. Your target is
9 in the skin, so you really want the drug to stay in the skin.

10 So you said, were they dysfunctional. It's very hard
11 to study penetration enhancers. We probably didn't have the
12 analytical techniques available to us. We do now, so that's
13 some of the stuff I do.

14 So I don't think -- you know, I wouldn't say they
15 were dysfunction. They were doing the best they could but,
16 you know, we have better science available now.

17 THE COURT: Thank you.

18 THE WITNESS: Thank you.

19 BY MS. WEISBRUCH:

20 Q. Did a commercial product result from the discovery that
21 is described the Bryhali® patents?

22 A. Yes. And we will see it on my next slide.

23 So Bryhali® is a commercial embodiment of the
24 Bryhali® patents. It's a topical lotion, and it's indicated
25 for the treatment of plaque psoriasis.

1 The active ingredient is halobetasol propionate at a
2 concentration of 0.01 percent. And the benefit, as I
3 explained in the previous slide, now with this lower
4 concentration of the superpotent corticosteroid, we have a
5 medicine that we can use for up to eight weeks.

6 Q. Did Bausch commercialize any other products that resulted
7 from the discovery described in the Bryhali® patent?

8 A. Yes. The other product was Duobrii®, and we will talk
9 about later in my slide.

10 Q. Did you review the prior art that Dr. Michniak-Kohn
11 relies on to reach her conclusions that the asserted claims
12 are obvious?

13 A. I did, yes.

14 Q. And at a high level, what is your view of
15 Dr. Michniak-Kohn's opinions?

16 A. So, first of all, I don't consider that the inventions of
17 the asserted claims would have been obvious to a person of
18 skill in the art in 2010.

19 Dr. Michniak-Kohn's presentation appears to be a
20 hindsight-driven analysis involving picking and choosing from
21 old references with the Bryhali® patents as a starting point.
22 And that's what I was trying to say about using old
23 references. This is a problem.

24 Real-world experience contradicts what actually
25 happened in the field, and it contradicts Dr. Michniak-Kohn's

1 analysis.

2 Q. Let's talk about some of those references.

3 Can you describe the references Dr. Michniak-Kohn
4 relies on?

5 A. Yes.

6 So Dr. Michniak-Kohn relies on combinations of five
7 references to support her opinion that the asserted claims of
8 the Bryhali® patents would have been obvious. So we see the
9 '295 patent from 1980, the Blum research study from 1986, the
10 '566 patent from 1994, the Japanese '228 document published in
11 1988, and the product information label for Temovate E® from
12 2000.

13 MS. WEISBRUCH: And if I could just make another note
14 for the record to, again, make it easier for us to talk about
15 these references, the '295 patent has been identified as DX-3;
16 Blum has been identified as DX-2; the '566 patent has been
17 identified as DX-4; JP '228 has been identified as DX-5; and
18 Temovate E® Label has been identified as DX-6.

19 BY MS. WEISBRUCH:

20 Q. Dr. Lane, could you describe your view of
21 Dr. Michniak-Kohn's analysis using these references?

22 A. Yes.

23 So we've just looked at the references, and it is my
24 opinion that Dr. Michniak-Kohn's analysis does not establish a
25 motivation to select the individual references or to pick the

1 claimed ingredients or excipients or concentrations from
2 within those references.

3 Again, I would like to emphasize that these are 20-
4 to 30-year old references that no other researchers thought to
5 combine. It actually includes references that teach away from
6 the invention of the Bryhali® patent.

7 Q. Let's take these one by one.

8 You started with the '295 patent?

9 A. Yes.

10 Q. Could you describe the '295 patent, please.

11 A. Yes.

12 So here we see the front page of the '295 patent, and
13 the publication date -- sorry, the year is 1980. That's
14 30 years prior to the priority date of the Bryhali® patents as
15 we saw earlier.

16 There are broad disclosures in the '295 patent. And
17 importantly, there is no specific reference to halobetasol
18 propionate. There's no specific reference to diethyl
19 sebacate. There's no specific reference to light mineral oil.
20 The concentration range is very broad when we consider the
21 very specific concentration of halobetasol in the Bryhali®
22 patents.

23 The '295 patent does not exclude formulations with
24 white petrolatum.

25 At the very beginning of the '295 patent, the authors

1 tell us that they want to achieve percutaneous absorption, so
2 delivery of the drug through the skin.

3 Q. And just to pick up on something you said, Dr. Lane, you
4 referred to a broad concentration range that's identified in
5 the '295 patent?

6 A. Yes.

7 Q. What is that concentration range?

8 A. I think we may have a slide to help us with that.

9 Q. I could also refer you to DX-2.

10 MS. WEISBRUCH: We can bring it up to the screen.

11 THE WITNESS: Okay. I think it's 0.01 to 3 percent,
12 but we better bring it up to make sure I'm not giving the
13 incorrect range.

14 MS. WEISBRUCH: It's DX-3. That was my mistake.

15 BY MS. WEISBRUCH:

16 Q. You have a copy in your binder.

17 A. Oh, thank you.

18 THE WITNESS: If we go to the last page of the
19 document, please.

20 Yes, go to the claims, please. Okay, great.

21 So if you can blow up Claim 1, please.

22 Great. So here you see a range of 0.001 to about 3
23 percent by weight of a corticosteroid, which is a very broad
24 range.

25 BY MS. WEISBRUCH:

1 Q. Would that range indicate to a person of skill in the art
2 that any corticosteroid could be used at any concentration
3 within that range?

4 A. Reading the patent and looking at that broad range, a
5 person of skill in the art would know you could not use any
6 topical corticosteroid in that range.

7 Q. Do the examples of the '295 patent focus on any
8 particular steroid?

9 A. They are focused on the topical corticosteroid called
10 halcinonide, and there's also another steroid but the chemical
11 name is quite complex. But there are really only two to three
12 steroids in the examples of that patent.

13 Q. Is halcinonide a superpotent corticosteroid?

14 A. It is not.

15 Q. You mentioned Blum earlier.

16 A. Yes.

17 Q. Could you describe Blum?

18 A. Yes, I have a slide, I believe, to help me with that.

19 Q. I can ask you a different question.

20 Does Slide Number PDX-3-30 reflect your understanding
21 of Dr. Michniak-Kohn's opinions on Blum?

22 A. Yes, this is Dr. Michniak-Kohn's slide when she was
23 talking about the Blum article today.

24 Q. What is the Blum article?

25 A. So the Blum article is describing the outcome of the

1 clinical study conducted on patients with psoriasis. It's
2 comparing three different topical corticosteroids
3 formulations. So it's comparing 0.02 percent ointment, a
4 0.05 percent ointment, and they are being compared with a
5 commercial Dermovate ointment.

6 As we see here --

7 THE WITNESS: We need to go back one slide, please.

8 Yes. So as we see here, the clinician who authored
9 the study noted in the treatment of severe chronic psoriasis
10 vulgaris, the ointment with the lower concentration,
11 0.02 percent halobetasol, was less effective than that with
12 the concentration of 0.05 percent and the commercial
13 Dermovate, which was a different superpotent topical
14 corticosteroid.

15 And again, I note that the authors state the
16 difference among the three groups that was not statistically
17 significant.

18 So Dr. Michniak-Kohn concluded that Blum discloses
19 that 0.02 percent halobetasol, 0.05 percent and Dermovate all
20 treated psoriasis, and differences among the three groups were
21 not statistically significant.

22 And she also noted that she considers that Blum
23 discloses that 0.02 percent halobetasol propionate was
24 effective in treating psoriasis.

25 BY MS. WEISBRUCH:

1 Q. And what is your response to Dr. Michniak-Kohn's opinions
2 on the Blum article?

3 A. So this is my own analysis of what the Blum study is
4 telling a person of skill in the art.

5 Blum would not lead a person of skill in the art to
6 the asserted claims of the Bryhali® patent. This study was
7 published in 1986, so that's 24 years before the priority date
8 of the Bryhali® patents.

9 There's actually nothing about formulations that were
10 being tested. So we know that these test formulations were
11 ointments, and we know the concentration of them.

12 But this study, in my opinion, teaches away from
13 using a 0.02 percent halobetasol preparation and actually
14 recommends the higher strength, 0.05 percent corticosteroid
15 preparation.

16 And the authors are quite effusive about the
17 findings. They tell us that 0.05 percent halobetasol would be
18 a welcome addition to the therapeutic armamentarium for
19 chronic localized severe skin diseases.

20 And they go on to reiterate their views that this is
21 a very promising formulation. They tell us that the
22 0.05 percent halobetasol ointment will provide a favorite
23 treatment weapon for skin disease. And they note that the
24 lower concentration, 0.02 percent halobetasol, was less
25 effective than the 0.05 percent. It was less effective than

1 the commercially available superpotent corticosteroid.

2 Q. You also mentioned the '566 patent earlier in your
3 testimony?

4 A. I did, yes.

5 Q. Could you describe the '566 patent, please?

6 A. Yes. So the '566 patent, in my opinion, does not lead a
7 person of skill in the art to the asserted claims of the
8 Bryhali® patent.

9 It's an old publication. It issued in 1994.

10 It's actually discussed in the specification of the
11 Bryhali® patents. There are no halobetasol compositions in
12 this patent at a concentration of less than 0.05 percent.

13 And we did see earlier that this patent is focused on
14 using penetration enhancers to drive the drug through the
15 skin. This is the opposite of the approach taken in the
16 Bryhali® patents.

17 There are two very specific oily solvents described
18 in the '566 patent. And the inventor tells us the present
19 invention relates to enhancement, as well as the control of
20 epidermal, dermal and transdermal penetration of various
21 topically applied preparations.

22 So again, this wish to achieve dermal and transdermal
23 penetration is stated elsewhere in the document.

24 We can substantially improve this, the invention is
25 telling us, by incorporating a compound into a composition

1 containing a dermal or transdermal penetration enhancing
2 amount of dibutyl adipate or a mixture of dibutyl adipate and
3 isopropyl myristate.

4 Q. The two specific oily solvents that you mention in your
5 slide, are those dibutyl adipate and isopropyl myristate?

6 A. Yes.

7 Q. Does the '566 patent disclose diethyl sebacate?

8 A. It does not.

9 Q. Does the '566 patent teach a person of skill in the art
10 to use a corticosteroid in combination with a dicarboxylic
11 acid ester other than dibutyl adipate?

12 A. It only teaches the person of skill in the art to use
13 dibutyl adipate.

14 Q. You also mention that the '566 patent is directed to
15 penetration enhancers on your slide -- in your testimony?

16 A. Yes.

17 Q. Are there any examples in the '566 patent that describe
18 enhanced penetration into the skin?

19 A. Yes. And this front page of the publication, you can see
20 a figure. And there's an X axis, which is time. And then
21 there's a Y axis, and that's describing the amount of drug
22 that is penetrated all the way through the skin.

23 So in these experiments, we clamp a piece of skin in
24 a special cell and we measure how much drug the formulation
25 drives through the skin.

1 So what you're seeing is that some of the
2 formulations are really driving a lot of the drug all the way
3 through the skin compared to some of the lower performing
4 formulations.

5 So that's a study we use when we're trying to test
6 what formulations do and how they deliver drug to the skin and
7 through the skin.

8 THE COURT: Do I understand you're saying that this
9 patent, in effect, teaches use of penetration enhancers, which
10 make it likelier that the active ingredient will be
11 systemically absorbed?

12 THE WITNESS: Yes, Your Honor. Because the inventor
13 says this is a very important achievement. He tells us we can
14 achieve systemic delivery in the document. I haven't shown
15 that, but it is in the patent.

16 THE COURT: Thank you.

17 BY MS. WEISBRUCH:

18 Q. Would a person of skill in the art be motivated to lower
19 the concentration of steroid in the test formulations
20 disclosed in the '566 patent based on the results that you've
21 just described?

22 A. This patent is all about penetration enhancement. I see
23 no motivation to lower the concentration of the
24 corticosteroid. The goal is systemic absorption.

25 Q. You also mentioned the JP '228 reference earlier in your

1 testimony?

2 A. Yes.

3 Q. Can you describe JP '228?

4 A. Sure. So JP '228 is an unexamined patent application
5 publication. It was published in 1988. It discloses only
6 generic corticosteroid structures. All the examples in this
7 publication are limited to a topical corticosteroid at a
8 concentration of 0.05 percent.

9 And the inventors tell us we have solved the problem
10 of inadequate transdermal absorption. So just as I said
11 earlier, they taught transdermal absorption is our goal and
12 our invention solves the problem of inadequate transdermal
13 absorption.

14 Q. You mentioned the generic corticosteroid structure that's
15 shown in JP '228?

16 A. Yes.

17 Q. And is that the chemical structure that's shown on your
18 slide PDX-3-33?

19 A. Yes, you see the structure towards the end of the slide.

20 Q. Would halobetasol propionate fall into the category of
21 corticosteroids encompassed by that chemical structure?

22 A. No, it does not.

23 Q. Do you know what category of steroids this structure is
24 describing?

25 A. I did search to try and identify what this corticosteroid

1 is, but I couldn't identify exactly what it is. Because it's
2 an old reference, it's possible it's just no longer available.

3 But it is -- to the best of my knowledge, it is not a
4 superpotent topical corticosteroid.

5 Q. Does JP '228 include any example formulations with a
6 concentration of steroid below 0.05 percent?

7 A. All the examples are limited to a concentration of
8 0.05 percent.

9 Q. Does JP '228 refer to a broad range of concentrations?

10 A. Yes. Again, if you look in the text, just above the
11 generic structure, we see that the steroid cream preparation
12 is characterized in that it contains 0.01 to 0.5 percent by
13 weight of the steroids.

14 So that's the range they're telling us about.

15 Q. Would that range indicate to a person of skill in the art
16 that the full range of the concentration could be used with
17 any steroid that falls within the steroid class shown in the
18 structure?

19 A. So a person of skill in the art would not take from that
20 statement that you could use any corticosteroid within that
21 range.

22 What you see in that patent are examples of
23 corticosteroids at concentrations of 0.05 percent.

24 Q. We've talked about Temovate E® this afternoon, and you've
25 also mentioned the Temovate E® Label in your earlier answer.

1 A. Yes.

2 Q. What is the Temovate E® Label?

3 A. So here we see the product information leaflet that you
4 get with the Temovate E® product.

5 So Temovate E® is a superpotent corticosteroid,
6 topical formulation. And this particular formulation teaches
7 an alternative approach to addressing the two-week limitation.
8 So that means you can actually use this formulation beyond two
9 weeks only if you limit the area of the body to which the
10 formulation is applied.

11 MS. WEISBRUCH: Your Honor, I'm told I have five
12 minutes left. Would the Court like me to continue?

13 THE COURT: If you're ready to take a break, I'm
14 ready to take a break.

15 MS. WEISBRUCH: We're here at your pleasure, Your
16 Honor.

17 THE COURT: We'll resume tomorrow.

18 MS. WEISBRUCH: Thank you, Your Honor.

19 THE COURTROOM DEPUTY: All rise.

20 (Proceedings concluded at 4:54 p.m.)

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FEDERAL OFFICIAL COURT REPORTER'S CERTIFICATE

I certify that the foregoing is a correct transcript
from the record of proceedings in the above-entitled matter.

/S/ Mary Jo Monteleone, RMR, CCR, CRCR
Official Court Reporter

10/06/2022
Date

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1 UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF NEW JERSEY

3 BAUSCH HEALTH IRELAND
4 LIMITED, et al.,

5 Plaintiff,

6 v.

7 PADAGIS ISRAEL
8 PHARMACEUTICALS LTD, et al.,

9 Defendant.

CIVIL ACTION NUMBER:

2:20-cv-05426

BENCH TRIAL (VOLUME III)

REDACTED

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12 Newark, New Jersey 07102
13 Friday, October 7, 2022
14 Commencing at 9:35 a.m.

15 B E F O R E:

16 THE HONORABLE STANLEY R. CHESLER,
17 UNITED STATES DISTRICT JUDGE,

18
19
20
21
22
23 Mary Jo Monteleone, Official Court Reporter
24 maryjomonteleone@gmail.com
25 (973) 580-5262

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1 (PROCEEDINGS held in open court before **The Honorable**
2 **STANLEY R. CHESLER**, United States District Judge, at
3 9:35 a.m.)

4 THE COURTROOM DEPUTY: All rise.

5 THE COURT: Be seated. Good morning, everybody.

6 ALL: Good morning.

7 THE COURT: Are we all ready to proceed?

8 I can see you are ready.

9 MR. STEINDLER: We have a couple of very quick
10 preliminary matters.

11 THE COURT: Okay.

12 MR. STEINDLER: So three points. The first point has
13 to do with the sealing point that I mentioned earlier.

14 Both parties have experts to address commercial
15 success. There will be presentation in both of those
16 commercial success experts of Bausch's confidential financial
17 information: sales, profitability, market shares, those kinds
18 of things. Internal projections.

19 We would ask the court be sealed. Obviously, we've
20 got some of our friends from the press here. But we would ask
21 that the courtroom to be sealed just for the two commercial
22 success experts.

23 And I understand that Padagis is not opposed to that.

24 MR. ZIMMERMAN: We don't oppose, Your Honor. It's my
25 understanding that our in-house counsel will be allowed to sit

1 in during that portion, but we don't oppose the sealing with
2 that limitation.

3 MR. STEINDLER: Yes, we reached that agreement.

4 THE COURT: Okay. All I want is the actual sales
5 figures sealed. That's it. And the share, market share.
6 Anything beyond that is -- is there any reason to seal it?

7 MR. STEINDLER: Well, let me ask this. There's going
8 to be testimony -- the reason we thought that it would be
9 better to have -- these are going to be very short witnesses,
10 both of the commercial success witnesses are going to be very
11 short.

12 But there's going to be discussion of as well as
13 presentation of the sales figures, internal projections and
14 things like that. Profitability reports, those kinds of
15 things.

16 THE COURT: As long as -- I will authorize that as
17 long as they're reasonably current ones. Okay?

18 MR. STEINDLER: Yes.

19 THE COURT: We don't have to go back into ancient
20 history.

21 MR. STEINDLER: We're not going back into ancient
22 history, Your Honor. That's correct.

23 THE COURT: Okay.

24 MR. STEINDLER: All right. Thank you. That's point
25 one.

1 THE COURT: Yes.

2 MR. STEINDLER: Point two, we have an agreed proposal
3 to, with respect to post-trial submissions with the opening
4 submissions, simultaneous submissions by both of us on the
5 4th of November and responsive submissions on the 22nd of
6 November, if that's acceptable, Your Honor.

7 THE COURT: Let me check with the person who's going
8 to be doing the grunt work on that.

9 (Discussion held off the record.)

10 MR. ZIMMERMAN: Your Honor, just to clarify.

11 THE COURT: Yes.

12 MR. ZIMMERMAN: Those would be the exchange dates
13 among the parties. And then we would submit the full
14 hyperlinked brief to you on November 30th.

15 THE COURT: I'd like you to move that whole thing up
16 by two weeks overall.

17 MR. ZIMMERMAN: Okay.

18 THE COURT: So the whole thing by November 15th.

19 MR. ZIMMERMAN: The hyperlink brief to you by
20 November 16th?

21 THE COURT: Everything, yes.

22 THE COURTROOM DEPUTY: 16th or 15th?

23 THE COURT: 15th.

24 Is that doable?

25 MR. STEINDLER: We can figure out a way to make that

1 happen, Judge. Understood.

2 MR. ZIMMERMAN: And, Your Honor, I assume if we get
3 it to you by the 15th, then you're okay if we work out a
4 schedule for the exchanges among ourselves?

5 THE COURT: Yes.

6 MR. ZIMMERMAN: All right?

7 THE COURT: That's fine.

8 MR. STEINDLER: Does that work?

9 THE COURT: Yes, that works.

10 You have to understand. I've got another nonjury
11 patent case coming right after you folks. And that one is
12 coming right before the expiration of a 30-month stay. So
13 I've got to leave some time to get that one resolved also
14 before the 30-month stay expires.

15 MR. STEINDLER: Fully understand, Your Honor. We'll
16 get this done.

17 And then the last one is really just a housekeeping
18 question.

19 Both of us thought it might be useful to submit to
20 you the slides that all of the witnesses have used. We
21 understand they're not evidence, but they're demonstratives.

22 But, A, would you agree to accept them? And, B, if
23 so, do you want them in hard copy as well as electronic?

24 THE COURT: I think electronically would be what we
25 want.

1 MR. STEINDLER: All right. No problem.

2 THE COURT: Okay?

3 MR. STEINDLER: Yep.

4 THE COURT: Thank you.

5 MR. STEINDLER: Thank you.

6 MS. WEISBRUCH: If the Court's prepared, we'll
7 proceed with the witness.

8 THE COURT: Please proceed.

9 DR. MAJELLA LANE, PLAINTIFF'S WITNESS,
10 having been previously sworn, testifies as follows:

11 DIRECT EXAMINATION (Continued)

12 BY MS. WEISBRUCH:

13 Q. Welcome back, Dr. Lane.

14 A. Thank you.

15 Q. When we left off yesterday, we had just discussed the
16 Temovate E® Label.

17 Does that sound right to you?

18 A. Yes.

19 MS. WEISBRUCH: So we'll wait a minute for your
20 presentation to switch over.

21 BY MS. WEISBRUCH:

22 Q. And that's the Temovate® Label that we just talked about.

23 I'd like to walk through Dr. Michniak-Kohn's
24 combinations of the five references that we discussed at the
25 end of yesterday.

1 At a high level, can you describe your understanding
2 of these combinations?

3 A. Yes. So here we see on the slide the five references
4 that Dr. Michniak-Kohn has relied on to support her opinion
5 that the asserted claims of the Bryhali® patents are invalid.

6 So five references, but four combinations.

7 The first combination is the '295 patent and Blum.

8 The '295 and Blum and the '566 patent is the second
9 combination.

10 The next combination is the '295 patent, Blum and the
11 Japanese '228 document.

12 And the final combination is the '295 patent, the
13 Blum paper, and the Temovate E® Label.

14 Q. And do you have an opinion on the combinations that you
15 just discussed?

16 A. Yes. It's my opinion that the combinations do not render
17 the asserted claims obvious.

18 Q. Okay. And on your Slide PDX-3-36, do you understand
19 PDX-3-36 to summarize Dr. Michniak-Kohn's view of the
20 combination of the '295 patent and Blum?

21 A. Yes. This is one of Dr. Michniak-Kohn's slides, where
22 she gives her opinion that the '307 and '502 patents are
23 invalid as obvious over the prior art.

24 So Dr. Michniak-Kohn states that there is motivation
25 to modify and combine Blum with the '295 patent. And she

1 stated that it is known that a reduction of drug concentration
2 could be achieved through formulation optimization, providing
3 an effective formulation.

4 And she goes on to state that the ways to optimize
5 topical pharmaceutical formulations to enhance drug release
6 and absorption include: to optimize the level of drug
7 saturation in the vehicle, to improve dissolution of the
8 active ingredient in the formulation, and to incorporate
9 penetration enhancers as excipients.

10 Q. What claims of the Bryhali® patents do you understand
11 Dr. Michniak-Kohn to be applying this combination of
12 references to?

13 THE WITNESS: So we can see that on my next slide,
14 please.

15 So the combinations Dr. Michniak-Kohn rely on to
16 render the asserted claims obvious refer to these specific
17 claims for the '307 patent: Claims 13, 16 and 20.

18 And turning to the '502 patent, the claims are 4 and
19 16.

20 BY MS. WEISBRUCH:

21 Q. What is your response to Dr. Michniak-Kohn's opinion that
22 the combination of the '295 patent and Blum renders those
23 claims obvious?

24 A. So there is no motivation, in my opinion, to look to a
25 30-year-old reference -- that's the '295 patent -- for a class

1 of oily solvents to select from for use in a corticosteroid
2 formulation from the whole universe of other solvents
3 disclosed in the art.

4 And in the real world, the oily solvents disclosed in
5 the '295 patent were not used in the Ultravate® formulation.

6 So continuing with what happened in practice, in the
7 real world no one ever combined the oily solvents of the '295
8 patent with the Blum paper.

9 So Blum actually taught away from the lower
10 concentrations of halobetasol claimed in the Bryhali® patents.
11 And there is no basis for selecting diethyl sebacate from the
12 broad class of sebacates disclosed in the '295 patent.

13 Q. Do you have any other opinions about Dr. Michniak-Kohn's
14 combination of the '295 patent and Blum reference?

15 A. Yes. Even if there were a motivation to combine the '295
16 patent with Blum, the combined references do not disclose or
17 render obvious all the elements of the asserted claims.

18 So the '295 patent and Blum specifically do not
19 disclose halobetasol at a concentration of 0.01 percent,
20 diethyl sebacate, light mineral oil, or the exclusion of white
21 petrolatum.

22 So there is no reasonable expectation of success that
23 combining the formulation -- specific formulation from the
24 '295 patent with the 0.02 percent concentration of Blum would
25 have been efficacious or that it would result in a

1 pharmaceutical composition that could be used for a period of
2 treatment for longer than two weeks.

3 BY MS. WEISBRUCH:

4 Q. And to move ahead to your Slide PDX-3-40.

5 Do you understand this slide to summarize
6 Dr. Michniak-Kohn's -- regarding Slide PDX-3-40, Dr. Lane, do
7 you understand this slide to represent Dr. Michniak-Kohn's
8 opinions on the combination of the '295 patent, Blum, and
9 either the '566 patent or JP '228?

10 A. Yes. In this slide, Dr. Michniak-Kohn is giving her
11 opinion on the motivation to combine the '295 patent with the
12 '566 patent or JP '228.

13 So Dr. Michniak-Kohn states that one of skill in the
14 art would have been motivated to combine the teachings of the
15 '566 and '295 patents in combination with Blum; and the '295
16 patent and JP '228 in combination with Blum.

17 Q. And what claims do you understand Dr. Michniak-Kohn to be
18 applying this combination of references to?

19 A. So again, the slide I have here shows you that the claims
20 that Dr. Michniak-Kohn is applying her analysis to are
21 Claims 13, 16 and 20 of the '307 patent; and Claims 4 and 16
22 of the '502 patent.

23 Q. And what is your response to Dr. Michniak-Kohn's opinion
24 that the combination of the '295 patent, Blum and the '566
25 patent render those claims obvious?

1 A. So it is my opinion that adding the '566 patent to the
2 '295 patent and Blum still doesn't give you a motivation. So
3 there's no motivation to combine the '566 patent with the '295
4 patent and Blum.

5 And the reasons for this is that the '566 patent
6 focuses on a particular oily solvent, dibutyl adipate, used
7 alone or in combination with isopropyl myristate. So this is
8 not part of the classic solvents, the sebacates, that are
9 disclosed in the '295 patent.

10 So there is no motivation to combine the disclosure
11 of the '566 patent, dibutyl adipate, with or without isopropyl
12 myristate, with the '295 patent that describes dialkyl
13 sebacate.

14 There's no basis for selecting diethyl sebacate or
15 the other two oily solvents based on the disclosure of the
16 dibutyl adipate, alone or in combination with isopropyl
17 myristate, as described in the '566 patent.

18 In addition, I would note that no formulator has ever
19 used dibutyl adipate and isopropyl myristate from the '566
20 patent in a commercial halobetasol product in the 16 years
21 following the issuance of the '566 patent.

22 So even if there were a motivation to combine the
23 '295 patent with Blum and the '566 patent, the combined
24 references still do not disclose or render obvious all the
25 elements of the asserted claims.

1 So this is specifically the '295 patent and Blum and
2 the '566 patent -- patent do not disclose halobetasol at a
3 concentration of 0.01 percent, diethyl sebacate, light mineral
4 oil, or the exclusion of white petrolatum.

5 Q. Now, let's discuss the combination of the '295 patent,
6 Blum and JP '228.

7 What claims do you understand Dr. Michniak-Kohn to be
8 applying this combination to?

9 A. So the claims that Dr. Michniak-Kohn's analysis are
10 directed to are shown here. For the '307 patent, it's
11 Claims 13, 16 and 20. And for the '502 patent, it's Claims 4
12 and Claims 16.

13 Q. And what is your response to Dr. Michniak-Kohn's opinion
14 that the combination of the '295 patent, Blum and JP '228
15 would render those claims obvious?

16 A. So as I explain here, the combination of JP '228 with the
17 '295 patent and with Blum still doesn't help us because -- it
18 doesn't help Dr. Michniak-Kohn.

19 There's no motivation to combine JP '228 with the
20 '295 patent and Blum. JP '228 discloses a series of
21 ingredients for formulations with corticosteroids generally
22 but not with halobetasol.

23 And there's no expectation that this combination of
24 JP '228 with the '295 patent and Blum would successfully
25 achieve the claimed invention because JP '228 only addresses

1 formulations in the context of corticosteroids generally,
2 because of the generic corticosteroid structure we saw, with
3 no disclosure of how the formulations would work with
4 halobetasol or the other specific corticosteroids claimed in
5 the Bryhali® patents.

6 And additionally, I would note that the JP '228
7 document is from 1988. And no one ever used diethyl sebacate
8 in a commercial halobetasol formulation in the intervening
9 22 years before the Bryhali® invention date.

10 And again, this is practical evidence. This is what
11 happened in the real world, that a POSA would not be motivated
12 to combine these references.

13 Q. Let's turn to the final combination of references that
14 Dr. Michniak-Kohn identified, which is the combination of the
15 '295 patent, Blum and the Temovate E® Label.

16 A. Yes.

17 Q. What claim or claims do you understand Dr. Michniak-Kohn
18 to be applying this combination of references to?

19 A. I understand that this combination of references is
20 directed to Claim 16 in Dr. Michniak-Kohn's analysis.

21 Q. And what is your response to Dr. Michniak-Kohn's opinion
22 that the combination of the '295 patent, Blum and the Temovate
23 E® Label renders Claim 16 of the '502 patent obvious?

24 A. So it is my opinion that there is no motivation to
25 combine the Temovate E® Label with the '295 patent and with

1 the Blum study because there is a four-week indication in
2 Temovate E® specifically to the drug clobetasol.

3 There was no comparable indication for commercial
4 halobetasol propionate, and that was the Ultravate®
5 formulation. So there was no similar four-week statement on
6 the Ultravate® Label.

7 The Temovate E® Label actually teaches away from the
8 Bryhali® patents by providing a different solution to the
9 two-week limitation problem.

10 Q. Is your understanding of how Dr. Michniak-Kohn is
11 applying these combinations based on your review of her expert
12 reports in this case?

13 A. I'm sorry. Could I have the question again?

14 Q. Sure. Is your understanding of how Dr. Michniak-Kohn is
15 applying the combinations of references we just discussed, is
16 that based on your understanding of her expert reports?

17 A. It is, yes.

18 Q. Okay. Just to step back for a moment, Dr. Lane.

19 In offering your opinions in this case, did you have
20 occasion to review the prosecution histories of the '307 and
21 '502 patents?

22 A. I did, yes.

23 Q. And how do the five references cited by Dr. Michniak-Kohn
24 that we just discussed and the combinations of those
25 references compare to what was done by the examiner during the

1 prosecution of the Bryhali® patents?

2 A. So when I reviewed the prosecution histories, it seemed
3 to me that the examiner took an approach of finding the
4 primary reference where the halobetasol was not disclosed at
5 the concentration that is in the Bryhali® inventions. And the
6 gaps that were filled in the primary reference were then
7 supplemented by secondary or tertiary references.

8 So it seemed to be, again, a picking and choosing of
9 different teaching from different references.

10 Q. A little -- or, I suppose, yesterday, in the afternoon,
11 we discussed the Duobrii® patents.

12 Do you remember that?

13 A. Yes.

14 Q. And I believe you stated in your previous testimony that
15 the Duobrii® patents have a priority date of June 18, 2015.

16 Is that right?

17 A. Yes.

18 Q. And again, just briefly, because I know you touched on
19 this yesterday, could you describe the Duobrii® patents at a
20 very high level?

21 A. Sure. So the Duobrii® patents are describing what we
22 call a combination product.

23 So a combination product is where we have more than
24 one drug. And so this is a medicine for the treatment of
25 psoriasis, or the invention is a medicine for the treatment of

1 psoriasis. So the two drugs are the superpotent
2 corticosteroid halobetasol propionate and a retinoid. And the
3 retinoid is tazarotene.

4 Q. You also mentioned yesterday that the field of
5 formulation science is more art than science.

6 Is that right?

7 A. Yes, it is.

8 Q. And that's because -- it's a highly unpredictable field?

9 A. It's unpredictable. We have no way of knowing the
10 outcome of experimentation that we conduct. There can be
11 failures. Formulation programs can take years. Sometimes,
12 they never result in a product.

13 Q. Do those same principles that we discussed yesterday also
14 apply to the formulation of combination products?

15 A. In the field of combination products, it's actually a lot
16 more difficult. Because, if you remember what I said
17 yesterday, the skin evolved to keep things out, not to let
18 them in. So the skin has a finite capacity to take in drugs.

19 So now, in this combination product, you are giving
20 yourself an even higher mountain to climb as a formulation
21 starts.

22 And if there are all sorts of interactions to
23 consider with one drug in the formulation, there are even more
24 interactions to consider when you have two drugs in a
25 formulation.

1 And the fact that there are really only two other
2 combination topical formulations on the market shows you how
3 difficult it is to put two drugs into a formulation for the
4 treatment of a skin disease.

5 Q. Did a commercial product result from the discovery that's
6 described in the Duobrii® patents?

7 A. It did, yes.

8 Q. And what was that product?

9 A. So the product that resulted from the Duobrii® patents
10 was Duobrii® lotion. I think we're waiting for a slide here.

11 Yes, here it is.

12 So this is the product that resulted from the
13 invention of the Duobrii® patents. It's a topical lotion
14 indicated for the treatment of plaque psoriasis.

15 The active ingredients are, as we mentioned earlier,
16 halobetasol propionate, 0.01 percent, the superpotent
17 corticosteroid; tazarotene, 0.045 percent, the retinoid. And
18 the benefits of this product is there's no limitation on its
19 use. It can be used indefinitely.

20 Q. Again at a very high level, could you just briefly
21 summarize your opinions relating to the validity of the
22 Duobrii® patents?

23 A. Yes. So, as I have tried to explain on this slide,
24 Padagis relies on combinations of five references to support
25 its argument that the asserted claims of the Duobrii® patents

1 would have been obvious.

2 And I understand those five references to be: the
3 '824 Publication, Gollnick, the Tazorac® Label, the IDP-118
4 study and a Gandhi patent.

5 My opinions are limited to the application of the
6 '824 Publication to the formulation limitations of the
7 asserted claims of the Duobrii® patents, and I understand that
8 Dr. Stein Gold will be addressing the other references.

9 Q. So let's discuss the '824 Publication.

10 What is the '824 Publication?

11 A. So I understand the '824 Publication to be a patent
12 application which finally issued as the '307 patent.

13 MS. WEISBRUCH: And I'll just note for the record the
14 '824 Publication is actually DX-142.

15 BY MS. WEISBRUCH:

16 Q. What is your response to Dr. Michniak-Kohn's opinion that
17 the '824 Publication would have led a person of skill in the
18 art to the formulation limitations of the asserted claims of
19 the Duobrii® patents?

20 A. So it is my opinion that the '824 Publication would not
21 lead a person of skill in the art to the formulation
22 limitations of the asserted claims of the Duobrii® patents.

23 So a person of skill in the art would have had no
24 reason to select the '824 Publication from all the other
25 references in this crowded field without the Duobrii® patents

1 in hand.

2 So, as I noted, the '824 Publication is a patent
3 application, but it has no clinical data.

4 And I was pleased to see that Dr. Michniak-Kohn
5 agreed with me. The '824 Publication does not stand out among
6 the multitude of references available to a person of skill in
7 the art in 2015.

8 Q. Do you have any further opinions on Dr. Michniak-Kohn's
9 view of the '824 Publication?

10 A. Yes. So, as we were discussing, the '824 Publication
11 would not lead a person of skill in the art to the formulation
12 limitations of the asserted claims of the Duobrii® patents.

13 So again, the Duobrii® patents are describing a
14 combination product. There's no reason why a POSA would have
15 been motivated to modify the disclosure of the
16 '824 Publication, which does not talk about a combination
17 product.

18 So you would not modify that disclosure to add in an
19 additional drug, tazarotene.

20 The prior art doesn't give us a reasonable
21 expectation that tazarotene could be dissolved in the liquid
22 oil portion of the formulation that is disclosed in the
23 '824 Publication. Even so, that does not give a formulator a
24 motivation to add tazarotene to the formulations disclosed in
25 the '824 Publication.

1 And, finally, a person of skill in the art would have
2 had no motivation to select the specific claimed tazarotene
3 concentration of 0.045 percent without having the Duobrii®
4 patents as a framework to work with.

5 Q. During Dr. Michniak-Kohn's testimony, did you hear her
6 refer to Example 4A of the '824 Publication?

7 A. I did, yes.

8 MS. WEISBRUCH: Can we please bring up Example 4A. I
9 think it's in Table 4 of the '824 Publication.

10 BY MS. WEISBRUCH:

11 Q. Dr. Lane, is this Table 4 of the '824 Publication?

12 A. Yes.

13 Q. Would a person of skill -- let's start with
14 Formulation 4A.

15 Would a person of skill in the art in 2015 have
16 expected that tazarotene could be dissolved in Formula 4A of
17 the '824 Publication?

18 A. There is no way that a person of skill in the art would
19 form that expectation. They would have to conduct testing.

20 Q. Were you present for the testimony of Dr. Pillai in this
21 case on Tuesday?

22 A. I was, yes.

23 Q. Did any of Dr. Pillai's testimony relate to the issue of
24 whether a POSA would expect that tazarotene would be soluble
25 in dicarboxylic acid esters?

1 A. So we heard from Dr. Pillai and he was giving testimony
2 that when the laboratory was testing the various solvents,
3 they had a problem with dibutyl sebacate, so another sebacate
4 solvent.

5 And they -- I think what Dr. Pillai said was there
6 appeared to be an incompatibility between tazarotene. So when
7 they tried to dissolve the tazarotene in that particular
8 solvent, eventually they concluded there was a problem.

9 So that's another example of how difficult it is to
10 form expectations in the field of formulation science.
11 Dr. Pillai and colleagues didn't know that would happen. They
12 had to test, and then they found out.

13 Q. Could you explain how a person of skill in the art could
14 have arrived at the asserted claims of the Duobrii® patents
15 using the '824 Publication?

16 A. Again, I think that the only way you can arrive at the
17 invention of the Duobrii® patents with the '824 Publication is
18 actually starting with the Duobrii® patents.

19 Q. Have you prepared a slide on that?

20 A. Yes.

21 So this slide is going into a little more detail
22 about the '824 Publication.

23 So, as I've stated, I do not believe the
24 '824 Publication would lead a person of skill in the art to
25 the formulation limitations of the asserted claims of the

1 Duobrii® patents.

2 So looking at the '824 Publication, we see a series
3 of formulations. And only two of those formulations fall
4 within the scope of the Duobrii® patent claims.

5 So, as I've said, I see no motivation for a POSA to
6 arrive at the specific inventions of the Duobrii® patents
7 using the '824, unless they start with the Duobrii® patents.

8 So I prepared a chart here. And I'm trying to show
9 you the broad disclosure of the '824 Publication in the last
10 column of the chart and how that lines up with what we see in
11 the asserted claims of the Duobrii® patents.

12 So we can look at each category.

13 So the '824 Publication, when discussing
14 monocarboxylic acid esters or dicarboxylic acid esters,
15 describes a huge range of compounds or chemicals that can fall
16 within that classification.

17 When you turn to the Duobrii® patents, there is only
18 one specific compound that is disclosed. So that's diethyl
19 sebacate.

20 Looking again to the last column on my chart, and
21 considering the lipophilic liquids that are disclosed to the
22 '824 Publication, there are actually eight different
23 lipophilic liquids here, and they fall into different chemical
24 classes and categories.

25 In contrast, there is only one lipophilic liquid

1 described in the asserted claims of the Duobrii® patents, and
2 that is light mineral oil.

3 Turning to the superpotent corticosteroid that is
4 disclosed in the '824 Publication, there are actually five
5 different superpotent corticosteroids disclosed.

6 But looking at the asserted claims of the Duobrii®
7 patents, there is only one superpotent corticosteroid that we
8 see: halobetasol propionate.

9 And the last row in my chart talks about the
10 formulations that are disclosed in the '824 Publication. And
11 the formulations we see in the '824 Publication can be
12 lotions, gels, creams or ointments. However, turning to the
13 Duobrii® patents, the specific formulation that we see is a
14 lotion.

15 Q. And just for expediency, I'll note for the record that
16 the paragraphs of the '824 Publication that you just referred
17 to for each of those categories, Paragraph 20, Paragraph 26,
18 Paragraph 17 and Paragraph 23.

19 Dr. Lane, did you hear Dr. Michniak-Kohn testify
20 yesterday that the term "liquid oil component," as used in the
21 Bryhali® patents, is indefinite?

22 A. I did, yes.

23 Q. How did the Court construe the term "liquid oil
24 component" in this case?

25 A. So the Court has ruled that the term "liquid oil

1 component" should be construed as includes all ingredients of
2 the formulation that are practically insoluble or insoluble in
3 water and which are liquid at room temperature of 22 degrees
4 Celsius.

5 Q. Would a person of skill in the art in 2010 understand
6 what it means for an ingredient to be "practically insoluble
7 or insoluble in water"?

8 A. Of course.

9 Q. Would a person of skill in the art in 2010 understand
10 what it means for an ingredient to be liquid at room
11 temperature of 22 degrees Celsius?

12 A. Certainly, a person of skill in the art would understand
13 that term.

14 Q. Do you recall Dr. Michniak-Kohn discussing sorbitan
15 monooleate during her testimony?

16 A. I do, yes.

17 Q. And what is sorbitan monooleate?

18 A. Sorbitan monooleate is an emulsifier. So we use it to
19 keep oil and water phases separate in topical formulations
20 such as creams or lotions.

21 Q. Would a person of skill in the art in 2010 have
22 understood that sorbitan monooleate is practically insoluble
23 or insoluble in water?

24 A. They certainly would, yes.

25 Q. Would a person of skill in the art have understood in

1 2010 that sorbitan monooleate is liquid at room temperature of
2 22 degrees Celsius?

3 A. Yes. A person of skill working in the field of topical
4 formulation would have known that.

5 Q. Does sorbitan monooleate fall within the Court's
6 construction of the liquid oil component?

7 A. It does, yes.

8 MS. WEISBRUCH: Could we please bring up Tables 1 and
9 2 from the '307 patent, please.

10 BY MS. WEISBRUCH:

11 Q. Can you briefly describe what's being calculated in
12 Table 2, Dr. Lane?

13 A. Sure.

14 So you have to look at Table 2 and following on from
15 Table 1.

16 So if you look at Table 1 we see four formulations:
17 A, B, C, and D. And there are components of A, B, C, and D
18 that contribute to solubilization of the drug substance in
19 this formulation. And those components are diethyl sebacate
20 and light mineral oil.

21 So looking at the solvents in the table, what the
22 inventors have done in Table 2 is they have calculated the
23 solubility of the drug substance, halobetasol propionate, in
24 the solvents. And so, for example, if you look at
25 Formulation A, the solvents that are contributing to

1 solubility of the active are 3 percent diethyl sebacate and
2 1 percent light mineral oil. So that gives you a total
3 concentration of 4 percent of those solvents in Formulation A.

4 And we could then calculate the saturation solubility
5 of halobetasol in the next column and the degree of saturation
6 in the last column. And that is what the inventors have done
7 for each of the solvents in the liquid oil component for B, C,
8 and D, along with A in Table 2.

9 Q. And we'll just take Formulation A as an example here
10 since that's the one you started with.

11 Formulation A includes sorbitan monooleate, correct?

12 A. Formulation A includes sorbitan monooleate. We can see
13 it in the list of formulation components.

14 Q. But sorbitan monooleate is not included in the
15 concentration of the liquid oil component that's calculated in
16 Table 2, right?

17 A. It is not.

18 Q. How do you understand the Court's construction of the
19 liquid oil component, which includes sorbitan monooleate and
20 the calculations done in Table 2, which do not include
21 sorbitan monooleate?

22 A. Yes. So I read the Judge's order on the term, and I
23 understand that I must apply the Judge's ruling on the order.

24 So as I stated, sorbitan monooleate falls within the
25 definition, or how the judge has construed the term. And I

1 have gone to Table 2 and done my best to read Table 2
2 following the Judge's order.

3 And, again, as I explained, the person of skill in
4 the art knows that, yes, sorbitan monooleate falls within how
5 the Judge has construed the term, but sorbitan monooleate
6 isn't a solvent for the drug halobetasol propionate. So
7 that's how a person of skill in the art would read table,
8 could read Table 2 to be precise.

9 MS. WEISBRUCH: I have no further questions for you
10 at this time, Dr. Lane. So I will pass the witness.

11 THE COURT: Thank you.

12 Your witness.

13 MS. PITZEL CRUZ: Your Honor, may I approach?

14 THE COURT: You may.

15 CROSS-EXAMINATION

16 BY MS. PITZEL CRUZ:

17 Q. Good morning, Dr. Lane.

18 A. Good morning.

19 Q. I'd like to start where you left off with discussing the
20 term "liquid oil component."

21 Is that okay with you?

22 A. Yes.

23 Q. And you would agree that the liquid oil component term
24 doesn't have a customary meaning in the field of
25 pharmaceutical formulations, correct?

1 A. Correct.

2 Q. Okay. And I believe the testimony that you just
3 presented, we can agree that in your reading -- or looking at
4 Table 2 of the '307 patent, that that Table 2 excludes the
5 calculation -- or excludes calculation of sorbitan monooleate
6 when it describes the liquid oil component.

7 Is that correct?

8 A. So it excludes the inclusion of the sorbitan monooleate
9 in the liquid oil component.

10 Q. Let me see if I can clarify that.

11 So you would agree that Table 2 excludes sorbitan
12 monooleate from the calculation of the concentration of liquid
13 oil component, correct?

14 A. Yes.

15 Q. Okay.

16 And because Table 2 excludes sorbitan monooleate from
17 the calculation of the liquid oil component, a person of skill
18 in the art would not be able to reconcile the Court's
19 construction of liquid oil component with the specification
20 and claims of Bryhali® patents, right?

21 A. I disagree.

22 Q. And you submitted a declaration during the claim
23 construction phase of this case, correct?

24 A. Correct.

25 Q. Okay.

1 MS. PITZEL CRUZ: If we could pull up DX-383, please.

2 And if we could turn to the last page of that
3 declaration, where the signature page is.

4 Sorry.

5 BY MS. PITZEL CRUZ:

6 Q. You submitted this declaration under penalty of perjury
7 and that it was true and accurate to the best of your
8 knowledge.

9 Is that correct?

10 A. That is correct.

11 MS. PITZEL CRUZ: And if we could turn back to
12 Paragraph 60 -- or turn to Paragraph 60 of DX-383.

13 BY MS. PITZEL CRUZ:

14 Q. In that declaration -- I'm just going to read part of the
15 declaration. It says: However, and as described before,
16 Table 2 expressly excludes sorbitan monooleate from the
17 calculation of the concentration of the liquid oil component.
18 A POSA would not be able to reconcile Perrigo's proposed
19 construction of the term "liquid oil component" with the
20 specification and claims of the Bryhali® patent.

21 Is that correct?

22 Did I read that correctly?

23 A. Yes.

24 MS. PITZEL CRUZ: If we could pull up JTX-001,
25 please, and turn to Table 2.

1 BY MS. PITZEL CRUZ:

2 Q. You would agree with me that the second heading in
3 Table 2 states: "Concentration of liquid oil component."

4 Correct?

5 A. Yes.

6 Q. It does not say a concentration of solvent component,
7 correct?

8 A. It does not say that.

9 Q. And if we limited this calculation to just solvents for a
10 liquid oil component, wouldn't that be applying the claim
11 construction that the Court rejected?

12 A. As I tried to explain, I understand I must follow the
13 Court's construction, and I've done my best to read Table 2
14 now following the Court's construction.

15 Q. And in order for you to read Table 2 according to the
16 Court's construction, you actually excluded sorbitan
17 monooleate from that calculation, which is contrary to the
18 Court's construction, correct?

19 A. Actually, I read the judge's order, and he said that
20 neither side had proposed a claim construction that was
21 problem-free, and he recognized that Table 2 concerned matters
22 of chemistry -- and it does involve matters of chemistry --
23 and those matters of chemistry are considered solvents. And
24 the person of ordinary skill in the art would understand
25 solvents are important in the calculation of solubility.

1 Q. And if a person of ordinary skill in the art expected
2 that Table 2 to, just limited to concentration of solvents,
3 you agree with me that that's not what's written here; it's
4 not written "concentration of solvents"?

5 A. I agree that "concentration of solvents" is not written
6 here.

7 Q. Thank you.

8 MS. PITZEL CRUZ: If we could turn to --

9 BY MS. PITZEL CRUZ:

10 Q. Or, Dr. Lane, you analyzed the asserted claims of the
11 '307 and '502 patent, correct?

12 A. Yes.

13 Q. And you understand that none of the asserted claims
14 require a commercial product.

15 Is that correct?

16 A. Could you clarify your question, please?

17 Q. Sure.

18 MS. PITZEL CRUZ: Maybe what we could do is put up
19 your slides.

20 Let's take a look at your Slide PDX-3-5.

21 BY MS. PITZEL CRUZ:

22 Q. And you have the asserted claims of '307 patent: Claims
23 13, 16, and 20 on this slide, correct?

24 A. Correct.

25 Q. Okay. And you would agree with me that none of these

1 claims have a claim limitation requiring a commercial product.

2 Is that correct?

3 A. I agree that's correct.

4 Q. Okay. And none of these claims, the asserted claims
5 we're looking at for the '307 patent, have any limitation
6 requiring efficacy comparable to Ultravate®.

7 Is that correct?

8 A. There is no mention of Ultravate® or a comparison to
9 Ultravate® in the claims that we are looking at.

10 Q. And if you look at the asserted claims, none of the
11 asserted claims of the '307 patent require efficacy comparable
12 to a 0.05 percent halobetasol formulation.

13 Is that correct?

14 THE COURT: Go slower and louder.

15 MS. PITZEL CRUZ: I'll just repeat it.

16 BY MS. PITZEL CRUZ:

17 Q. None of the asserted claims of the '307 patent require
18 efficacy comparable to a 0.05 percent halobetasol formulation.

19 Is that correct?

20 A. That is correct.

21 Q. And none of the -- would that also apply to the asserted
22 claims of the '502?

23 Correct?

24 A. I believe you're correct, but it would be good to just
25 see the claims, if you don't mind.

1 Q. Sure. We'll just go through the '307 patents.

2 A. Okay. Thank you.

3 Q. And if we are looking at these '307 asserted claims, none
4 of the asserted claims require -- or include a limitation to a
5 superpotent corticosteroid.

6 Is that correct?

7 A. I'm sorry, I didn't get all of your question.

8 Q. None of the asserted claims of the '307 patent include a
9 limitation to superpotent corticosteroids.

10 Is that correct?

11 A. Well, we're talking about halobetasol propionate. That's
12 a superpotent corticosteroid.

13 MS. PITZEL CRUZ: If we look at -- let's look at --
14 let's see.

15 Actually, if we could turn to the next slide in
16 Dr. Lane's slides, PDX-4 -- 3-6. Yes.

17 BY MS. PITZEL CRUZ:

18 Q. When we look at Claim 1, you'll see that there are
19 several different corticosteroids listed, correct?

20 A. Yes.

21 Q. And it's not just limited to halobetasol, correct?

22 A. In Claim 1 it's not just limited to halobetasol.

23 Q. Okay.

24 MS. PITZEL CRUZ: If we turn --

25 BY MS. PITZEL CRUZ:

1 Q. So you would agree with me that the disclosure of the
2 '307 and the '502 patent claims is not limited to superpotent
3 corticosteroids.

4 A. Are you asking me about Claim 1 or the patents --

5 Q. I'm sorry, I'm actually asking you about the patents
6 generally.

7 If we look at the patent specifications of the '307
8 and '502 patents, the specification is not limited to only
9 superpotent corticosteroids, correct?

10 A. Correct.

11 Q. In fact, the patent specification describes that other
12 corticosteroids, including those of potency Classes 3 to 7,
13 upper mid strength to least potent can be used.

14 Is that correct?

15 A. I believe that is in the specification, yes.

16 Q. Okay.

17 Looking at Claim 1 of the '502 patent, you would
18 agree with me that Claim 1 recites the compound fluocinonide
19 at a concentration of less than 0.05 percent, correct?

20 A. It does, yes.

21 Q. And in your direct yesterday, you provided examples of
22 fluocinonide 0.05 percent that were classified as potent and
23 upper mid strength corticosteroids, correct?

24 A. I can't hear your question, I'm sorry.

25 Q. Sure.

1 In your direct yesterday, you provided examples of
2 fluocinonide 0.05 percent that were classified as potent and
3 upper mid strength, correct?

4 A. Yes.

5 Q. Okay. And there's no data in the '502 patent
6 demonstrating that the claimed fluocinonide formulations that
7 we see in Claim 1 are superpotent, correct?

8 A. Again, I'm not sure I follow your question.

9 Q. Sure.

10 Is there any data in the '502 patent, any examples
11 describing a formulation of the invention using fluocinonide
12 at less than 0.05 percent?

13 A. Is there any experimental data or tests?

14 Q. Yes.

15 A. I don't see experimental data or testing.

16 Q. And is there any information in the '502 patent that
17 would indicate that a formulation that we see in Claim 1 that
18 is including fluocinonide at a concentration of less than
19 0.05 percent would be a superpotent corticosteroid
20 formulation?

21 A. Again, are you asking me is there experimental data or
22 testing?

23 Q. That's part of the question, yes.

24 Is there any data?

25 A. Is your question is there any data?

1 I'm sorry. Just to get a clear question.

2 Q. Is there any data in the '502 patent specification --

3 A. Yes.

4 Q. -- that describes the claimed fluocinonide formulation of
5 less than 0.05 percent that indicates that would be a
6 superpotent corticosteroid formulation?

7 A. Again, experimental data?

8 Q. Yes, that was part of the question.

9 A. We don't see experimental data about --

10 Q. And just yes or no.

11 A. We don't see experimental data.

12 Q. Thank you.

13 You would agree with me that the examples of the '307
14 and '502 patent do not include any corticosteroid other than
15 halobetasol, correct?

16 A. Correct.

17 Q. And you would agree with me that the halobetasol patents,
18 the '307 and the '502 patent, do not include any clinical data
19 for any of the formulations.

20 Is that correct?

21 A. Okay. So clinical data, do you mean tests in patients?

22 Q. Yes.

23 A. So could I have the question again, please?

24 Q. You would agree with me that the halobetasol patents, the
25 '307 and '502 patent, do not include any clinical data for any

1 of the formulations that are disclosed in the patent, correct?

2 A. That is correct.

3 Q. Okay. And you would agree with me that the halobetasol
4 patents do not include any information regarding treatment for
5 more than two weeks with the claimed formulations, correct?

6 A. As we were discussing, there are no clinical data in the
7 patent.

8 Q. So just with a yes-or-no answer, you would agree with me
9 that the halobetasol patents do not include any information
10 regarding treatment for more than two weeks with the claimed
11 formulations.

12 Is that correct?

13 A. There's no experimental data.

14 Q. Okay. And if we look here, Claim 16 is one of the
15 asserted claims.

16 And you would agree with me that there's no data
17 or -- well, let's just start there.

18 You'd agree with me that there's no data in the
19 specification of the halobetasol patents that provides a
20 combination of clobetasol and diethyl sebacate.

21 Is that correct?

22 A. And, again, are we looking at experimental data?

23 Q. Yes.

24 A. We do not see experimental data about clobetasol and
25 diethyl sebacate.

1 Q. And you would agree with me that the '502 patent and the
2 '307 patent don't include any formulations or examples --
3 well, let's just start with examples.

4 If we look, you would agree with me that the
5 specification of the '502 and the '307 patent do not include
6 any examples of clobetasol and diethyl sebacate.

7 Is that correct?

8 A. That is correct.

9 Q. And you would agree with me that for betamethasone
10 propionate, diflorasone diacetate, and fluocinonide,
11 similarly, there are no examples in the halobetasol patents of
12 those specific corticosteroids and diethyl sebacate.

13 Is that correct?

14 A. That's correct.

15 Q. Okay.

16 Is it your position that because there is no example
17 in the halobetasol patents of these corticosteroids I just
18 mentioned, clobetasol, betamethasone, diflorasone and
19 fluocinonide with diethyl sebacate, that a POSA would not know
20 if a combination of those corticosteroids and diethyl sebacate
21 would work?

22 A. A person of skill in the art would read the patent and
23 they would read the examples.

24 So they see in Claim 1 the claims referring to a
25 number of corticosteroids. So they would know that they could

1 use the invention with those corticosteroids read in Claim 1.
2 Q. So even though the halobetasol patents don't have any
3 examples of clobetasol, you would understand -- one of skill
4 in the art would be able to understand from the disclosure of
5 clobetasol in this listing of claims that the -- they could
6 prepare a formulation of clobetasol and diethyl sebacate.

7 Is that correct?

8 A. I believe the claims are telling us you can make those
9 formulations.

10 Q. And so you wouldn't need experimental data to understand
11 that from the disclosure of the patent that you could make a
12 formulation of clobetasol, according to the invention?

13 A. So, again, I believe that if we look at the claims, the
14 inventors are telling us you can make those formulations.

15 Q. And, Dr. Lane, do you recall yesterday that you discussed
16 the unpredict- -- and today -- the unpredictable nature of
17 science, correct?

18 A. I did.

19 Q. And, in fact, you stated there are no predictable
20 outcomes in this field, correct?

21 A. I believe that that's what I said.

22 Q. And you also stated that each drug at each concentration
23 requires a unique vehicle, correct?

24 A. Yes.

25 Q. And just going back to my questions --

1 MS. PITZEL CRUZ: If we could go back to the claims
2 of the '502 patent.

3 BY MS. PITZEL CRUZ:

4 Q. You would agree with me that none of the claims of the
5 '502 include any limitation requiring efficacy comparable to
6 Ultravate®.

7 Is that correct?

8 A. You're asking me about Ultravate®?

9 Q. Yes.

10 A. So we don't see Ultravate® mentioned in the claims.

11 Q. And none of the claims of the '502 patent, the asserted
12 claims that we see on the slide, require efficacy comparable
13 to a 0.05 percent halobetasol formulation.

14 Is that correct?

15 A. Correct.

16 Q. I would like to switch gears a little bit.

17 You recall that you discussed a person of skill in
18 the art during your testimony.

19 Is that correct?

20 A. Yes.

21 MS. PITZEL CRUZ: And if we take a look at that
22 definition that you had that would be Slide 10 of your slide.

23 Actually, I apologize. I wanted to look at your --
24 sorry.

25 Actually, I did want to look at that. Sorry.

1 BY MS. PITZEL-CRUZ:

2 Q. Looking at this definition of a POSA, there is nothing in
3 the definition that limits a POSA to only individuals that
4 speak English.

5 Is that correct?

6 A. I don't think we should limit the definition of a POSA to
7 people who speak English.

8 Q. And you would agree that in looking at the art that a
9 person of skill in the art is assumed to -- is presumed to be
10 familiar with all of the relevant scientific field and
11 literature.

12 Is that correct?

13 A. That's my understanding, yes.

14 Q. I'd like to turn to one of the references you discussed
15 today, the Blum reference.

16 A. Yes.

17 MS. PITZEL CRUZ: If we could pull up DX-002, please.

18 BY MS. PITZEL-CRUZ:

19 Q. You recall testifying about the Blum reference, Dr. Lane.

20 Is that correct?

21 A. Yes, I did.

22 MS. PITZEL CRUZ: If we could turn to Table 1 of the
23 Blum reference.

24 BY MS. PITZEL CRUZ:

25 Q. You would agree with me that Table 1 is presenting data

1 regarding the overall evaluation of the efficacy of all
2 patients with psoriasis.

3 A. Correct.

4 Q. And you would agree with me that in the left-hand column
5 the table indicates the percentage of patients who were cured
6 or significant under the extent of clinical improvement,
7 correct?

8 A. Correct.

9 Q. And you would agree with me that Table 1 is reporting
10 that 86.4 percent of the cured and significant patients of the
11 Dermovate products.

12 Is that correct?

13 A. Yes.

14 Q. And you would agree with me that for the 0.02 percent
15 halobetasol product, the Table 1 is reporting a result of
16 cured and significant of 81.4 percent.

17 Is that correct?

18 A. It is, correct.

19 Q. And for the 0.05 percent halobetasol treatment, you would
20 agree with me that Table 1 is reporting that 90.2 of the
21 patients were cured or have significant improvement, correct?

22 A. Correct.

23 MS. PITZEL CRUZ: If we could turn to Slide 22 of
24 your presentation.

25 BY MS. PITZEL CRUZ:

1 Q. And this is a quote from Blum that you discussed during
2 your testimony.

3 Is that correct?

4 A. Yes.

5 MS. PITZEL CRUZ: And if we turn back to Blum and the
6 section that you have cited in the article.

7 BY MS. PITZEL CRUZ:

8 Q. So in the middle you have the -- you had quoted that
9 the -- the first part in blue you say: In the treatment of
10 severe chronic psoriasis vulgaris, the ointment with the lower
11 concentration was less effective than the concentration of
12 0.05 percent, correct?

13 A. Yes.

14 Q. But then on your slide, you left out the next sentence
15 that says: However, the difference among the three groups is
16 not statistically significant.

17 Is that correct?

18 A. I don't think that --

19 Q. Yes or no?

20 A. This isn't on my slide, that's correct.

21 MS. PITZEL CRUZ: If we turn back to Slide 31 of your
22 presentation.

23 THE WITNESS: Yes.

24 BY MS. PITZEL CRUZ:

25 Q. Again, we see this quote. And, again, you've left off

1 the mention that the three treatments were not statistically
2 different.

3 Is that correct?

4 A. The statement isn't here.

5 MS. PITZEL CRUZ: Dr. Lane, if I could take you back
6 to the Blum reference, DX-002. If we could look at Page 6,
7 towards the bottom of the paragraph that starts with the
8 sentence "therefore."

9 THE WITNESS: Yes.

10 BY MS. PITZEL CRUZ:

11 Q. Do you see that, it says: Therefore, just like finding
12 the dose for systemic medication, in order to develop a
13 dermatological preparation, it is most important to conduct
14 double-blind trials to find the right concentration in the
15 treatment of patients with psoriasis?

16 Did I read that correctly?

17 A. Yes.

18 Q. And you would agree with me that the authors of Blum
19 conclude that double-blind trials should be conducted to find
20 the right concentration in the treatment of patients with
21 chronic plaque psoriasis, correct?

22 A. Correct.

23 MS. PITZEL CRUZ: While we're in this reference, if
24 we could turn to the first page of the Blum reference, DX-002.

25 BY MS. PITZEL CRUZ:

1 Q. You would agree with me that the title, as it appeared in
2 the Chinese journal, includes the information 0.02 percent,
3 0.05 percent, the code name for halobetasol "CGP 14 458" and
4 Dermovate, correct?

5 A. Correct.

6 MS. PITZEL CRUZ: If we could turn to Page 3.

7 BY MS. PITZEL CRUZ:

8 Q. You would agree with me that the version of this article,
9 as it appeared in the Chinese journal, also included an
10 abstract in English.

11 Is that correct?

12 A. Yes.

13 Q. And you will agree with me that others in the field have
14 cited Blum in English, in the English language.

15 Is that correct?

16 A. I actually haven't seen citations, but I have no reason
17 to contradict you.

18 MS. PITZEL CRUZ: If we could bring up DX-156.

19 BY MS. PITZEL CRUZ:

20 Q. This is a book entitled *Topical Corticosteroids*.

21 Do you see that, Dr. Lane?

22 A. I do.

23 MS. PITZEL CRUZ: If we could turn to Page 2.

24 BY MS. PITZEL CRUZ:

25 Q. You'll see that this was published in 1992.

1 Is that correct?

2 A. Yes, yes.

3 MS. PITZEL CRUZ: And if we turn to Page 4.

4 By MS. PITZEL CRUZ:

5 Q. We see this is a chapter on halobetasol propionate.

6 Is that correct?

7 A. Yes.

8 MS. PITZEL CRUZ: If we turn to Page 11, Table 3.

9 BY MS. PITZEL CRUZ:

10 Q. We see that there are summaries of various clinical
11 trials of HBP, halobetasol propionate.

12 Is that correct?

13 A. I think that's what is said here, yes.

14 Q. If we look at the top left first entry of this table, we
15 see that there were psoriasis comparisons of 0.02 percent
16 halobetasol, 0.05 percent halobetasol and what's indicated as
17 0.05 percent CBP.

18 Do you see that?

19 A. Yes.

20 Q. And the table below indicates that CBP is
21 clobetasol-17-propionate?

22 A. Yes.

23 MS. PITZEL CRUZ: If we could turn to the page that
24 includes the references.

25 BY MS. PITZEL CRUZ:

1 Q. We see that Reference Number 4 is an article by Blum and
2 Yawalkar from 1986?

3 A. Yes.

4 Q. And is that the Blum reference we've been discussing?

5 A. I believe that it is, yes.

6 MS. PITZEL CRUZ: Let's switch gears now and take a
7 look at the '295 patent. If we could bring that up, DX-003.

8 BY MS. PITZEL CRUZ:

9 Q. And do you recall testifying about the '295 Patent,
10 Dr. Lane?

11 A. I do, yes.

12 MS. PITZEL CRUZ: And so if we could turn to
13 Column 1, Lines 40 to 44, of the '295 patent.

14 BY MS. PITZEL CRUZ:

15 Q. You would agree with me that Column 1, Lines 40 to 44,
16 says -- states, In accordance with the present invention, it
17 has now been found that sebacates, such as dialkyl sebacates,
18 wherein alkyl contains 1 to 10 carbomers, for example, dibutyl
19 sebacate and diisopropyl sebacate, are excellent vehicles for
20 corticosteroids.

21 Do you see that?

22 A. Yes.

23 Q. So you'd agree with me that the '295 patent discloses the
24 use of sebacates, such as dialkyl sebacates, as excellent
25 vehicles for corticosteroids, correct?

1 A. That's what it's saying here, yes.

2 Q. And it's indicating that the dialkyl sebacates are those
3 that contain carbons of 1 to 10 carbons.

4 Is that correct?

5 A. Yes.

6 Q. Diethyl sebacate is a dialkyl sebacate with two carbons.

7 Is that correct?

8 A. That is correct.

9 MS. PITZEL CRUZ: If we could turn to Column 2, Lines
10 61 through 66, of the '295 patent.

11 BY MS. PITZEL CRUZ:

12 Q. This section of the '295 patent discusses a lotion
13 formulation of the invention.

14 Is that correct?

15 A. It does, yes.

16 Q. And you would agree with me that this portion of the '295
17 patent that disclose -- that states that "for lotion
18 formulations, the lotion will contain from about 0.05 to about
19 0.6 percent and preferably from about 0.02 to about
20 0.05 percent weight of the active ingredient," correct?

21 MS. WEISBRUCH: We'd object to this question. It's
22 outside of the scope of Dr. Lane's direct testimony.

23 She did not offer an opinion on this section of the
24 '295 patent.

25 THE COURT: Sustained.

1 MS. PITZEL CRUZ: Your Honor, she did talk about the
2 ranges of the corticosteroid disclosed in this patent, and she
3 didn't mention this one.

4 MS. WEISBRUCH: We would say Your Honor has made his
5 ruling.

6 This was clearly not within the scope of Dr. Lane's
7 direct testimony.

8 THE COURT: I think this is beyond the scope of the
9 direct.

10 MS. PITZEL CRUZ: Okay. If we could turn to Claim 1
11 of the '295 patent.

12 BY MS. PITZEL CRUZ:

13 Q. And you would agree with me that Claim 1 does not require
14 white petrolatum.

15 Is that correct?

16 A. We do not see the words "white petrolatum" in Claim 1.

17 Q. Okay.

18 MS. PITZEL CRUZ: So let's turn to the '566 patent,
19 and let's take a look at one of your slides, PDX-3-32.

20 BY MS. PITZEL CRUZ:

21 Q. I'd like to take a look at the third bullet point you
22 have on the slide, where it states, Directed to use of
23 penetration enhancers - opposite approach taken in the Bryhali
24 patents.

25 Do you see that?

1 A. Yes.

2 Q. But you would agree with me that the formulations in
3 Table 1 of the Bryhali® patents include propylene glycol,
4 correct?

5 A. In Table 1, I believe there was propylene glycol.

6 Q. And propylene glycol is a penetration enhancer.

7 Is that correct?

8 A. As I explained to the Judge yesterday, solvents don't
9 always act as penetration enhancers.

10 Sometimes they do, and sometimes they don't.

11 Q. So let's look at this first quote that you have on the
12 slide. And it states, The present invention relates to
13 enhancement as well as the control of epidermal, dermal, and
14 transdermal penetration of various topically applied
15 preparations.

16 Did I read that correctly?

17 A. Yes.

18 Q. And that's a quote you took from the '566 patent,
19 correct?

20 A. Correct.

21 Q. So you would agree with me that this quote describes that
22 the present invention relates to enhancement and control of
23 epidermal penetration of various topically applied
24 concentrations -- preparations, correct?

25 A. Epidermal, dermal, and transdermal, that's what it's

1 describing.

2 Q. This quote is not limited to only transdermal
3 penetration.

4 Is that correct? Yes or no?

5 A. It's not limited to transdermal penetration.

6 Q. And if we look at the second quote that you've included
7 from the '566 patent on the bottom portion, this also
8 describes dermal and transdermal penetration.

9 Is that correct?

10 A. That's correct.

11 Q. Do you recall yesterday that you were asked a question by
12 Your Honor about the '566 patent?

13 A. Yes.

14 Q. Okay. And in answering that question, you stated that
15 because the inventor says this is a very important
16 achievement, he tells us we can achieve systemic delivery in
17 the document.

18 Do you recall that?

19 A. I do.

20 Q. I took a look at the '566 patent to determine where it
21 discusses anything about importance.

22 MS. PITZEL CRUZ: So if we could pull back DX-004.

23 If we could look at Column 1, beginning at Line 62. Just read
24 this.

25 BY MS. PITZEL CRUZ:

1 Q. The patent states, "For the proper treatment of skin
2 disorders or skin diseases, it is important that the
3 pharmacologically active agent penetrate the stratum corneum
4 and be made available at appropriate concentrations at the
5 site of action, which can be the stratum corneum, the viable
6 epidermis, the epidermis junction, the dermis itself, or all
7 of the aforementioned layers of skin, depending upon the type
8 of disorder or disease condition."

9 Is that correct?

10 Did I read that correctly?

11 A. Yes.

12 Q. And you didn't mention this portion of the patent in your
13 answer yesterday, did you?

14 A. I did not.

15 Q. And you would agree with me that in order to treat
16 psoriasis, the corticosteroid needs to penetrate into the
17 skin, correct?

18 A. Yes.

19 Q. And that was known prior to 2010.

20 Is that correct?

21 A. That would have been known prior to 2010.

22 MS. PITZEL CRUZ: Let's turn now to JP '228.

23 BY MS. PITZEL CRUZ:

24 Q. Do you recall testifying about this reference, Dr. Lane?

25 A. I do.

1 MS. PITZEL CRUZ: If we could pull up DX-5, which is
2 the JP '228 reference, and turn to Page 10 of 17. If we look
3 at the portion underneath "means of solving the problem."

4 BY MS. PITZEL CRUZ:

5 Q. So if we look at the bottom paragraph there it states, In
6 short, the present invention relates to a steroid cream
7 preparation characterized in that it contains 0.01 percent to
8 0.5 percent by weight of the steroids represented.

9 Did I read that correctly?

10 A. Yes.

11 Q. So you would agree with me that the JP '228 reference
12 does include a range of 0.01 to 0.5 percent by weight of the
13 steroid in the formulations.

14 Is that correct?

15 A. For this steroid, yes.

16 MS. PITZEL CRUZ: And if we could turn to Page 10 of
17 JP '228, DX-005, and look at the portion underneath "chemical
18 structure."

19 BY MS. PITZEL CRUZ:

20 Q. The -- JP '228 discloses that 2 to 40 percent by weight
21 of one or more type of solvent selected from among diisopropyl
22 adipate, diethyl sebacate, and triacetin.

23 Is that correct?

24 A. That is correct.

25 Q. So you would agree with me that the formulations of

1 JP '228 include diisopropyl adipate, diethyl sebacate, or
2 triacetin as a solvent.

3 Is that correct?

4 A. Those are the solvents stated, yes.

5 Q. And if we look at this portion, it also says that the
6 aforesaid steroid is dissolved nearly to saturation is
7 incorporated by emulsification as a discontinuous phase.

8 Do you see that?

9 A. Yes.

10 Q. And so you would agree that JP '228 discloses that the
11 steroid is dissolved nearly to saturation.

12 Is that correct?

13 A. Yes.

14 Q. And the steroid is dissolved in the discontinuous phase?

15 A. Yes.

16 MS. PITZEL CRUZ: If we could turn now back to the
17 Temovate® Label.

18 BY MS. PITZEL CRUZ:

19 Q. Do you recall testifying about the Temovate® Label today?

20 A. Yes.

21 MS. PITZEL CRUZ: So if we could take a look at
22 DX-006.

23 BY MS. PITZEL CRUZ:

24 Q. You're familiar with this document.

25 Is that correct?

1 A. Yes.

2 Q. And the Temovate E® Label discloses clobetasol propionate
3 at 0.05 percent.

4 Is that correct?

5 A. Yes.

6 Q. I believe you testified earlier that the label discloses
7 treatment for a duration up to four weeks when the application
8 is limited to 5 to 10 percent of the body.

9 Is that correct?

10 A. Yes.

11 Q. And Temovate E® product was indicated for the treatment
12 of psoriasis.

13 Is that correct?

14 A. Yes.

15 MS. PITZEL CRUZ: We can pull that down. So I'd like
16 to turn back to one of your slides, PDX-3-25.

17 BY MS. PITZEL CRUZ:

18 Q. I'd like to focus on the first bullet point you have on
19 your slide where it says, "The inventive formulations of the
20 Bryhali® patents provide delivery of the corticosteroid
21 preferentially into the skin, rather than through the skin and
22 into the systemic circulation."

23 Do you recall that on your slide?

24 A. Yes.

25 Q. And there's no requirement in the asserted claims of the

1 '307 or the '502 patent that there's preferential delivery of
2 the active ingredients into the skin rather than the systemic
3 circulation, correct?

4 A. I don't believe that language is included in the claims.

5 Q. You didn't present any data in your testimony to support
6 your conclusion that the halobetasol patents demonstrate
7 preferential delivery of halobetasol into the skin.

8 Is that correct?

9 A. In my testimony yesterday, I didn't, but it is in my
10 report.

11 Q. Okay. And, in fact, if we take a look at the patent --

12 MS. PITZEL CRUZ: Let's pull up JTX-001, which is the
13 '307 patent, Column 4, Lines 40 through 45.

14 BY MS. PITZEL CRUZ:

15 Q. The patent says, "It is hypothesized that it is this
16 solubilization within the formulation, that upon application
17 of the formulation to the skin of a patient, provides delivery
18 of the corticosteroid preferentially into the skin rather than
19 providing transdermal delivery through the skin and into the
20 systemic circulation," correct?

21 A. Correct.

22 Q. And you would agree with me that there's no data in the
23 patents regarding whether there is systemic absorption of
24 halobetasol.

25 Is that correct?

1 A. There is no measurement of systemic absorption in the
2 patent.

3 Q. Earlier today during your testimony you talked about the
4 proceedings at the patent office with respect to the '307 and
5 '502 patents.

6 Is that correct?

7 A. I recall being asked about the prosecution history.

8 Q. Is it your position that the patent office was picking
9 and choosing from references during prosecution of the
10 halobetasol patent?

11 A. Well, what I could see was one reference was taken, and
12 it didn't have everything that met what the claims were
13 describing. So I guess that's what I would see as picking and
14 choosing.

15 I hope it's not disrespectful.

16 MS. PITZEL CRUZ: If we could turn now to the
17 '824 Publication.

18 BY MS. PITZEL CRUZ:

19 Q. Do you recall testifying about that earlier today?

20 A. I do, yes.

21 MS. PITZEL CRUZ: If we could turn to your slide,
22 which is PDX-3-49.

23 BY MS. PITZEL CRUZ:

24 Q. I just want to take a look at your second bullet point.

25 So you would agree that your slide states that the

1 '824 Publication is merely a patent application with no
2 clinical data, correct?

3 A. Yes.

4 Q. Is it your position that the disclosure of the
5 0.01 percent halobetasol formulation prior to 2015 would have
6 no interest to one of skill in the art?

7 A. I think what I'm trying to say is there was a lot of
8 information out there. And I wouldn't say no interest, but
9 there is no reason to suddenly pick -- it wouldn't stand out,
10 as Dr. Michniak-Kohn has said.

11 Q. Is it your understanding that a reference must stand out
12 to be relevant to a person of skill in the art's analysis?

13 A. I would say that, you know, there's a lot of literature
14 out there and that we both agree that this one wouldn't
15 necessarily stand out. There's a lot of references.

16 Q. And that wasn't my question. Just a yes-or-no answer,
17 please.

18 Is it your understanding that a reference must stand
19 out to be relevant to a person of skill in the art's analysis?

20 A. I'm not sure it must stand out, but as I tried to
21 explain, this one didn't stand out.

22 MS. PITZEL CRUZ: If we could pull up the
23 '824 Publication, DX-142, please, and turn to Table 4.

24 BY MS. PITZEL CRUZ:

25 Q. You would agree with me that Formulation 4A in Table 4 is

1 the vehicle for Duobrii® and Bryhali®.

2 Is that correct?

3 A. Formula 4A is the vehicle for Duobrii® and Bryhali®, is
4 the question.

5 I was just clarifying that from counsel.

6 So you're asking me if all the components in 4A are
7 the same components in the Duobrii® formulation?

8 Q. We'll take it one at a time.

9 Looking at the Duobrii® formulation, the vehicle of
10 the Duobrii® formulation is the exact same formulation for the
11 vehicle that's listed in Table 4.

12 Is that correct?

13 A. That's correct.

14 Q. And looking at the Bryhali® product, Table 4, Formula 4A,
15 describes the formulation for the Bryhali® product.

16 Is that correct?

17 A. I believe that it does.

18 Q. Was it known prior to 2010 that halobetasol propionate is
19 lipophilic?

20 A. It was known, yes.

21 Q. It was known prior to 2010 that lipophilic drugs dissolve
22 in lipophilic solvents.

23 Is that correct?

24 A. I think you can't say they dissolve in all lipophilics
25 that are solvents, but you would know that there was

1 solubility of lipophilic substances in lipophilic solvents.

2 Q. So you would agree with me that prior to 2010 it was
3 known that lipophilic compounds would have solubility in
4 lipophilic solvents.

5 Is that correct?

6 A. Again, lipophilic drugs should dissolve, but you don't
7 know for certain that they'll dissolve in all solvents and you
8 don't know to what extent they're soluble.

9 So I think that's the best way of explaining it.

10 Q. The pharmaceutical scientists routinely conduct
11 solubility testing.

12 Is that correct?

13 A. Well, routinely is a very loaded word.

14 Solubility is what I would call a standard test that
15 we use.

16 Q. And if you're developing formulations, solubility studies
17 would be included.

18 Is that correct?

19 A. Solubility tests are important to conduct in formulation
20 science.

21 Q. But solubility studies would be conducted if you're
22 developing formulations.

23 Is that correct?

24 A. You may have to conduct solubility studies, yes, when
25 you're developing formulations.

1 MS. PITZEL CRUZ: With that, Your Honor, I pass the
2 witness.

3 THE COURT: Thank you. All right, redirect.

4 MS. WEISBRUCH: I've got a brief redirect, Your
5 Honor, but I see that it's 11:00.

6 Would Your Honor like redirect, or should we take our
7 morning break.

8 THE COURT: We'll take our break. Okay.

9 THE COURTROOM DEPUTY: All rise.

10 MS. PITZEL CRUZ: Your Honor, just for clarity,
11 during the break --

12 THE COURT: I'm sorry?

13 MS. PITZEL CRUZ: Just for clarity during the break,
14 we wouldn't have the witness discussing anything with counsel.

15 MS. WEISBRUCH: That's correct.

16 THE WITNESS: I promise.

17 THE COURT: Say that one more time.

18 THE COURTROOM DEPUTY: They're not going to discuss
19 with the witness any testimony that the witness --

20 THE COURT: Actually, they can, all right? Now that
21 she is off cross, all right, the sequestration provisions do
22 not apply. Okay?

23 The sequestration provisions apply while she is still
24 under cross but for redirect you can talk to your witness.
25 Okay?

1 (Recess taken from 11:03 a.m. to 11:17 a.m.)

2 THE COURTROOM DEPUTY: All rise.

3 THE COURT: Be seated. All right. Let's proceed.

4 MS. WEISBRUCH: Thank you, Your Honor.

5 REDIRECT EXAMINATION

6 BY MS. WEISBRUCH:

7 Q. Dr. Lane, I have three questions for you and we will
8 spare your voice, hopefully.

9 First, just speaking generally, would dissolving a
10 superpotent corticosteroid like halobetasol in an oily solvent
11 be the only option for a POSA who was seeking to make a
12 pharmaceutical formulation using those superpotent
13 corticosteroids?

14 A. No. We also see suspensions.

15 So in suspensions, the drug isn't in solution and
16 there are a number of suspension formulations, so solid
17 particles of the drug in formulations of superpotent
18 corticosteroids.

19 MS. WEISBRUCH: If I could take you to Slide PDX-3-32
20 from your presentation.

21 BY MS. WEISBRUCH:

22 Q. Regarding the fourth bullet point that Ms. Pitzel Cruz
23 asked you about, can you explain why you understand the '566
24 patent to be teaching transdermal delivery specifically?

25 A. Yes. So we talked about this yesterday and I was

1 explaining the figure to the Judge. On the X axis is time, on
2 the Y axis is the amount of drug that penetrates. So that
3 experiment is measuring how much drug goes all the way through
4 the skin.

5 So that's what we call transdermal delivery. It's
6 not what we want for the superpotent corticosteroids. And all
7 the experiments in this particular patent are focused on
8 measuring transdermal permeation, so all the way through the
9 skin and into the blood stream.

10 Q. Speaking generally, again, Ms. Pitzel Cruz walked you
11 through some concentration ranges that appear in the various
12 references you discussed earlier today.

13 A. Yes.

14 Q. Do any of those broad concentrations -- I'll start that
15 again.

16 Do any of those broad concentration ranges tell a
17 person of skill in the art that they can use any steroid at
18 any concentration that falls within that range?

19 A. No, those broad ranges do not disclose to a person of
20 skill in the art that you can use any steroid at any
21 concentration. And it comes back to what I said, we have to
22 do the experiments and we have to do the testing. There are
23 no routine outcomes.

24 Q. Ms. Pitzel Cruz also asked you about whether there was
25 any data in the Bryhali patent that supports the idea that

1 delivery into the skin -- or preferential delivery I think is
2 what she called it -- is occurring?

3 A. Yes. So the data that support the inventor's opinion
4 that preferential delivery into the skin is evident for their
5 formulations is shown in the vasoconstriction data.

6 I don't know if we can show the table, but there is
7 data in the Bryhali patent showing vasoconstriction testing.
8 And they clearly show the low-concentration formulations of
9 the invention are localizing the drug in the skin, compared to
10 a much higher concentration of Ultravate®, which has the same
11 local score, but clearly the rest of the drug in the
12 Ultravate® formulation is going all the way through the skin.

13 Q. Just so we have a clean record, you were referring to
14 Table 3 of the '307 patent.

15 Is that correct?

16 A. Yes. Table 3 describes the vasoconstriction testing and
17 that test --

18 THE WITNESS: Great. Thank you. We see it here.

19 So we have A, B, C, and D, and they are formulations
20 of the invention. And they contain different concentrations
21 of halobetasol propionate.

22 And then you see a column that says "VCA mean score."
23 So that's like a blanching response or whitening response in
24 the skin.

25 THE COURT: And the VCA score is a proxy for the

1 effectiveness of the drug?

2 THE WITNESS: The effectiveness of the drug in the
3 skin.

4 THE COURT: Thank you.

5 THE WITNESS: So really the important point is the
6 low concentration formulations of the invention, A, B, C, and
7 D, still show comparable local efficacy to a higher
8 formulation, Ultravate®, which has 0.05 percent halobetasol
9 propionate.

10 MS. WEISBRUCH: Thank you, Dr. Lane. I have no
11 further questions.

12 I pass the witness.

13 THE COURT: Any further cross?

14 MS. PITZEL CRUZ: Very short, Your Honor.

15 THE COURT: Okay. Go ahead.

16 RECROSS-EXAMINATION

17 BY MS. PITZEL CRUZ:

18 Q. Dr. Lane, with respect to the preferential delivery that
19 we just discussed and the Table 3 that you were looking at,
20 the VCA data -- is that correct?

21 A. Yes.

22 Q. The VCA data does not include any information that
23 describes the systemic absorption of the halobetasol.

24 Is that correct?

25 A. As we were discussing, VCA is the local activity of the

1 drug in the skin, which is where we need it to act.

2 Q. And we agreed earlier that there is no data in the '307
3 or the '502 patent that describes the systemic absorption of
4 the halobetasol formulations, correct?

5 A. Systemic absorption was not measured.

6 That's correct.

7 MS. PITZEL CRUZ: Okay. Thank you.

8 No further questions.

9 THE COURT: I gather no further redirect.

10 MS. WEISBRUCH: No further redirect, Your Honor.

11 THE COURT: Thank you, Doctor. You're excused.

12 (Witness excused.)

13 MS. PITZEL CRUZ: Your Honor, my apologies.

14 With the Court's permission, we'd like to move into
15 evidence DX-156 and DX-383.

16 MS. WEISBRUCH: No objection.

17 THE COURT: Admitted into evidence.

18 MS. PITZEL CRUZ: Thank you.

19 (Exhibit Number DX-156 is received in evidence.)

20 (Exhibit Number DX-383 is received in evidence.)

21 MR. BRUNO: Bausch next calls Dr. Linda Stein Gold to
22 the stand.

23 THE COURTROOM DEPUTY: Are these her binders or do
24 you want me to move them?

25 MR. STEINDLER: I'll get them.

1 DR. LINDA STEIN GOLD, PLAINTIFF'S WITNESS,
2 having been duly sworn, testifies as follows:

3 THE COURTROOM DEPUTY: Please state your full name
4 for the record.

5 THE WITNESS: Linda Stein Gold.

6 THE COURTROOM DEPUTY: Thank you.

7 DIRECT EXAMINATION

8 BY MR. BRUNO:

9 Q. Welcome back, Dr. Stein Gold, and it's good to have you
10 in person with us.

11 A. Thank you.

12 Q. As a reminder, can you very briefly summarize your
13 expertise for the Court?

14 A. I am a medical dermatologist, and I have a lot of
15 experience with the topical treatments of medications for
16 psoriasis.

17 Q. What opinions did you reach regarding the validity of the
18 Bryhali® patents in this case?

19 A. So I reached a number of opinions, and I summarized them
20 on the next slide.

21 There are five opinions overall.

22 The first one is that a person of ordinary skill in
23 the art -- and I'm going to refer to this as a POSA from now
24 on.

25 A POSA would not have been motivated to reduce the

1 concentration of a corticosteroid, especially -- a superpotent
2 corticosteroid below 0.05 percent with any expectation that
3 this is going to work.

4 They wouldn't have expected that a 0.01 percent
5 halobetasol would achieve any type of similar efficacy or
6 potency to the full-strength halobetasol.

7 A POSA would not have expected to ever be able to use
8 a superpotent steroid for any period approaching eight weeks.

9 And Bryhali® actually showed an unexpected result in
10 that it satisfied an unmet need that we've had for a really
11 long time: giving us an efficacious superpotent steroid that
12 could be administered for much more than two weeks.

13 And then, finally, other pharmaceutical companies,
14 even though halobetasol had been around for decades, had not
15 been experimenting with developing a concentration that was
16 lower than the standard 0.05 percent.

17 Q. What opinions did you reach regarding the active
18 ingredient and formulation limitations of the Duobrii®
19 patents?

20 A. So listed here I have a number of opinions, first of all,
21 regarding the active ingredient and the vehicle.

22 As Dr. Pillai explained yesterday, it is a really
23 high bar to be able to create a fixed combination. So a POSA
24 wouldn't have been motivated to make a fixed combination.

25 And as I explained prior, a lotion formulation tends

1 to be our least efficacious, or one of our least efficacious
2 formulations. So that's not necessarily a go-to vehicle.

3 We would not have expected a POSA to develop a
4 concentration of tazarotene at the 0.045 percent with a
5 reasonable expectation of success, meaning efficacy and
6 safety.

7 And certainly would not have been motivated to
8 decrease that concentration of halobetasol by 80 percent to a
9 0.01 percent in this combination with reasonable expectation
10 of success.

11 And, finally, dermatologists were really skeptical
12 that this was a good idea at all.

13 Q. And what about the synergy limitations? Can you
14 summarize the synergy limitation opinions that you offer?

15 A. Yes.

16 First of all, nothing in the prior art regarding
17 these two medications tell us anything about synergy or the
18 synergy limitations as discussed here.

19 So given that it's not even discussed in the art, a
20 POSA wouldn't have been motivated to even try to achieve
21 synergy.

22 And then, finally, Duobrii® actually demonstrated the
23 unexpected results with these synergy limitations, both
24 efficacy and side effects.

25 Q. Do you have an opinion about the definition of a POSA of

1 the Bryhali® and Duobrii® patents?

2 A. Yes.

3 We spent a lot of time on the definition of POSA, so
4 I'm not going to read through it. But this is the definition
5 and Padagis' definition as well.

6 Q. Okay. Do you understand Padagis to be taking a
7 meaningfully different position on the definition of a POSA?

8 A. Nothing would have changed.

9 Q. Okay. Before we get into your specific opinions, let's
10 first discuss the state of psoriasis treatment and drug
11 development as of 2010 when the Bryhali® patents were
12 invented.

13 What was the state of drug development for psoriasis
14 at that time?

15 A. So, actually, there was really a paradox in research and
16 development.

17 Although most psoriasis patients have localized
18 disease, the vast majority of our research and development was
19 really looking at these biologic drugs. And these are drugs
20 that are really just for the worst maybe 10 to 15 percent of
21 psoriasis patients.

22 But topical therapy was the mainstay of therapy for
23 the vast majority of psoriasis patients with both localized
24 needs and in addition to systemic therapies as well.

25 Q. What was the state of topical treatment for psoriasis in

1 2010?

2 A. So we had a number of topical therapies, but the gold
3 standard was still superpotent topical steroids.

4 You saw pictures of what these psoriasis patients
5 looked like. We wanted to get these patients under control as
6 quickly and as completely as possible.

7 So we were utilizing superpotent steroids like
8 Ultravate®, but they had that two-week limitation.

9 Q. What other topical treatments were available for
10 psoriasis?

11 A. So we have a whole host of topical therapies. There's
12 all kinds of things: tar, anthralin, salicylic acid, urea.

13 And then more commonly, besides topical
14 corticosteroids, we have topical vitamin D analogs and topical
15 vitamin A analogs.

16 Q. And is another name for vitamin A analogs "retinoids"?

17 A. Yes.

18 Q. Okay. And what retinoid was being used for psoriasis at
19 the time? Or, actually, let me ask the question in a slightly
20 different way.

21 What retinoid was commercially available for the
22 treatment of psoriasis as of 2010?

23 A. So there were a number of different retinoids. But just
24 one was used for psoriasis, and that was called "tazarotene,"
25 or it went by the brand name Tazorac®.

1 And that was available in two different
2 concentrations. We had a low concentration, the 0.05 percent;
3 and then a higher concentration, the 0.1 percent.

4 Q. And in 2010, how was Tazorac® being prescribed for
5 psoriasis?

6 A. So it's really kind of a paradox again because we have
7 the problem of trying to get psoriasis under control.

8 Ideally, we said, you know, we want to use
9 combination therapy, use drugs that work by different
10 mechanisms of action.

11 Tazorac® makes sense because it calms down those
12 cells, let them get educated appropriately as they make their
13 way through the skin. But it's so irritating that people just
14 didn't prescribe it.

15 Q. Do you have any personal experience with people not
16 prescribing tazarotene?

17 A. I do.

18 So I lecture on topical therapy with psoriasis all
19 over the country and, actually, all over the world.

20 And I was at a meeting where we were talking about
21 topical therapy, and I just simply asked the audience -- there
22 was probably hundreds of people -- I said, How many people
23 here use topical tazarotene for psoriasis?

24 Even though it's FDA approved, it's been proven,
25 almost nobody raised their hands. It just wasn't being used.

1 Q. Now, you listened to the testimony of Dr. Stern, correct?

2 A. I did.

3 Q. Do you agree with Dr. Stern's opinion that a person of
4 ordinary skill in the art in 2010 would have been motivated to
5 achieve a reduced concentration of halobetasol to as low as
6 0.01 percent?

7 A. I don't agree with him. And --

8 Q. And why not?

9 A. So the reason is, basically, we want stronger medicines,
10 not weaker medicines. So I have a number of reasons why this
11 just doesn't make any sense.

12 The first was, we really thought that halobetasol --
13 it's been around for 20 years. We heard from Dr. Pillai that
14 they tried to optimize the concentration straight out of the
15 gate. We thought it was optimized.

16 We want not lower concentrations. We want more
17 powerful drugs, not weaker drugs. And the art taught that as
18 you decrease that concentration, you tend to get a less potent
19 and less efficacious drug.

20 And then, finally, there was no good, real-world
21 experience that showed a good benefit from using something
22 less than the 0.05 percent halobetasol.

23 Q. Let's talk about each of these in just a little more
24 detail.

25 Why would clinicians have believed that Ultravate®

1 was optimized?

2 A. So we thought this was optimized because this was a drug
3 that was put out by a premier pharmaceutical company, Bristol
4 Myers Squibb.

5 We know that when you get a drug, before it gets --
6 by the time it gets to the FDA, it's been studied. We look at
7 different concentrations of the drug, different uses of the
8 drug, and we finally come down to a safety-efficacy tradeoff
9 that we believed is optimized. And that was what we thought
10 with halobetasol.

11 Q. Was this opinion you just expressed reflected anywhere in
12 the prosecution history of the Bryhali® patents?

13 A. Yes.

14 Gordon Dow also stated that he felt that BMS had
15 optimized halobetasol.

16 Q. The second reason you gave was that dermatologists would
17 have sought stronger therapy.

18 Why do you say this?

19 A. I say this because this is what the facts show us.

20 You know, when we look at what dermatologists
21 prescribe and we look at the prescribing habits of
22 dermatologists, they prescribe superpotent steroids far more
23 than any other type of steroids.

24 Even if you add the Class 2 and the Class 3 together,
25 it doesn't really match the superpotents. We've got to get

1 the patient under control. Give us the biggest guns that you
2 have.

3 Q. And what factors determine potency?

4 A. So I think I described this earlier, but I like to
5 describe the topical drug as a marriage. It involves the
6 active ingredient, but it also involves the vehicle. And each
7 of them plays a really important role in the efficacy, the
8 tolerability, and the patient acceptability of the drug.

9 Q. Do you know how steroid efficacy will be affected if you
10 change one of these factors?

11 A. So I lecture on this. And one of the things I like to
12 say is, we don't necessarily know for sure what's going to
13 happen when you change the drug.

14 You know, if you change the concentration, you change
15 the vehicle especially, you can either change the vehicle and
16 you can make it stronger, or you can change the vehicle and
17 make it weaker. You just have to test it to understand.

18 Q. Can you give an example that illustrates just how much a
19 vehicle can matter?

20 A. Yes. So my favorite example is betamethasone
21 dipropionate.

22 This is one ingredient, betamethasone dipropionate.
23 The same active ingredient is married to different vehicles in
24 this chart.

25 So it can have a marriage that gives it a superpotent

1 concentration, the strongest drug, but it can also change the
2 vehicle and give it a lesser potent drug. In fact, it can go
3 all the way down from a Class 1 all the way down to a Class 5.

4 And I want you to notice that the stronger drugs
5 often are more like the ointment formulations because they're
6 more occlusive. The weaker drugs are usually the lotions. We
7 think of them as not being as occlusive.

8 And just as a general rule, a lotion is usually
9 less -- often less favorable because it's usually a little
10 less efficacious.

11 Q. Generally speaking, what would you expect if you changed
12 the concentration of the active ingredient?

13 A. Well, if you change the concentration of the active
14 ingredient, that means you're delivering less active drug.
15 And less active drug usually means less potency, less efficacy
16 overall.

17 Q. Why wouldn't a POSA seek to create a less potent, less
18 efficacious drug, as Dr. Stern suggests?

19 A. Okay. So we have a whole a lot of topical
20 corticosteroids. We have corticosteroids that are Class 2,
21 Class 3, Class 4, 5, 6, 7. We have tons of them. That's not
22 an unmet need.

23 We already have less potent drugs. If you want a
24 less potent drug, just prescribe one that's on the market.
25 Why do you want to go make a new one? We have those already.

1 It doesn't make sense to make something that's less
2 potent. We want more potent, or something else that gives us
3 another benefit for the patient.

4 Q. Was the predominant treatment at the time to start a
5 patient on weaker treatment and then scale up?

6 A. No.

7 Q. And why not?

8 A. As I mentioned, these patients are suffering. They're
9 suffering physically. The psoriasis, it's itchy. It's
10 painful. They're humiliated by it. They're suffering from
11 anxiety and depression. You want to get the patient under
12 control as quickly as possible.

13 Q. Is the view you just expressed contained anywhere in the
14 prosecution history of the Duobrii® patents?

15 A. Yes. Dr. Jeffrey Sugarman is actually a dermatologist
16 who practices on the other end of the country from me, and he
17 really has the same views.

18 Q. What did articles say at the time?

19 A. Well, there were a number of articles that really talked
20 about how should we get patients under control with topical
21 therapy.

22 And the mainstay of thought was to use as potent a
23 drug as possible initially, get them under control, and then
24 you can pull back later.

25 Q. And have you provided some examples of articles that

1 support your position here?

2 A. Yes. Weigle 2013 and Uva 2012 both explain this.

3 Q. And, for the record, Weigle 2013 is PTX-368, and Uva 2012
4 is PTX-356?

5 A. Yes.

6 Q. The third reason you gave for not reducing the
7 concentration of halobetasol was that the art taught away from
8 using lower dosages to treat psoriasis.

9 Why do you say that?

10 A. I say that because that's what we see in the clinical
11 trials. Blum has gotten a lot of talk so far, but I'm going
12 to come back to it.

13 First of all, I just want to say this was not a
14 well-run study. This was a study that if it was trying to get
15 published today probably would not have been published because
16 it just wasn't conducted well.

17 They don't describe well the patients that come in to
18 the study. They say they had to have at least 20 percent body
19 surface area. Was it 18 percent or was it 2 percent? They
20 don't tell us.

21 They don't explain what was the extent of their
22 psoriasis in terms of how severe was it. Was it almost clear?
23 Was it mild, moderate or severe? They don't tell us.

24 So -- and they don't even explain their -- their
25 efficacy assessments.

1 So it's not the best study. But even given the
2 limitations, he still comes to some conclusions.

3 He looks at comparing the 0.05 percent halobetasol
4 ointment to the 0.02 percent halobetasol ointment. And,
5 overall, he concludes that the 0.05 percent would be the
6 favorite treatment weapon.

7 Q. Okay. And you had mentioned that Blum specifically
8 compared the 0.05 to 0.02.

9 Where do we find that in Blum?

10 A. Well, he basically makes an overall statement stating
11 that especially in severe psoriasis -- so now we were actually
12 getting a defined group where he is actually calling out the
13 "severe," so we understand what he's actually assessing.

14 He said in the severe psoriasis, the 0.02 was less
15 effective. And he goes on to state that you really need to
16 look at that severe category in order to get the most reliable
17 measurement of the way of comparing the two different
18 formulations, or the two different concentrations.

19 Q. Do you know if Blum's data supports this conclusion?

20 A. Blum's data does support this conclusion.

21 Again, you know, it's hard for me to make a whole lot
22 from this just because I don't -- I don't love the way this
23 study was done, as somebody who runs clinical trials.

24 But what he does show us is that, overall, we have a
25 lower efficacy with the severe patients and we have a lower

1 efficacy of the overall patients as well.

2 Q. What would a POSA understand from the adverse event data
3 in Blum?

4 A. So this is where it's really interesting.

5 So he takes the concentration and takes it from a
6 0.05 percent and takes it down to a 0.02 percent. Yet when he
7 talks about the side effect profile, at least in terms of
8 local side effects, and irritation, which he defines as
9 erythema, it's not on the slide, but in the body of the work,
10 he explains that the lower concentration actually had a higher
11 incidence of -- the lower concentration had a higher incidence
12 of local side effects than the higher concentration did.

13 And when we worry about atrophy or thinning of the
14 skin, one of the problems that comes with potent steroids, the
15 incidence of atrophy in the low and the high was the same. So
16 we really weren't looking like we were saving much in terms of
17 side effects.

18 So we had, potentially, a less effective drug that
19 was maybe equivalent or maybe a little bit worse in terms of
20 side effects.

21 Reading this article, I have absolutely no reason to
22 go ahead and make that 0.02 percent concentration.

23 THE COURT: What do you mean by "atrophy"?

24 THE WITNESS: So when you apply a steroid to the
25 skin, especially a potent steroid, it can thin the skin. So

1 it can thin the top layer, the epidermis; it can thin the
2 lower level, the dermis.

3 And the way you know that that's there is you start
4 to see blood vessels coming to the surface. The skin can get
5 so thin that it can tear just from little things. So we call
6 that "atrophy" or "thinning."

7 THE COURT: All right.

8 BY MR. BRUNO:

9 Q. Are you aware of a 0.02 percent halobetasol ointment ever
10 having been commercialized?

11 A. No.

12 Q. And you also mentioned that a POSA would have no
13 experience with a superpotent corticosteroid below
14 0.05 percent.

15 Why do you say that?

16 A. Because that's not what we had.

17 And so these are an example of superpotent steroids
18 from the time. And when we look at the concentrations, nobody
19 had been able to take that 0.05 percent. It's kind of the
20 magic concentration at that point to achieve the superpotent
21 steroid efficacy level.

22 Q. Now, one of the opinions you identified earlier was that
23 the Bryhali® patents demonstrate unexpected results.

24 How do the Bryhali® patents demonstrate unexpected
25 results?

1 A. So the Bryhali® patents actually have a concentration of
2 halobetasol where we take it from 0.05 percent all the way
3 down to 0.01 percent. So that's an 80 percent reduction in
4 concentration.

5 Yet that lower concentration actually had a potency
6 that was the same as the higher. It had an efficacy that was
7 the same as the higher. And you could use this four times
8 longer than the full-strength halobetasol.

9 So that -- that was completely unexpected.

10 Q. Let's talk about some general principles.

11 MR. BRUNO: Let's move to the next slide.

12 BY MR. BRUNO:

13 Q. If you were going to drop the concentration, what would
14 the expectation be?

15 A. So, in general, just as a general rule, the concentration
16 is related to the potency, which is related to the efficacy.
17 And all of this is related to the safety.

18 So they're all kind of hold-hands. They're all tied
19 in together.

20 Q. And so what happens when you drop the concentration?

21 A. So if you drop the concentration down, as a general rule,
22 you drop the concentration, you tend to drop the potency.

23 And usually if you drop the potency, that means the
24 efficacy, the actual treatment of the psoriasis, goes down.
25 But the safety should go up because we're getting exposed to

1 less active drug.

2 Q. And just to be clear, this is just a representative
3 example?

4 A. Just an example, a teaching example. That's all.

5 Q. Now, how do these general principles apply to Bryhali®?

6 A. So, actually, if we go to the next slide, the first one
7 was we drop the concentration by 80 percent. Yet we've heard
8 a lot, at this point, about the vasoconstrictor assay, which
9 is that -- measures the potency of the drug.

10 And what we heard from multiple people at this point
11 is that the potency of the drug, even though it was 80 percent
12 less drug, the potency remained in that superpotent steroid
13 classification.

14 Q. How does the efficacy of Bryhali® compare to Ultravate®?

15 A. Well, the only way to know how the efficacy compares is
16 to do a head-to-head study. And unlike the Blum study, this
17 study was actually really nicely done.

18 Moderate to severe psoriasis patients. Four arms of
19 the study. Two actives head to head plus two vehicles.

20 So the investigator doesn't know, Are you on active
21 drug or are you on vehicle?

22 I don't know.

23 So I got to be really honest in my assessments.

24 And what we found was, head to head, these drugs were
25 very comparable in efficacy. In fact, the difference is maybe

1 1.5 percent difference in efficacy. Very, very similar even
2 though we dropped the concentration by 80 percent.

3 Q. The last factor you mentioned was safety.

4 How does the safety of Bryhali® compare to
5 Ultravate®?

6 A. So, again, halobetasol has never been allowed to be used
7 for more than two weeks. The cream, the ointment, it doesn't
8 matter. The FDA is very strict. This drug cannot be used for
9 longer than two weeks in the Ultravate®.

10 But now we have Bryhali®. We dropped that
11 concentration by 80 percent. And if you look at the label,
12 this is now allowed to be used for eight weeks, so four times
13 longer. We have never had a superpotent steroid that allowed
14 us to use the drug for eight weeks.

15 Q. What would you expect with a dropping concentration from
16 Ultravate® to Bryhali®?

17 A. So if we -- if we're going from Ultravate® and we're
18 going to go to Bryhali®, we're going to drop that
19 concentration down. And I'm just going to use this as an
20 example.

21 The expectation would be you drop the concentration
22 by 80 percent, you expect the potency to go from a superpotent
23 now probably to somewhere in a midpotency. That's the
24 expectation.

25 The efficacy, because it's usually linked, you know,

1 to concentration, we expect it to go down. But we do expect
2 the safety to go up.

3 Q. Now let's reset the chart.

4 What actually happened when we dropped the
5 concentration from Ultravate® to Bryhali®?

6 A. So what happened was unexpected in every one of these
7 areas.

8 So we dropped the concentration. We understand that.
9 We dropped it by 80 percent. Yet the potency remained in that
10 superpotent steroid classification based on the
11 vasoconstrictor assay.

12 The efficacy, again, looking head to head, it's a
13 touch down. It's 1.5 percent, maybe, down. But it's
14 virtually the same.

15 And the safety, as opposed to going up a little bit,
16 it went up tremendously. Now eight weeks for a superpotent
17 steroid.

18 Q. Would a POSA expect that you could develop a superpotent
19 corticosteroid that could safely be used for eight weeks?

20 A. No.

21 Q. Why not?

22 A. Because this wasn't something that we had seen before.

23 We did talk earlier about Temovate E®. This isn't
24 halobetasol. This is clobetasol, which is a different
25 molecule. And it allows a four-week use, but there are strict

1 words in the package label about safety. And they basically
2 mention it can be used on, you know, less than 10 percent of
3 the body. And you have to watch these patients for the
4 development of HPA axis suppression.

5 Q. What would a POSA understand from the fact that there was
6 a four-week administration indicated in the Ultravate® -- I'm
7 sorry, let me start again.

8 What would a POSA understand from the fact that there
9 was a four-week administration indicated for Temovate E® but
10 not for Ultravate®?

11 A. These are different drugs, and so, you know, even after
12 20 years, we haven't changed the indication, we haven't
13 changed the percentage. You know, that's what would have been
14 safe.

15 Q. Does the Temovate E® Label warn about the downsides of a
16 four-week usage?

17 A. It does. And it mentions that HPA axis suppression which
18 comes from the potential of having a systemic absorption of a
19 superpotent topical corticosteroid.

20 Q. You also offered an opinion that the Bryhali patents
21 satisfy a long-felt need. What long-felt need did the Bryhali
22 patents satisfy?

23 A. So, again, these patients are suffering. We want to use
24 the most potent medication possible, and our hands have been
25 tied because we can use a potent drug but we're then advised

1 you have to stop after two weeks. But the patient -- it takes
2 longer than two weeks -- as Dr. Stern agrees, it takes longer
3 than two weeks to get that psoriasis under control. You're
4 kind of just starting to get improvement and then you've got
5 to pull back.

6 Q. How long did that need exist for?

7 A. That need has existed pretty much since we've had topical
8 therapy and superpotent steroids. So that need has been
9 around for decades.

10 Q. And what do you understand Dr. Stern's position to be
11 about how long that need has existed for?

12 A. He agrees.

13 Q. How did the Bryhali patents meet that long-felt need?

14 A. So the Bryhali patents actually allow us, with a very
15 sophisticated vehicle, to use a lower concentration of active
16 drug, understanding if we can lower that concentration of
17 drug, the impact to the systemic circulation should go down
18 and we should now have a safer drug that therefore should be
19 able to be used for longer.

20 Q. What is your understanding on how the length of the
21 existence of a need affects the obviousness of the inventions
22 claimed in the Bryhali patent?

23 A. So, you know, if the unmet need has been there for a long
24 period of time and it hasn't been fulfilled, it's not that
25 obvious.

1 Q. You also offered an opinion that others did not achieve
2 the inventions of the Bryhali® patents. How do you determine
3 that?

4 A. So it just -- it hadn't been studied. This is a review
5 of ClinicalTrials.gov looking at the different clinical trials
6 that were being undertaken with this drug, halobetasol, and
7 they either don't claim their concentration or they only use
8 the standard 0.05 percent. There's --

9 MR. ZIMMERMAN: Your Honor, Your Honor, this is not
10 the slide that was produced to us pursuant to the exchange
11 schedule. We've never seen this slide before.

12 THE WITNESS: Yeah. It hasn't been changed.

13 MR. BRUNO: Your Honor, I don't understand the slide
14 to have been changed.

15 Can I confer with opposing counsel for just a moment?

16 THE COURT: Confer.

17 (Discussion held off the record.)

18 MR. BRUNO: It's not a problem, Your Honor. We'll
19 show the slide in this form instead, which apparently --

20 THE WITNESS: It was a build.

21 MR. BRUNO: Okay. So we'll continue the examination.

22 BY MR. BRUNO:

23 Q. Is it your understanding that defendants experimented
24 with halobetasol?

25 A. They did, and it's evidenced in ClinicalTrials.gov that

1 they actually looked at halobetasol I believe in the cream and
2 the ointment formulations but just using the full-strength
3 0.05 percent.

4 Q. Now, let's address each reference related to your
5 opinions on the Bryhali® patents, briefly.

6 What do you think a POSA would take away from Blum?

7 A. So a POSA would take away from Blum that there was
8 basically --

9 THE WITNESS: If you could just go back.

10 A POSA would take away from Blum that there is no
11 benefit that was gained by using the lower concentration
12 0.02 percent. They did not look at a 0.01 percent. But there
13 was no gain in using the 0.02 percent. It seemed to be less
14 efficacious and have potentially, at least for local side
15 effects, similar, maybe even a little bit worse, local side
16 effects.

17 And they looked at the 0.02 percent formulation, but
18 this never came to market.

19 BY MR. BRUNO:

20 Q. What do you think a POSA would understand from the
21 Temovate® Label?

22 A. Temovate E® Label still states that these are drugs that
23 have to be used with caution. If you choose to use them for
24 longer than two weeks, you, you know, need to watch for HPA
25 axis suppression.

1 And these are different drugs. Clobetasol is not
2 halobetasol, and there's no information on using halobetasol
3 for any longer than two weeks.

4 MR. BRUNO: Now, let's put up your summary slide for
5 the Bryhali® patents again.

6 BY MR. BRUNO:

7 Q. And are these the opinions you've just walked the Court
8 through?

9 A. They did. I'm not going to read them again, but this
10 just summarizes everything I just stated.

11 Q. Now, I'd like to switch gears for a moment.

12 Is it your opinion that Claim 16 of the '502 patent
13 is -- has written description?

14 A. Yes.

15 MR. BRUNO: Let's pull up Claim 16 of the '502
16 patent, which is JTX-4.

17 BY MR. BRUNO:

18 Q. And to remind the Court, what does Claim 16 of the '502
19 patent require?

20 A. So the method of Claim 13, wherein the method comprises
21 applying the pharmaceutical for a period of longer than two
22 weeks. Basically just saying you can take this topical
23 medication and use it for more than two weeks.

24 MR. BRUNO: Now let's pull up Column 2, Lines 42
25 through 62 of the '502 patent.

1 Actually, let's try -- no, Column 2 -- this is
2 Column 4, I believe.

3 THE WITNESS: This is Column 4?

4 BY MR. BRUNO:

5 Q. What do you understand the part of the patent that is up
6 on the screen to be saying about how the prior art dealt with
7 safety?

8 A. So basically what this explains to us is that there is an
9 unmet need because we have this limitation of two weeks for
10 superpotent steroids, and we have an unmet need to use them
11 for a longer period of time to get the psoriasis patients
12 basically under control.

13 MR. BRUNO: Now let's pull up Column 3, Lines 6
14 through 14.

15 BY MR. BRUNO:

16 Q. What do you understand this portion of the '502 patent
17 specification to be teaching about the need to address the
18 two-week limitation?

19 A. So basically what this makes reference to is the fact
20 that any and all of the superpotent corticosteroids have the
21 problem of potentially getting into the systemic circulation
22 and causing the HPA axis suppression.

23 MR. BRUNO: Now let's turn to Column 9, Lines 6
24 through 23.

25 BY MR. BRUNO:

1 Q. What do you understand this portion of the specification
2 to be teaching?

3 A. So basically what it's explaining to us is that there is
4 an enhanced vehicle. And because we can potentially reduce
5 the concentration of the corticosteroid, we should then be
6 able to administer the lower concentration which should then
7 be safer and decrease the potential risk for HPA axis
8 suppression.

9 Q. And so is it your view that the '502 patent teaches that
10 the invention solves the two-week problem of the prior art?

11 A. It does.

12 MR. BRUNO: Let's also pull up Column 4, Lines 2
13 through 12.

14 BY MR. BRUNO:

15 Q. Does this paragraph inform your opinion?

16 A. Yes.

17 Q. And how does it do that?

18 A. Because, again, it talks about when you have a much
19 reduced concentration of topical corticosteroid, the chance of
20 getting -- or it's much more likely then you have a
21 significantly reduced exposure to the systemic circulation,
22 therefore, you decrease the likelihood of having any type of
23 systemic side effect so you should be able to use it
24 potentially for a longer period of time.

25 So it just explains the whole rationale.

1 Q. Ad do you understand this to be reflected elsewhere in
2 the '502 patent specification?

3 A. Yes.

4 Q. Let's turn now to the Duobrii® patents.

5 MR. BRUNO: If we can go back to the slides.

6 BY MR. BRUNO:

7 Q. And these are the opinions that you summarized at the
8 beginning of your testimony today?

9 A. Yes, they are.

10 Q. Now you previously discussed the state of psoriasis
11 treatment in 2010.

12 What, if anything, had changed by 2015?

13 A. So what we find is -- and I've summarized this here --
14 that, you know, it had been years later, but we didn't have
15 any major changes really in topical therapy. Topical
16 superpotent steroids were still the gold standard. Bryhali®
17 actually hadn't yet been marketed so it wasn't available. And
18 so we had that disconnect in terms of the research and
19 development being put into biologic drugs again for a smaller
20 segment of the psoriasis population.

21 And we know that when we ask our patients how are we
22 doing in terms of treating psoriasis, we're just not doing
23 that well.

24 Q. Are there any articles that support your view that
25 patients wanted better topical treatment?

1 A. Yes, Duffin in 2013 was one of several articles that
2 basically said patient satisfaction scores with topical
3 therapy were not very good.

4 Q. Now let's turn to an exemplary claims of the Duobrii®
5 patents.

6 Can you walk the Court through Claim 1?

7 A. So Claim 1 really has kind of three components to it.
8 The first part talks about the active ingredients; the second
9 part talks about the vehicle formulation; and then the third
10 part really describes the synergy limitations. And that
11 includes the idea of having a synergistic efficacy results and
12 a synergistic reduction of the adverse events.

13 Q. What elements do the asserted claims of the Duobrii®
14 patents add?

15 A. So I've outlined them here. And there are a lot of them,
16 so this is kind of a summary statement. Just to highlight
17 one, it actually calls out the fact that we're providing a
18 method of relief of psoriasis four weeks after the eight-week
19 application of the topical.

20 Q. Now, earlier you identified your opinions on the active
21 ingredient and vehicle formulation limitations.

22 Let's walk through each of these now.

23 A. Okay.

24 Q. Why would a POSA not have sought to develop a topical
25 psoriasis combination product?

1 A. So basically to form a combination drug, first of all,
2 it's not something that happens very commonly. And as
3 Dr. Pillai had mentioned, the FDA has a fairly high bar of
4 getting these combination products FDA approved. It just
5 takes a lot to get them approved.

6 Q. And how rare are topical combination products?

7 A. They're rare. So we have only two -- two potential fixed
8 combinations with potentially different vehicles.

9 Q. Now, Dr. Stern said that there was a long history of
10 combinations.

11 Do you agree with that?

12 A. So that's actually not correct. There's a long history
13 of combinations in acne, but acne is a very different disease
14 than psoriasis.

15 Prior to this, there was only two other drugs that
16 were formulated in a fixed combination.

17 Q. Is there any other reason a POSA would not have combined
18 halobetasol and tazarotene in a single dosage form?

19 A. Well, the prior art actually taught us, don't do that.

20 Q. And how did it do that?

21 A. Well, actually, when you look at Gollnick, Gollnick
22 actually describes -- and it's really interesting when you
23 look at what Gollnick is teaching us. He actually reviews two
24 different studies looking at combining tazarotene with topical
25 corticosteroids. And what he tells us and teaches us from

1 these prior studies is, don't let these drugs anywhere near
2 each other.

3 These studies are conducted either morning and night
4 or they're conducted on different days. And I have not seen a
5 clinical trial which instructed, use medication on alternating
6 days.

7 What this teaches somebody is there's a reason not to
8 use these drugs together. Use them as far apart as possible.
9 And that is what he is showing in two separate studies.

10 Q. You also said that a POSA would not have been motivated
11 to develop a lotion. Why is that?

12 A. Well, we already talked about the efficacy that the
13 vehicle helps to contribute. And I mentioned lotions, as a
14 general rule, tend to be the lesser efficacious of the
15 different types of formulations.

16 Q. You also opined that a POSA would not have sought to
17 reduce the concentration of tazarotene to 0.05 percent. At
18 the time of the invention of the Duobrii® patents, was
19 tazarotene commercially available at a concentration of
20 0.045 percent?

21 A. It was not. Tazarotene was already available in a low
22 dose, the 0.05 percent, and a high dose, the 0.1 percent.

23 And what's really interesting here is when you look
24 at the side effect profile, when you go from a 0.1 and cut it
25 in half -- and it's not on the slide but it's on the PI, the

1 package insert -- you decrease the irritation profile by less
2 than half a percent. So you're really not doing much by going
3 50 percent less.

4 So to go another 10 percent, you'd expect you're not
5 going to change the irritation profile at all. You're still
6 going to have an irritating drug.

7 Q. And what would a POSA have understood from the fact that
8 there were already two concentrations on the market?

9 A. Again, there's two concentrations you would expect that
10 they have already been optimized.

11 Q. And what was the general understanding about tazarotene
12 as a treatment for psoriasis?

13 A. Again, it makes sense intellectually, but it was not
14 being used by the average prescribing medical dermatologist.

15 Q. So would a POSA have been motivated to reduce the
16 concentration of tazarotene below 0.05 percent?

17 A. No.

18 Q. You also opined that a POSA would not have experimented
19 with 0.01 percent halobetasol. Why is that?

20 A. So, again, we don't want weaker drugs. And the common
21 sense, especially at the time, was you decrease the
22 concentration by 80 percent, you give me a less efficacious
23 drug. I'm not asking for less efficacious drug. Nobody at
24 the time needed that. They needed stronger drugs.

25 Q. Would a POSA have sought to experiment with a

1 0.01 percent halobetasol propionate in combination with
2 tazarotene?

3 A. No.

4 Q. And why not?

5 A. Well, there's several reasons why not. First of all, the
6 teaching was, don't put these two drugs together, keep them
7 apart. And maybe the teaching was they're not compatible or
8 there's a reason why or they're just going to be too
9 irritating. We don't know why, but the teaching was, keep
10 them apart. And we don't know whether at this low
11 concentration it's even going to work.

12 Q. And so you've excerpted -- well, what does the screen
13 show?

14 A. Basically Dr. Sugarman also mentioned that people at the
15 time did not feel that the 0.01 concentration was going to be
16 efficacious enough for patients with psoriasis.

17 Q. Now, you've also said that a POSA wouldn't think that the
18 halobetasol would affect -- decrease the irritancy of
19 tazarotene. Is that reflected in the prosecution history of
20 the Duobrii® patents?

21 A. It is.

22 So what we are doing is, we're worried about
23 tazarotene being too irritating, so you need big guns to come
24 in and try to calm that down. So why would you take a steroid
25 and decrease it by 80 percent and expect that that's going to

1 have any effect on tazarotene at all. It didn't make any
2 sense.

3 Q. Wouldn't Gollnick 1999 have encouraged a POSA to combine
4 a low dose of halobetasol and tazarotene?

5 A. Gollnick actually advised the POSA, do not -- not only
6 don't combine them, but you either use them 12 hours apart,
7 morning and night, or don't even do that. Use them on
8 alternate days. Keep them nowhere near each other.

9 Q. And how many studies are reflected in the Gollnick
10 article?

11 A. He has two different studies.

12 Q. What do you learn from the first Gollnick study?

13 A. So the first Gollnick study looks at using these morning
14 and night. And, first of all, in neither of the studies does
15 he use a superpotent steroid. Not at all.

16 Here he goes up to a high-potency steroid, and we
17 find that the mid- and the high-potency steroids perform about
18 the same, yet when we look at the people who couldn't even
19 tolerate this at all because they dropped out, we see that the
20 mid potency, even though they still have a lot of dropouts,
21 was better than the high potency.

22 Q. And so what would a POSA understand from Gollnick's
23 additive study?

24 A. They would understand that it's probably a better idea,
25 go ahead and pick a mid-potency topical corticosteroid.

1 Q. What would a POSA understand from Gollnick's second
2 study?

3 A. So the second study is interesting because the
4 terminology is different. That high potency that they're
5 talking about is really what we consider to be a low-,
6 mid-potency topical steroid. It's a Class 5; 1 being the
7 highest, 5 meaning closer to low than anything. So he doesn't
8 really even study high-potency or superhigh-potency steroids.

9 So it leaves kind of unpredictability as to what's
10 the best match, what should we be doing. It -- to be honest,
11 I think it leaves a POSA with confusion.

12 Q. Does either study in Gollnick teach you to use a
13 fixed-dose combination drug?

14 A. No.

15 Q. You also mention skepticism of the invention.

16 How is there skepticism?

17 A. So as Dr. Pillai had mentioned, that sometimes companies,
18 including Bausch, would look to people who treat a lot of
19 patients with topical therapy and have advisory boards. And
20 there was definitely skepticism. I definitely know that they
21 were told that this is a waste of money and doesn't make any
22 sense to use these -- even though they weren't necessarily
23 asking for advice on the potencies, they were given advice on
24 the potencies.

25 MR. ZIMMERMAN: Your Honor, this is outside the scope

1 of her reports.

2 MR. BRUNO: Your Honor, this is reflected in her
3 reports -- or her rebuttal report in Paragraphs 336 to 338.
4 It's already reflected in the record by the testimony of
5 Dr. Pillai.

6 MR. ZIMMERMAN: She never mentioned anything that
7 Dr. Pillai had said or had been told in her reports in those
8 paragraphs.

9 THE COURT: Please verify that.

10 MR. ZIMMERMAN: Which paragraphs are you saying,
11 Chris?

12 MR. BRUNO: 336 to 338 of the rebuttal report.

13 THE WITNESS: Yeah. He talked about it. He spoke
14 about it yesterday.

15 THE COURT: Okay.

16 MR. BRUNO: And as for Dr. Pillai, he spoke about it
17 on the first day of trial.

18 THE COURT: I'm sorry?

19 MR. BRUNO: As for Dr. Pillai himself at trial, I
20 believe he testified that there were a number of
21 dermatologists that were skeptical and, in fact, referred to
22 one as referring to it as crazy.

23 THE COURT: Please show that to opposing counsel.

24 (Counsel confer.)

25 THE WITNESS: I'm just repeating what he stated.

1 THE COURT: Hold on.

2 MR. BRUNO: Your Honor, I'll ask a slightly different
3 question.

4 MR. ZIMMERMAN: Your Honor, we would move to strike
5 the testimony about relying on Dr. Pillai, the last question
6 and answer, as outside the scope.

7 MR. BRUNO: Your Honor, the witness is allowed to
8 rely on testimony that's been adduced at this trial.
9 Dr. Pillai -- I don't think opposing counsel is disputing that
10 Dr. Pillai testified that dermatologists were skeptical at the
11 time.

12 MR. ZIMMERMAN: Pillai's testimony is what it is, but
13 she never gave an opinion based on this. So it's outside the
14 scope for her.

15 MR. BRUNO: Your Honor, I don't know how she could
16 have given an opinion based on testimony that hadn't been
17 adduced until trial.

18 THE COURT: If Dr. Pillai testified about it at
19 trial, I'm not going to strike it. Overruled.

20 Let's go.

21 BY MR. BRUNO:

22 Q. And Dr. Stein Gold, what was your opinion at the time
23 that you had heard about IDP-118?

24 A. My opinion was it didn't make any sense. Fortunately,
25 they didn't listen to me.

1 Q. Now, let's talk about the synergy limitations.

2 MR. BRUNO: And let's put on the screen the opinions
3 that you stated earlier, just to orient the Court.

4 BY MR. BRUNO:

5 Q. Did the examiner expressly consider the synergy
6 limitations during prosecution of the Duobrii® patents?

7 A. Yes.

8 Q. Was Gandhi in front of the examiner?

9 A. Yes.

10 Q. In your opinion, do any of the references teach the
11 claimed synergistic efficacy?

12 A. No.

13 Q. In your opinion, do any of the references teach the
14 claimed synergistic reduction of adverse events?

15 A. No.

16 Q. What do you understand synergy to mean in the
17 dermatological literature?

18 A. So this can be a little bit confusing because synergy is
19 used in two different ways.

20 When we look at the literature -- and I'm going to
21 try to explain this as simply as possible. But sometimes we
22 use synergy, the word "synergy," to be complimentary or
23 meaning that two drugs work in harmony together. They make
24 sense to be used together. They would be synergistic. And
25 that just means that they work maybe by different mechanisms

1 of action. And that's kind of what we would refer to as more
2 of the complimentary effect.

3 So that's in direct contrast to the nuanced
4 definition of what we're talking about today.

5 Here we're talking about for a fixed combination you
6 have two active ingredients. So you have the efficacy of the
7 first active, you have the efficacy of the second active and
8 when you add those together the efficacy of the fixed
9 combination is greater than the added amount of the two when
10 you take the vehicle out of each arm.

11 THE COURT: In short, you're saying, one plus one
12 does not equal two; one plus one equals three.

13 THE WITNESS: Exactly.

14 BY MR. BRUNO:

15 Q. Do you have support for these different views of synergy?

16 A. Yes.

17 Q. And what is your support?

18 A. So Kircik actually helps to define this in his article in
19 2011 where he talks about, very commonly we use the
20 complimentary effect and very rarely do we actually talk about
21 the nuanced effect.

22 Q. How do you understand Kircik 2011 to relate to the
23 Court's construction of synergistic efficacy in this case?

24 A. So his nuanced definition is the definition that we're
25 using here today.

1 Q. How do you understand Kircik 2011 to relate to the
2 Court's construction of synergistic efficacy?

3 Oh, sorry. Let me ask that question again?

4 How do you understand Kircik 2011 to relate to the
5 Court's construction of synergistic reduction?

6 A. So synergistic reduction is just going to be the same
7 thing but it's just opposite. The side effect profile or the
8 adverse reactions of the fixed combination is going to be less
9 than adding the two together.

10 So it's, again, the nuanced definition.

11 Q. Is it common for literature to apply the other
12 complimentary effect meaning of synergy?

13 A. So medicine is an art, and we always talk about mixing
14 and matching drugs that make sense because they work by
15 different mechanisms of action. So we use synergistic a
16 little bit soft and talk about it, you know, it's
17 complimentary, it's synergistic. We use that quite commonly
18 in the literature.

19 Q. Have you used synergy in the complimentary effect sense
20 in the literature?

21 A. I have. I have published using it meaning more
22 harmonious or complimentary.

23 Q. Do any references that Padagis relies on show the claimed
24 synergies?

25 A. No.

1 Q. And why doesn't Gollnick 1999 show the claimed synergy?

2 A. So what's interesting is Gollnick uses the word
3 "synergy," but then he goes on to show us no data. In fact,
4 it's not even additive.

5 When he looks at his data, it's not one plus one
6 equals three or two and a half; it's one plus one is a little
7 it better than one.

8 So he doesn't demonstrate that at all.

9 Q. Why doesn't Gandhi 2012 teach the claimed synergies?

10 A. So Gandhi also uses the word "synergy," but there's no
11 data, no citations, no nothing. So when we have an absence of
12 any data with the word, we would -- a person -- a POSA would
13 generally assume that you're using it in the softer
14 complimentary way.

15 Q. Do any of the references identified by Padagis show any
16 data that could teach the synergies claimed in the Duobrii®
17 patents?

18 A. Not with these two particular drugs.

19 Q. Why would a POSA not have been motivated to achieve the
20 synergy limitations?

21 A. Because we haven't seen it before with these two
22 particular drugs. Again, it's a very high bar to show it.
23 We've seen it very few times with fixed combinations. We have
24 seen it before, but it's -- it's not very common.

25 Q. And how difficult exactly is it to obtain synergy?

1 A. It's rare.

2 Q. Are you aware of any publications reporting the claimed
3 synergy of IDP-118?

4 A. I am. In fact, I only know of potentially three fixed
5 combinations that show synergy, two of which, you know when it
6 happens, it's so exciting that we write a paper on it.

7 And so here's two papers, one of these happens to
8 have me as an author, which is about this particular fixed
9 combination that was kind of exciting because we saw that the
10 drug had a synergistic effect.

11 Q. And is that paper Kircik 2019?

12 A. It is.

13 Q. Why did you write a paper about the synergy of IDP-118?

14 A. Because we saw good efficacy and we saw a synergistic
15 effect. And again, we are trying to get psoriasis under
16 control as well as we can and this looked like it was a good
17 solution.

18 Q. Are there benefits to a patient even after stopping the
19 administration of Duobrii®?

20 A. So this is really an interesting issue.

21 When we use superpotent steroids, they're great, they
22 kick in fast. But when you stop them, they go away fast. And
23 especially a really potent steroid, when you stop it, it can
24 rebound, the disease can come back worse.

25 With tazarotene, it's been shown, at least as

1 monotherapy, using it by itself, because it goes into the cell
2 and it reprograms the cells, it kicks in slowly, but then it
3 has a prolonged effect.

4 So we saw from clinical trials with tazarotene by
5 itself that a good month after you stopped the drug, you can
6 still have a sustained effect.

7 So when you put these two drugs together, who is
8 going to win? The superpotent steroid or the tazarotene? Are
9 we still going to see a sustained effect? You don't know
10 unless you test it because you have the superpotent that wants
11 to rebound and the tazarotene that wants to keep effect.

12 And, in fact, we found that there was a sustained
13 effect with the fixed combination.

14 Q. What does this mean for patient outcomes?

15 A. So what it means is you have the possibility maybe of a
16 drug holiday. If you get -- and this is a *post hoc* analysis
17 that we did.

18 But in the clinical trials, if you stop the drug,
19 there's a good possibility that you're going to keep your
20 effect or maybe even get better. And we saw, even for some
21 patients who were almost clear, over 8 percent of them then
22 became clearer even without using the drug.

23 So you can stay where you are or you might even get a
24 little bit better even without any drug. So that's important
25 for patients.

1 Q. This chart is a little bit complicated.

2 Can you just explain to the Court what it's
3 reflecting?

4 A. Yeah. So it's just showing we divide the patients based
5 on their outcome after eight weeks with the drug. After eight
6 weeks, if you wait another four weeks, what happens.

7 So the clear patients, well, half of them stayed
8 clear. So that was good. So that means half of them didn't
9 need any drug and they stayed clear.

10 Of the almost clears, half of them stayed almost
11 clear, and 8 percent actually did better.

12 And so we see that with the mild and the moderates,
13 too. And good number of them stayed at where they are and
14 some of them actually got even better with no drug for a full
15 four weeks.

16 Q. Is there an asserted patent claim that addresses these
17 post-treatment benefits?

18 A. There is.

19 Q. And what claim is that?

20 A. That's Claim 7.

21 Q. Is that Claim 7 of the '787 patent?

22 A. It is.

23 Q. Is Duobrii®'s synergistic reduction unexpected?

24 A. It is.

25 Q. Why is that?

1 A. So what we have is we have two drugs, and potent topical
2 steroids themselves can sometimes cause stinging and burning.
3 We know, for instance, one of our very -- most potent drugs,
4 40 percent of patients have stinging and burning with
5 clobetasol spray.

6 So -- and you can see stinging and burning with a
7 steroid. And we don't know what's going to happen when you
8 put the still very likely to cause irritation with the
9 tazarotene and this very low potency steroid together, you
10 don't expect that you're going to have better efficacy than we
11 expected and still decrease the side effects. Usually the two
12 go opposite, not together.

13 Q. Is the opinion you just stated reflected in the
14 prosecution history of the Duobrii® patents?

15 A. Yes. Dr. Jeffrey Sugarman also mentioned that he did not
16 expect the low concentration of halobetasol to have enough
17 kick to overcome the irritancy of the tazarotene.

18 Q. Would a fixed-combination product achieving synergistic
19 efficacy also be likely to achieve a synergistic reduction of
20 an adverse event?

21 A. No. Again, they tend to go opposite. So as you get more
22 efficacious, you usually have more side effects or more
23 irritation. So you don't expect them to go together, you
24 usually expect them to go opposite.

25 Q. Now let's briefly address each reference related to your

1 opinions on the Duobrii® patents.

2 What do you think a POSA would take away from
3 Gollnick?

4 A. Basically do not let these drugs anywhere near each
5 other. Either use them on morning and night or use them on
6 completely different days.

7 Q. What would a POSA take away from Gandhi?

8 A. They don't teach anything about the claimed synergy.
9 They don't disclose these particular formulations. They
10 never talk -- never talks about going down to a 0.01 percent
11 of the steroid or 0.045 percent of the tazarotene, doesn't
12 necessarily disclose this particular vehicle.

13 They also had this particular reference when the
14 patent was coming up.

15 Q. What would a POSA take away from the Tazorac® Label?

16 A. That we already have two concentrations, and there wasn't
17 a real reason to decrease it by 10 percent. It already
18 teaches us that we would expect the irritation to be pretty
19 much the same.

20 Q. And what would a POSA take away from the
21 ClinicalTrials.gov IDP-118 study?

22 A. So this basically just lists the fact that these were
23 being studied. It's kind of a discussion of a Phase 2
24 clinical trial. But, again, with all the data that we have
25 surrounding this, there's no expectation that this is going to

1 be a successful Phase 2 study.

2 Q. And why do you say that?

3 A. Because often Phase 2 studies, you know, the range varies
4 but most drugs that come -- most drugs that come into Phase 2
5 aren't successful and go on to Phase 3.

6 Q. What are your final opinions with respect to the Bryhali®
7 patents?

8 A. So Bryhali® basically offers us an 80 percent lower
9 concentration that still achieves a superpotent steroid
10 classification, and we can use it for a full eight weeks.

11 Q. And what are your final opinions with respect to the
12 Duobrii® patents?

13 A. Duobrii® offers us a fixed-dose combination that allows
14 synergistic efficacy or efficacy beyond what we would have
15 expected with a synergistic reduction of adverse events in a
16 lotion formulation.

17 MR. BRUNO: I have no further questions.

18 THE COURT: Thank you. Your witness.

19 MS. PITZEL CRUZ: May I approach, Your Honor?

20 THE COURT: You may.

21 CROSS-EXAMINATION

22 BY MR. ZIMMERMAN:

23 Q. Good afternoon, Dr. Stein Gold.

24 A. Good afternoon.

25 Q. I'd like to pick up right where you left off.

1 MR. ZIMMERMAN: So if we could go to PDX-4-67.

2 BY MR. ZIMMERMAN:

3 Q. In the bottom right-hand corner, you provide some
4 statistics on failure for Phase 2 studies.

5 That's based on new chemical entities, correct?

6 A. That's based on all Phase 2s, yeah.

7 Q. So those aren't the statistics for combining two drugs
8 that have already been approved, right?

9 A. That's right. These are for any Phase 2 going to Phase
10 3.

11 Q. And you would agree that it's more likely that a new
12 molecule fails than a combination of two drugs that the FDA
13 has already approved?

14 A. I don't agree with that.

15 Q. You don't agree with that?

16 A. I don't agree with that.

17 Q. And what is your basis for that?

18 A. The basis is that the FDA has reached a very high bar for
19 fixed combinations. They mandate that the efficacy has to be
20 a certain amount above each of the individual contributions of
21 the individual drugs.

22 So it's a high bar. In fact, most of the fixed
23 combinations for acne would not be approved today.

24 Q. So let me see if I can rephrase that.

25 Are you aware of any data studying the failure rates

1 of already-approved molecules in a combination product
2 compared to new chemical entities?

3 A. I'm not aware of a head-to-head study on that.

4 Q. Are you aware of any data showing the failure rate in
5 studies for already approved -- combinations of
6 already-approved FDA molecules?

7 A. If I can elaborate a little bit?

8 Q. I'm just asking if you're aware of any data.

9 A. I'm aware of data of drugs that were approved in the past
10 that would not have been approved today.

11 Q. I'm asking if you're aware of the -- any data showing the
12 failure rate for Phase 2 studies of combination products that
13 are already approved.

14 A. No.

15 Q. Okay.

16 MR. ZIMMERMAN: Now, I'd like to turn to the IDP-118
17 clinical study. If you could look at DX-64. And it's in your
18 binder, but I'll bring it up on the screen for you.

19 BY MR. ZIMMERMAN:

20 Q. This is the ClinicalTrials.gov study, correct?

21 A. Yes.

22 Q. And you reviewed this in detail in forming your opinions?

23 A. I reviewed it.

24 Q. And if we look at the arms and interventions section,
25 you'll see that it describes IDP-118 as a lotion, correct?

1 A. Yes.

2 Q. And it indicates that it has 0.01 percent halobetasol?

3 A. Yes.

4 Q. And 0.045 percent tazarotene, correct?

5 A. Yes.

6 Q. So a prior art discloses a lotion containing 0.01 percent
7 halobetasol propionate and 0.045 percent tazarotene, correct?

8 A. Yes.

9 Q. Okay. That was known as of the publication date, which
10 was January 24, 2014, correct?

11 A. Yes.

12 Q. And the IDP-118 study also indicates that this drug was
13 being used for the treatment of plaque psoriasis, correct?

14 A. Yes.

15 Q. Now, you're familiar with this concept of the person of
16 ordinary skill in the art.

17 I believe you testified about them in your direct
18 testimony, correct?

19 A. Yes.

20 Q. Okay. And the person of skill in the art is to,
21 presumed, to know of all the prior art, right?

22 A. Yes.

23 Q. So if the person of skill in the art is sitting at their
24 desk and they read the IDP-118 study and they say, I see that
25 there's this combination product, a fixed-dose lotion of

1 0.01 percent halobetasol propionate and 0.045 percent
2 tazarotene, I'd like to find out what vehicle this is in. And
3 they looked at the article.

4 What is the only reference on their desk that they
5 would find that discloses a 0.01 percent halobetasol in a
6 vehicle?

7 MR. BRUNO: Objection, incomplete hypothetical.

8 THE COURT: I'm sorry?

9 MR. BRUNO: It's an incomplete hypothetical.

10 MR. ZIMMERMAN: No, it isn't, Your Honor.

11 THE COURT: I'm going to overrule that.

12 Answer, if you know.

13 THE WITNESS: So the Bryhali patent.

14 BY MR. ZIMMERMAN:

15 Q. In 2014, had the Bryhali patents published?

16 A. I believe they're 2010.

17 Q. 2010. Okay.

18 Would they also have had the '824 Publication, the
19 POSA?

20 MR. BRUNO: Objection, outside the scope.

21 THE WITNESS: Yeah, I didn't comment on the '824.

22 THE COURT: Overruled.

23 BY MR. ZIMMERMAN:

24 Q. So would they have had the '824 Publication in front
25 them?

1 A. I don't know what the date of the '824 Publication is.

2 Q. Okay. So you didn't review the '824 Publication --

3 A. I don't know the date.

4 Q. Oh, it's just the date you need?

5 A. What was the date?

6 Q. I will represent to you that it is prior to 2010.

7 A. Okay.

8 Q. So are you familiar with the '824 Publication?

9 MR. BRUNO: Objection. Misleading the witness. That
10 representation is inaccurate.

11 MR. ZIMMERMAN: I'm sorry.

12 THE COURT: Objection overruled.

13 Cross-examination permits leading questions.

14 MR. ZIMMERMAN: I'll correct it.

15 BY MR. ZIMMERMAN:

16 Q. It's prior to 2015.

17 But my question is: Have you reviewed the
18 '824 Publication?

19 A. I have.

20 If you want to put it up, it would be helpful.

21 Q. I will put it up.

22 MR. ZIMMERMAN: It's DX-142.

23 BY MR. ZIMMERMAN:

24 Q. Dr. Stein Gold, you'll agree that the '824 Publication
25 has the same specification as the Bryhali® patents, right?

1 A. Yes.

2 Q. Okay. So the person of skill in the art looks at the
3 IDP-118 study and says, I need to figure out what the vehicle
4 is.

5 The '824 application provides 0.01 percent
6 halobetasol in a vehicle, correct?

7 A. So I'm not sure about the formulation. That would be
8 better for the formulating person.

9 MR. ZIMMERMAN: Okay. If we could look at Table 1,
10 Formulation C. I'm sorry, the next Table 1.

11 BY MR. ZIMMERMAN:

12 Q. You'll see that Table 1 has a Formulation C with
13 0.01 percent halobetasol.

14 A. Yes.

15 Q. And Table 4 has a Formulation A with halobetasol
16 propionate at 0.01 percent, correct?

17 A. Yes.

18 Q. So the '824 Publication gave you two vehicle choices for
19 0.01 percent halobetasol, correct?

20 A. There are two that are listed.

21 Q. So, Dr. Stein Gold, I'd like to shift gears a little bit.

22 You looked at the two halobetasol patents, JTX-001
23 and 004, correct?

24 A. Yes.

25 Q. And the claims of those patents don't require a

1 composition that's as efficacious as Ultravate®, do they?

2 A. Not specifically.

3 Q. And the claims of those patents encompass compositions
4 with halobetasol propionate compositions less than
5 0.01 percent, correct?

6 A. They do.

7 Q. And, in fact, the claims of the patents don't recite a
8 lower limit on the concentration of halobetasol propionate, do
9 they?

10 A. No.

11 MR. ZIMMERMAN: If we could look at JTX-1, and
12 specifically the claims. And we'll go to Claim 1.

13 BY MR. ZIMMERMAN:

14 Q. Dr. Stein Gold, Claim 1 is halobetasol propionate at
15 0.04 percent, correct?

16 A. Yes.

17 Q. And then the claims reduce that down to 0.025 and then
18 0.01 or less, right?

19 A. Yes.

20 Q. Okay. In order to determine if a composition of the type
21 claimed in JTX-001 with a concentration of halobetasol
22 propionate less than 0.01 percent would exhibit comparable
23 efficacy to Ultravate®, you would actually have to conduct a
24 clinical test, right?

25 A. Yes.

1 Q. And the halobetasol patents don't contain any such
2 clinical testing, do they?

3 A. They contain the VCA data, which is a clinical test, yes.

4 Q. They don't contain clinical testing of any kind for
5 compositions below 0.01 percent HP, do they?

6 A. No.

7 Q. And, in fact, there's no discussion of a formulation of
8 halobetasol propionate with a concentration of less than
9 0.01 percent anywhere in the halobetasol patents, is there?

10 A. No.

11 Q. Now, you agree that it's possible for a lower
12 concentration of a corticosteroid to have the same potency
13 classification as a higher concentration of that same
14 corticosteroid, correct?

15 A. It's rare.

16 Q. But it's possible?

17 A. Can I qualify it?

18 Q. You testified that it's possible, didn't you?

19 A. It's possible.

20 Q. And you agree that a clinician would expect that a
21 decrease in the concentration of the topical drug would lead
22 to greater tolerability and safety, correct?

23 A. Not necessarily, no.

24 Q. But that's been seen with topicals, right?

25 A. There are many factors that go into tolerability and

1 safety, as I talked about earlier, including the vehicle.

2 Q. So let me ask you: Would a clinician expect that a
3 decrease in the concentration of a drug may lead to greater
4 tolerability and/or greater safety?

5 A. If you leave everything else the same and you have the
6 same ointment formulation and you decrease -- within
7 everything else the same, if you change one variable, that
8 might be true; but if you change more than one variable, you
9 don't know.

10 MR. ZIMMERMAN: If we could bring up Dr. Stein Gold's
11 deposition at Page 153, Lines 6 through 11.

12 BY MR. ZIMMERMAN:

13 Q. Dr. Stein Gold, you were asked at your deposition: So
14 would a clinician expect that a decrease in the concentration
15 of a drug may lead to greater tolerability and/or greater
16 safety?

17 And your response was: That -- that has been seen
18 with topicals.

19 Correct?

20 A. That's if everything else --

21 MR. BRUNO: Objection, improper impeachment.

22 THE WITNESS: If everything else --

23 THE COURT: Objection overruled.

24 BY MR. ZIMMERMAN:

25 Q. So I asked you that question -- I'm sorry. You were

1 asked that question.

2 And your response was: That -- that has been seen
3 with topicals.

4 Right?

5 It's a yes-or-no question?

6 A. Yes.

7 Q. Thank you.

8 A. Yes, but...

9 MR. ZIMMERMAN: Your Honor, I see that we're
10 10 minutes over the lunch break and I'm at a stopping point.
11 Is that -- I can keep going if the Court prefers. You tell
12 me --

13 THE COURT: My boss tells me that you can go to 1:00.

14 MR. ZIMMERMAN: Go to 1:00. Okay.

15 THE COURT: She runs the mechanics in this courtroom,
16 I just make legal decisions.

17 MR. ZIMMERMAN: If we can look at DX-002,
18 Dr. Stein Gold. And it's not a memory test, it's the Blum
19 article.

20 BY MR. ZIMMERMAN:

21 Q. Now, you agree that this discloses a 0.02 percent HP
22 lotion, correct?

23 A. That's not correct.

24 Q. I'm sorry, it discloses a 0.02 HP formulation?

25 A. Yes.

1 Q. And that 0.02 percent halobetasol propionate formulation
2 was statistically equivalent to the 0.05 percent formulation,
3 correct?

4 A. The study was not designed to show statistical
5 significance.

6 Q. They did a statistical analysis and said that the results
7 of the 0.02 percent, 0.05 percent and Dermovate were
8 statistically not significantly different, right?

9 A. It was not powered, correct.

10 Q. Okay. And so based on the study, you couldn't tell if
11 the results for those three drugs were meaningfully different,
12 right?

13 A. Not correct.

14 Q. Well, they said there are no statistically significant
15 differences between the results, correct?

16 A. That's true.

17 MR. ZIMMERMAN: Now, if we bring up your Slide 4-16.

18 BY MR. ZIMMERMAN:

19 Q. You quote two sections of the Blum reference, right?

20 A. Yes.

21 Q. And, in fact, those two sections are almost right next to
22 each other in the article, aren't they?

23 A. Yes.

24 Q. And, in fact, there's one sentence that comes between
25 those two sections, right?

1 A. Yes.

2 Q. And you specifically cropped that sentence out of your
3 demonstrative to avoid putting it on the screen and before the
4 Court, right?

5 A. I have no problem with that sentence.

6 Q. Right. But I'm asking you: You cropped that sentence
7 out of your demonstrative, didn't you?

8 A. I put up what I thought was important in the article.

9 Q. Okay. And in doing that, you cropped out one sentence
10 between the two paragraphs you presented, right?

11 A. That's true.

12 Q. And the sentence you cropped out, if we bring it up,
13 reads, However, the difference among the three groups was not
14 statistically significant.

15 That's the sentence you left out, right?

16 A. Yes.

17 MR. ZIMMERMAN: Now, Dr. Stein Gold, if you could
18 look at JTX-1, which is the '307 patent.

19 BY MR. ZIMMERMAN:

20 Q. You agree that the person of skill in the art would
21 expect that a concentration of halobetasol propionate --

22 A. Could you put it up?

23 Q. Sure.

24 So you've reviewed the patent, correct?

25 A. Yes.

1 Q. Okay. And you would agree that a person of skill in the
2 art would expect that a concentration of 0.01 percent
3 halobetasol propionate would be able to be safely used for a
4 period of longer than two weeks, correct?

5 A. Yes.

6 Q. Okay. Now, the '307 and '502 patents don't ever
7 expressly say that, do they?

8 A. Say it again. Which sentence?

9 Q. The '307 and '502 patents don't expressly teach using
10 that composition for longer than two weeks -- apart from the
11 language of the claim, right?

12 A. Well, they go through it in the specifications, the whole
13 analysis.

14 Q. And in the specification, do they ever say, the product
15 can be used for longer than two weeks?

16 A. They don't say those words in that sentence. They use a
17 paragraph to discuss it.

18 Q. Okay. And if you could -- it's in your binder. If you
19 could tell me what paragraph that is.

20 A. So I think we went through it in my direct examination.

21 MR. ZIMMERMAN: Okay. If we bring up Column 4, Lines
22 2 to 12.

23 BY MR. ZIMMERMAN:

24 Q. This is one of the sections you went through on your
25 direct with counsel, right?

1 Is that correct, Dr. Stein Gold?

2 A. Yes, this is one of the ones that I went through.

3 Q. Okay. Can you show me where in this section it says used
4 for longer than two weeks?

5 A. So, you know what, I'm going to have to pull the patent
6 and find it, because it's not in this particular section.

7 Q. The other section you referred to was Column 9, Lines 6
8 through 23.

9 And I will tell you, in your white binder from your
10 counsel, and if you need help, I can move those for you.

11 A. I'm sorry. Which number was it?

12 Q. It was Column 9, Lines --

13 A. JTX- --

14 Q. JTX-1.

15 A. Okay. (Reviewing). Okay. It's not in this section.

16 Q. Do you believe there's a section in the patent that says
17 use it for longer than two weeks?

18 A. I believe that there's a section that states that with
19 the lower concentration, we should be able to use it longer
20 than two weeks or for an extended period of time.

21 They state the problem upfront, is that the
22 superpotent steroids can only be used for two weeks. And then
23 they solve the problem later by saying, we're using an
24 enhanced vehicle with a lower concentration that should be
25 used more safely for longer.

1 Q. It says more safely. It doesn't say longer than two
2 weeks, does it?

3 A. I'll have to -- I'd have to read to see if it -- I'm not
4 sure, I'll have to say. I don't know.

5 Q. And can we agree that there's nothing in the patent that
6 says use up to eight weeks?

7 A. Nothing says eight weeks.

8 Q. And there's no test data in the patent for using it
9 longer than two weeks?

10 A. There's no test data.

11 Q. And there's no test data for using it longer than eight
12 weeks?

13 A. No.

14 Q. And it's your view that the patents teach that you can
15 use it for longer than two weeks, even though there's not a
16 single piece of data, right?

17 A. The patents describe something that needs to be tested,
18 but there's good rationale why it would work.

19 Q. And my question is: You accept the representation in the
20 patents that it can be used for longer than two weeks even
21 though there's no data?

22 A. Yes.

23 Q. Okay. And would you agree that same rationale can be
24 applied to the analysis of prior art that if there's good
25 reasoning but no data, you can accept the representation?

1 A. It depends on the situation.

2 Q. Okay. But in some situations, you would agree it could
3 be accepted?

4 A. It would have to be tested.

5 Q. It would have to be tested?

6 A. Right. You would take that as your hypothesis. It makes
7 sense. And then you would go ahead and test it, just like
8 this was tested.

9 Q. When you referred to the compositions of the halobetasol
10 patents being able to be used for longer than two weeks or
11 eight weeks, you're only talking about Bryhali®, right?

12 A. Yes. But halobetasol -- the fixed combination as well
13 has no limit --

14 Q. Okay.

15 A. -- so it's not just Bryhali®.

16 Q. So besides Bryhali® and Duobrii® --

17 A. Yes.

18 Q. -- you're not talking about any other composition being
19 able to be used for longer than two weeks or eight weeks?

20 A. I don't know of any others that were tested.

21 Q. Okay. And we can agree that there's no test data for any
22 formulations other than Bryhali® and Duobrii® for two to eight
23 weeks?

24 A. I'm not aware of any.

25 Q. Okay. Now, Dr. Stein Gold, you previously testified that

1 combination therapy is the standard of care and it was the
2 standard of care in 2015.

3 Do you recall that testimony?

4 A. I testified that that would be what you would see in
5 clinical guidelines, although it wasn't necessarily what was
6 being done in actual practice.

7 Q. Okay. But it's your opinion that drug developers would
8 not have been motivated in 2015 to develop fixed-dose
9 combination topical products for psoriasis, right?

10 A. Not as, necessarily, a fixed-dose combination.

11 Q. Okay. Would drug developers have been motivated to
12 develop combination therapies for psoriasis in 2015?

13 A. So as the prior art shows us, we used combination
14 therapies but just used different products at different times.

15 Q. Okay. And you agree that two of the reasons for
16 combining tazarotene and halobetasol propionate together was
17 for the sake of convenience and patient compliance, right?

18 A. Yes.

19 Q. And you also agree that combining those two actives in a
20 single vehicle would help solve issues relating to layering
21 the products as separate ingredients in separate vehicles,
22 right?

23 A. Yes.

24 MR. ZIMMERMAN: Okay. So if we could turn to
25 PTX-368, Dr. Stein Gold.

1 BY MR. ZIMMERMAN:

2 Q. This is the Weigle article you referred to in your
3 slides.

4 MR. ZIMMERMAN: And specifically if we go to Page 6.

5 BY MR. ZIMMERMAN:

6 Q. You'll see that it states: Perilesional adverse
7 effectives, i.e., itching, burning, are common and can be
8 managed with alternate-day application or use with topical
9 corticosteroids and moisturizers.

10 Do you see that sentence?

11 A. I do.

12 Q. And so this is motivating a POSA to use tazarotene with a
13 topical corticosteroid to manage the local irritation of
14 tazarotene, right?

15 A. Yeah. But here they're teaching alternative days. So
16 again, they're teaching that these should be separated, that
17 these should not be used together, that there's probably some
18 kind of a problem with using them at the same time.

19 Q. No, no. If you read the sentence --

20 A. Yes, with alternative-day application.

21 Q. Yes. So you can reduce the effects of Taz by applying it
22 alternate days, every other day, or you can reduce the itching
23 of Taz by combining it with a corticosteroid.

24 Correct?

25 A. Yes.

1 Q. Okay. So this article teaches that you should combine
2 tazarotene and a corticosteroid to reduce the itching caused
3 by tazarotene.

4 A. So it's not teaching me when to use that topical
5 corticosteroid, and all of the prior art teaches don't use
6 them together. So this is in line with that.

7 Q. Okay. But it does teach using tazarotene and
8 corticosteroids together so that the corticosteroid reduces
9 the irritation caused by the tazarotene.

10 Yes?

11 A. Potentially, at different times.

12 Q. Okay. Dr. Stein Gold, if you could look at your
13 Slide 44.

14 Now, you wrote on this slide that topical combination
15 drugs are rare for psoriasis, right?

16 A. Yes.

17 Q. And you believe that statement to be true, right?

18 A. When you consider all of the topical products that we
19 have for psoriasis, yes.

20 Q. Okay. And it's a yes-or-no question.

21 You wrote this on the slide. You believe it to be
22 true. Right?

23 A. Yes.

24 Q. Okay. Dr. Stein Gold, would you agree that, in fact,
25 fixed combinations are commonplace in dermatology, providing

1 significant efficacy and tolerability benefits?

2 A. They're commonplace?

3 Q. Commonplace.

4 A. I wouldn't say they're commonplace, no.

5 MR. ZIMMERMAN: Okay. If we could look at PTX-44.

6 BY MR. ZIMMERMAN:

7 Q. Dr. Stein Gold, do you recognize this document?

8 A. Yes.

9 Q. And, in fact, you're an author on this article, aren't
10 you?

11 A. Yes.

12 Q. And it's an article about using fixed combinations of
13 halobetasol propionate 0.01 percent and tazarotene
14 0.045 percent lotion --

15 A. Yes.

16 Q. -- in treating plaque psoriasis.

17 A. Yes.

18 Q. Right?

19 A. Yes.

20 Q. So this is a plaque psoriasis article, right?

21 A. Yes.

22 Q. Okay. And your co-authors were Suzanne Harris, Tina Lin,
23 and Dr. Pillai, who testified here, all of whom are from
24 Bausch, right?

25 A. Yes.

1 Q. If we look at the first page of the article, under
2 "Background," you wrote: Fixed combinations are commonplace
3 in dermatology, providing significant efficacy and
4 tolerability benefits.

5 Didn't you?

6 A. That's dermatology. It's not -- it's not for psoriasis.

7 Q. Dr. Stein Gold, I expressly asked you if fixed
8 combinations are commonplace in dermatology. I read you that
9 exact sentence, and you told me you didn't agree with it.

10 A. I'm sorry. I thought you were talking about psoriasis.
11 So I misheard you.

12 Q. Well, but let's go back.

13 This statement is in a paper, and the title of that
14 paper deals with plaque psoriasis, right?

15 A. We were talking about dermatology in general. That's not
16 -- there's only two fixed combinations in psoriasis.

17 Q. Okay. So let me make sure. I just want to make sure we
18 have the facts right.

19 A. Yeah.

20 Q. You wrote in this article: Fixed combinations are
21 commonplace in dermatology, providing significant efficacy and
22 tolerability benefits. Right?

23 A. Yes.

24 Q. You wrote that sentence?

25 A. Yes.

1 Q. Okay. And if we look at the title of the paper, the
2 title is about plaque psoriasis, correct?

3 And it's a yes-or-no question.

4 A. Yes.

5 Q. Thank you.

6 MR. ZIMMERMAN: Now, if we would shift gears and look
7 at PTX-380.

8 BY MR. ZIMMERMAN:

9 Q. Do you recognize this, Dr. Stein Gold, as an article you
10 wrote?

11 A. Yes.

12 Q. And if we look under Page 1169 of the article, under
13 "Funding," you'll see that it was funded by Ortho
14 Dermatologics, which is a division of Bausch, right?

15 A. Yes.

16 Q. Now, if we go to Page 1162 of the article, it states:
17 Psoriasis therapies employing both Taz and TCS, which is a
18 topical corticosteroid, have demonstrated improved efficacy
19 over monotherapy with either treatment.

20 Do you see that?

21 A. I don't see where you're reading, but yes.

22 MR. ZIMMERMAN: It's Page 1162 of the article.

23 Keep scrolling down. Scroll further down. There we
24 go.

25 BY MR. ZIMMERMAN:

1 Q. Do you see that sentence, Dr. Stein Gold?

2 A. Yes.

3 Q. And you agree that's based on studies conducted prior to
4 2015, correct?

5 A. Yes.

6 Q. Okay. The article also states: Combination therapy
7 yielded greater duration of post treatment maintenance of
8 effects. Correct?

9 A. Yes. I can comment further on that, but yes.

10 Q. And that, too, is based on information from prior to
11 2015, correct?

12 A. Yes.

13 Q. The article then states that: When used together,
14 tazarotene and a topical corticosteroid can also mitigate the
15 safety and tolerability concerns associated with use of either
16 as monotherapy, as evidenced by low incidences of AEs and
17 steroid rebound in clinical trials.

18 Do you see that sentence?

19 A. Yes.

20 Q. And again, that's based on data before 2015, correct?

21 A. Based on that 52 reference.

22 Q. Okay. Now, Dr. Stein Gold, I'd like to talk little bit
23 about synergy.

24 A. Uh-huh.

25 Q. And you talked about synergy being rare, right?

1 A. I only know of three fixed combinations that have it.

2 Q. Okay. And what are those three fixed combinations?

3 A. One is this drug. One is the -- it's been shown in the
4 calcipotriene betamethasone dipropionate. And one is with an
5 acne drug called adapalene benzoyl peroxide.

6 Q. Okay. So the second drug you mentioned is, in fact,
7 Taclonex®, right?

8 A. Yes.

9 Q. Okay. So can we agree that there are three fixed-dose
10 combination products to treat plaque psoriasis?

11 A. I need you to explain further what you're talking about.

12 Q. So the three are Duobrii®, which we all know and have
13 discussed?

14 A. Right.

15 Q. Taclonex®, which is a combination that contains a topical
16 corticosteroid and a vitamin D analog?

17 A. Yes.

18 Q. And Enstilar®?

19 A. That's the same drug.

20 Q. Okay. So --

21 A. So there's two drugs, two fixed combinations that
22 have -- there's only two fixed combinations in psoriasis.
23 That's all.

24 Q. Okay. So Enstilar® and Taclonex®, you're going to --

25 A. They're all the same.

1 Q. -- treat them the same?

2 A. It's the same -- same concentration, same drug. Just
3 different --

4 Q. Okay. So we agree Taclonex® is a fixed-dose combination
5 that contains a topical corticosteroid and a vitamin D analog
6 for psoriasis, right?

7 A. Yes.

8 Q. And it was approved in 2006?

9 A. Yes.

10 Q. And you agree that product shows synergistic efficacy
11 within this Court's claim construction?

12 A. I agree only for one of the vehicles that I've seen.

13 Q. Okay. Now, the Enstilar® product.

14 A. Yes.

15 Q. Does it also demonstrate synergistic efficacy within this
16 Court's claim construction?

17 A. I have not seen that.

18 Q. Okay. And, in fact, it's not that it doesn't. The study
19 hasn't been done that allows to do the analysis, right?

20 A. Nobody thought to do the study to do the analysis.

21 Q. Okay. And I'm not casting aspersions. I'm just saying
22 the study that has the vehicle arm that would allow you to
23 subtract it out, to do the math, hasn't been run, right?

24 A. They didn't conduct the study that way. They weren't
25 expecting it. They didn't look for it.

1 Q. Okay. So I want to make sure. You've testified that
2 synergy is rare.

3 A. Yes.

4 Q. But in the context we're talking about, fixed-dose
5 combinations for the treatment of psoriasis, there's three
6 products, right; Duobrii®, Taclonex® and Enstilar®?

7 A. No, there's two products. There's this drug and then
8 there's fixed combination of calcipotriene and betamethasone
9 dipropionate that comes in multiple vehicles.

10 One of those vehicles only in the scalp, only the
11 studies for the scalp, showed synergy at least one time point.

12 Q. Okay. So we'll limit it. Then there are two fixed-dose
13 combination products.

14 A. Right.

15 Q. Duobrii® and Enstilar®.

16 A. Duobrii® and -- not Enstilar®.

17 Q. I'm sorry, Duobrii® and Taclonex®?

18 A. Yes.

19 Q. Okay. And we can agree that both of those products
20 demonstrate synergy, right?

21 A. So one formulation of that fixed combination in the scalp
22 did show synergy.

23 Q. Okay. So both of the drugs -- there's synergy for
24 Taclonex®. You've told us there's synergy for Duobrii®. They
25 both demonstrate synergy within the scope of this Court's

1 claim construction.

2 Yes or no?

3 A. Yes.

4 Q. Okay. So this rare event, as you've characterized it,
5 actually happens for all of the products in that class. The
6 only products that exist in that class, fixed-dose
7 combinations for the treatment of psoriasis, demonstrate
8 synergy under this Court's claim construction, right?

9 It's a yes-or-no question.

10 A. No.

11 Q. No?

12 A. No.

13 Q. Okay. Which one doesn't?

14 A. Enstilar®.

15 Q. Now --

16 A. And I don't know if Taclonex® ointment does. I haven't
17 looked at the --

18 Q. Okay. Are you saying that --

19 A. So --

20 Q. -- there's data showing that Enstilar® doesn't?

21 A. I'm showing that I have not seen data showing that it
22 does.

23 Q. Okay. So just a minute ago you told me Enstilar® didn't
24 count. It was the same thing. Now you're telling me
25 Enstilar® is different. So I want to stop and parse this very

1 carefully.

2 A. Right.

3 Q. It's either that there are three products, Duobrii®,
4 Enstilar® and Taclonex®, and two out of the three demonstrate
5 synergy; or there's only two products, Enstilar® -- I'm
6 sorry -- Taclonex® and Duobrii®, and they both demonstrate
7 synergy.

8 Can you tell me which one it is?

9 A. So Taclonex® comes in three formulations. One of those
10 formulations showed synergy --

11 Q. Okay.

12 A. -- only in the scalp.

13 Q. Okay. And Duobrii® demonstrates synergy?

14 A. And Duobrii® does, yes.

15 Q. And there's no clinical data on Enstilar® that allows you
16 to determine whether there's synergy or not?

17 A. No data.

18 Q. Okay. So even if we say that it's a class of three --
19 Enstilar®, Taclonex® and Duobrii® -- you'll agree that there's
20 synergy for two out of the three, and the third one no test
21 data. Correct?

22 A. Correct.

23 Q. Thank you.

24 THE COURTROOM DEPUTY: Lunch?

25 THE COURT: Lunch.

1 MR. ZIMMERMAN: Okay.

2 THE COURT: The boss has spoken. Have a good lunch.
3 I'll see you after lunch.

4 THE COURTROOM DEPUTY: All rise.

5 (Lunch recess taken at 1:04 p.m.)

6 AFTERNOON SESSION

7 (In open court at 1:36 p.m.)

8 (Parties present.)

9 THE COURTROOM DEPUTY: All rise.

10 THE COURT: Be seated, everybody. All right. Let's
11 continue.

12 MR. ZIMMERMAN: Thank you, Your Honor.

13 BY MR. ZIMMERMAN:

14 Q. Dr. Stein Gold, before the break, we were talking about
15 synergy, and I'd like to continue on that topic for just a
16 moment.

17 MR. ZIMMERMAN: If you could look at JTX-009-2.

18 BY MR. ZIMMERMAN:

19 Q. This is part of the briefing package for an FDA meeting
20 for IDP-118.

21 A. Yes.

22 Q. Do you see this is a letter dated May 11, 2011, from Dow
23 Pharmaceutical Sciences to the FDA?

24 A. Yes.

25 MR. ZIMMERMAN: And if we could turn to Page 47, page

1 ending in 589, there's a section entitled "Background
2 Overview."

3 BY MR. ZIMMERMAN:

4 Q. Do you see that?

5 A. Yes.

6 Q. And there it states: The concept for combining a
7 retinoid (tazarotene) with a high-potency corticosteroid
8 (halobetasol propionate) for the treatment of plaque psoriasis
9 is based on the known efficacies and safety of each of these
10 active components as exemplified by the approved listed drugs
11 Tazorac® cream and Ultravate® Cream.

12 Do you see that?

13 A. Yes.

14 Q. And do you agree that both of those drugs were approved
15 safe and effective?

16 A. Yes.

17 Q. You'll see farther down Bausch told the FDA that the
18 concept for combining tazarotene with halobetasol propionate
19 is based on, quote, the potential for additive or synergistic
20 effects due to different mechanisms of action.

21 Do you see that?

22 A. Yes.

23 Q. Okay. And you agree that tazarotene and halobetasol
24 propionate have different mechanisms of action, right?

25 A. Yes.

1 Q. And you agree that Bausch was representing to the FDA
2 that one of the reasons to combine these two actives was the
3 potential for additive or synergistic effects due to their
4 different mechanism of action, right?

5 A. Here, I believe that "synergistic" is more of a synonym
6 for "additive."

7 Q. Okay. So even though the document uses the word "or" and
8 says "additive or synergistic," you're interpreting the
9 document to mean "additive or additive"?

10 A. Because if you go to the next sentence, it says,
11 basically, on clinical trials, studies reported in the
12 literature.

13 So the teachings we have from the literature is that
14 they work by different mechanisms of action. We don't have
15 any teachings in the literature that talks to us about synergy
16 of these two elements.

17 Q. You'll agree that the literature has several references
18 to synergy when dealing with topical corticosteroids and
19 halobetasol, or other corticosteroids and tazarotene, right?

20 A. The literature has no data reporting that.

21 Q. Right. But they use the word "synergy," right?

22 A. They use the word, yes.

23 Q. Like Gollnick --

24 A. In the complementary way that we talked about.

25 Q. Gollnick uses the word "synergy," right?

1 A. Yes.

2 Q. Gandhi uses the word "synergy," right?

3 A. Yes.

4 Q. They don't say "additive," meaning 1 plus 1, right?

5 A. No.

6 Q. Okay. Now, in the document we're looking at, JTX-009-2,
7 Bausch didn't define "synergy" in its FDA submission, did it?

8 A. No.

9 Q. Rather, Bausch believed in the meaning of synergy would
10 be understood by the FDA, right?

11 A. Understood based on the prior states, as mentioned here,
12 based on the prior clinical trials and what was reported in
13 the literature.

14 As you read the whole sentence, you have to read the
15 sentence in order to understand what they're -- and I didn't
16 write this, so I don't know what their thought process was.
17 All I can do is just try to interpret it based on the full
18 sentence.

19 Q. Okay. And you would agree with me that the prior art
20 literature, Gandhi, Gollnick, is pharmacological discourse,
21 right?

22 A. I don't really know what that means.

23 Q. Okay. So you don't know what the phrase "pharmacological
24 discourse" is?

25 A. No.

1 Q. Okay. And would you believe that Bausch's correspondence
2 with the FDA is pharmacological discourse?

3 A. As I just explained, I'm not sure what "pharmacological
4 discourse" means. So I can't comment on that.

5 MR. ZIMMERMAN: Okay. If you could bring up your
6 Slide 4-58.

7 BY MR. ZIMMERMAN:

8 Q. Okay. So you cited to the Kircik 2011 article, right?

9 A. I did.

10 Q. Okay. And it's listed as DX-140. And I will tell you
11 DX-140 is not an article by Kircik.

12 MR. ZIMMERMAN: So if we could look at PTX-43.

13 BY MR. ZIMMERMAN:

14 Q. Is this the Kircik article you're referring to?

15 A. Yes.

16 Q. Okay. I just want to make sure that we're on the right
17 thing.

18 So if we could go back to your Slide 4-58.

19 You quoted the Kircik article and it says: Within
20 pharmacological discourse --

21 A. Discourse.

22 Q. -- synergy indicates not only that agents are compatible,
23 but that the product of their combined action is greater than
24 the sum of the efficacy of the constituent parts?

25 Do you see that?

1 A. I'm sorry. I didn't understand what you were saying. I
2 didn't understand your second word to be "discourse."

3 Q. Oh. Okay.

4 A. I didn't know what you were saying.

5 Q. So can we agree that Bausch's correspondence with the FDA
6 is pharmacological discourse?

7 A. Yes.

8 Q. Okay. And things like --

9 A. No, I'm sorry. Can you say that again? Can we agree
10 what?

11 Q. That Bausch's correspondence with the FDA is
12 pharmacological discourse?

13 A. No. I can't agree with that.

14 Q. Oh. You wouldn't agree with that?

15 A. No, I don't agree with that.

16 Q. And you don't think Gollnick is pharmacologic discourse,
17 do you?

18 A. No.

19 Q. And you don't think Gandhi is pharmacological discourse,
20 do you?

21 A. No.

22 Q. And you don't think the IDP-118 study is pharmacological
23 discourse, do you?

24 A. No.

25 Q. You don't think any single document that cites to the

1 word "synergy" in this case is pharmacological discourse
2 except Bausch's post-patent filing statements regarding
3 Duobrii®, right? It's a yes-or-no question.

4 A. That is correct.

5 Q. Okay. I think we're clear on where you stand.

6 So parsing it that way, anything favorable to Bausch
7 after the patent filing date counts as synergy within the
8 Court's definition, in your view, right?

9 MR. BRUNO: Objection. Argumentative.

10 THE COURT: Sustained.

11 THE WITNESS: I need to hear the question again.

12 MR. ZIMMERMAN: Okay. I'll withdraw the question.

13 BY MR. ZIMMERMAN:

14 Q. Dr. Stein Gold, it's your opinion that a person of skill
15 in the art would not have expected tazarotene to be effective
16 for psoriasis at a concentration of 0.045 percent, correct?

17 A. They wouldn't know if it was or not.

18 Q. And my question is: Prior to doing the testing, would
19 they have expected it to be effective for treating psoriasis?

20 A. It's hard to say. There's no data showing that that
21 concentration would work.

22 Q. You don't think that people would have thought -- people
23 of skill in the art would have thought it was close enough to
24 the 0.05 percent that was approved and marketed that it would
25 be effective for psoriasis?

1 A. I know at some point tazarotene loses efficacy, and we
2 see that with other disease states even though they're not
3 psoriasis.

4 So where does it lose efficacy? At the 0.049?
5 0.048? 0.035? We don't know without having tested it.

6 Q. Okay.

7 MR. ZIMMERMAN: If we could bring up JTX-009-5 and
8 the page ending in 662.

9 BY MR. ZIMMERMAN:

10 Q. I will represent to you that this is a portion of
11 Bausch's IND for Duobrii®. You'll see there's a section where
12 Bausch told the FDA that 0.045 percent tazarotene was expected
13 to provide, quote: The potential for efficacy in the
14 treatment of psoriasis similar to that of Tazorac® Cream
15 0.05 percent.

16 Do you see that sentence?

17 A. It says "the potential."

18 Q. Yes.

19 A. So that means --

20 Q. Do you see that sentence?

21 A. Yes.

22 Q. Do you have any reason to disagree with Bausch's
23 statement that it offered the potential for efficacy similar
24 to that of Tazorac®?

25 A. The potential, yes.

1 Q. Yes, you agree with the sentence, or yes, you agree that
2 Bausch had no reason to dispute that this would be true?

3 Let me strike that.

4 Would you agree that it was Bausch's position that
5 the two concentrations had the potential for similar efficacy?

6 A. My interpretation of this is that's what they're hoping
7 for.

8 Q. And they wouldn't have represented that to the FDA if
9 they didn't have a scientific basis for it, right?

10 A. I don't know that they -- I haven't seen a scientific
11 basis for it.

12 Q. Okay.

13 MR. ZIMMERMAN: If we go to Page 8 of this same
14 document.

15 BY MR. ZIMMERMAN:

16 Q. Bausch stated: The adjunctive use of tazarotene with
17 topical mid- to high-potency corticosteroids has been shown to
18 enhance the efficacy in treatment and provide a synergistic
19 effect, allowing for longer durations of treatment and
20 remission.

21 Do you see that?

22 A. Yes.

23 Q. And, again, it's your position that this use of synergy
24 by Bausch is not pharmacological discourse, right?

25 A. My understanding of synergy here is that they have -- and

1 they go on to the next sentence there, that's where they're
2 explaining it.

3 Q. And there's no statement in the next sentence that it's
4 not talking about true synergy meaning one plus one is more
5 than two.

6 A. There's no statement anywhere that provides any data on
7 the nuanced definition of synergy.

8 Q. And you say "nuanced" definition. Kircik 2011 didn't say
9 that, did he? Kircik said that that was the established
10 definition in pharmaceutical discourse, right?

11 A. Yes.

12 Q. And so the term "nuanced," trying to cabin that
13 definition, is your interpretation, right?

14 A. That we've used for the definition of synergy relating to
15 this trial, yes.

16 Q. Okay. Now, this statement that we just looked at about
17 synergistic effect, you'll agree that it was based on
18 references from 1998 and 1999, correct?

19 A. You'll have to pull up References 9 and --

20 MR. ZIMMERMAN: Okay. If we could do that.

21 BY MR. ZIMMERMAN:

22 Q. You'll see Reference 9 is a 1988 article by Lebwohl and
23 Reference 10 is a 1999 article by Poulin.

24 A. Okay.

25 Q. So you'll agree that Bausch's representation was based on

1 art from 1988 -- I'm sorry, 1988 and '99?

2 (Reporter clarification.)

3 BY MR. ZIMMERMAN:

4 Q. You'll agree that Bausch's representation regarding
5 synergy was based on art from 1998 and 1999, correct?

6 A. Yes.

7 Q. So Bausch told the FDA, based on references from 1988 and
8 19- -- strike that.

9 So Bausch told the FDA, based on references published
10 in 1998 and 1999, that adjunctive use of tazarotene with
11 topical mid- to high-potency corticosteroids had been shown to
12 provide a synergistic effect allowing for longer durations of
13 treatment and remission. Right?

14 A. That's what they wrote in their paper.

15 Q. Okay.

16 MR. ZIMMERMAN: And then if we go further down on
17 Page 8.

18 BY MR. ZIMMERMAN:

19 Q. Bausch stated: Further, application of a mid- or
20 high-potency topical corticosteroid in conjunction with
21 tazarotene has been shown to markedly reduce the incidence of
22 adverse reactions and improve tolerability in the early weeks
23 of treatment when adverse reactions associated with tazarotene
24 are most likely. And they cited to Reference Number 14 for
25 that.

1 Do you see that?

2 A. Yeah, we would have to look at Reference 14.

3 Q. And we will.

4 Do you see that Reference 14 on Page 79 is an article
5 by Tanghetti from 2000?

6 A. And I see this is an observation study. It's just
7 somebody looking, it's not a true scientific study. It's just
8 somebody looking at potentially pictures.

9 Q. But you'll agree that Bausch's representation was based
10 on a reference from 2000, correct?

11 A. Yes.

12 MR. ZIMMERMAN: If we could turn to DX-151.

13 BY MR. ZIMMERMAN:

14 Q. This is an article that you wrote, correct,
15 Dr. Stein Gold?

16 A. Yes.

17 Q. Now, you would agree that prior to 2015, clinical studies
18 had established the benefit of using topical corticosteroids
19 as adjunctive therapy with tazarotene to treat plaque
20 psoriasis, correct?

21 A. Yes.

22 Q. Okay. And if you turn to Page 293 of your article,
23 there's a statement that says: Tazarotene, which induces a
24 longer remission after treatment.

25 A. Yes.

1 Q. Do you see that?

2 And you agree that this reference to "longer
3 remission after treatment" refers to a maintenance effect with
4 tazarotene that can last up to four weeks after therapy has
5 stopped?

6 A. With monotherapy, correct.

7 Q. Okay. And you agree that the maintenance effect for
8 tazarotene was known prior to 2015, correct?

9 A. As monotherapy, yes.

10 Q. Okay. Now Dr. Stein Gold, does Bausch compensate you for
11 your presentations regarding Duobrii®?

12 A. No.

13 Q. And do they provide funding for your articles related to
14 Duobrii®?

15 A. They hire a medical writer to help with putting the
16 papers together.

17 Q. And do you know how much they compensate that medical
18 writer?

19 A. I have no idea.

20 Q. Okay. So do you or any of the organizations that you're
21 affiliated with, such as your practice or your hospital,
22 receive any funding from Bausch based on your speaking
23 engagements?

24 A. So it depends on what you mean. I do multiple types of
25 speaking.

1 Q. And so what I'm trying to get at is, when you speak for
2 Bausch about Duobrii® or Bryhali® --

3 A. Yes.

4 Q. -- do they compensate you or any of your entities for
5 those engagements?

6 A. So I don't know that I've ever spoken for Bausch on
7 Duobrii® or Bryhali® --

8 Q. Okay.

9 A. -- and as a promotional speaker for that particular drug.
10 I don't remember. I'm not sure that I ever did.

11 Q. Okay. But if you had, would you have been compensated
12 for it?

13 A. If I was speaking for them as a promotional speaker for
14 any of their drugs, I would be compensated, yes.

15 Q. Okay.

16 MR. ZIMMERMAN: If we could bring up -- I'm sorry,
17 strike that.

18 If we could bring of JTX-4 and specifically look at
19 Claim 1 of the '502 patent.

20 BY MR. ZIMMERMAN:

21 Q. You'll see that it claims corticosteroids other than
22 halobetasol propionate, correct?

23 A. Yes.

24 Q. And can we agree that the '502 patent does not provide
25 any efficacy data for any of the claimed corticosteroids other

1 than halobetasol propionate?

2 A. Yes.

3 Q. And it doesn't provide formulation details for any of
4 those corticosteroids either, other than halobetasol
5 propionate, correct?

6 A. You'd have to double-check with the formulator.

7 What my understanding, but I'm not a formulator, is
8 that they provided basically a recipe for a vehicle, and with
9 that particular recipe, you could then substitute in various
10 other topical corticosteroids. But you'd have to ask the
11 formulators.

12 Q. Okay. But it's your understanding that the vehicle was
13 interchangeable for all of the corticosteroids?

14 A. Possibly. But, again, that's a formulation question.

15 Q. Okay. And you would defer to the formulation expert on
16 that point?

17 A. My understanding is they provided a recipe in the patent,
18 and with this particular recipe for this enhanced vehicle you
19 can then take another steroid, potentially another
20 high-potency steroid, and put it in.

21 Q. And what I'm trying to get at is, if the formulator
22 testified otherwise, would you defer to the formulator?

23 A. Probably.

24 Q. Okay. Now I'd like to go through just a couple of your
25 slides to make sure we're on the same page with just a few

1 fine points.

2 MR. ZIMMERMAN: If we could bring up your Slide 410.

3 BY MR. ZIMMERMAN:

4 Q. In the third line down, it says: Ultravate® was
5 considered to be the gold standard for halobetasol
6 formulations.

7 So how many halobetasol propionate formulations were
8 there at that time other than Ultravate®?

9 A. Just -- just Ultravate®.

10 Q. So it was the gold standard in a class of one?

11 A. It was the gold standard -- can I explain what that
12 means?

13 So it was that when this drug was formulated, BMS
14 would have optimized it and picked the gold -- you know,
15 whatever the gold standard formulation, best efficacy and
16 safety for that particular topical treatment.

17 Q. Okay. So we're on the same page that you're saying it
18 was the gold standard, but it was also the only one.

19 A. Yes.

20 Q. Okay. And then you highlighted a section that said: It
21 would have been expected in the field that Bristol Myers
22 optimized the concentration of this halobetasol formulation.

23 You don't have any actual evidence as to what BMS
24 did, right?

25 A. The only evidence I have is my prior experience with

1 Phase 1 -- with Phase 2 and 3 studies.

2 Q. And that had nothing to do with halobetasol propionate,
3 right?

4 A. Right. Just similar drugs getting --

5 Q. So I want to be very clear. You have no actual evidence
6 that BMS optimized the formulation of Ultravate®, right?

7 A. I was not there when they were doing the optimization.

8 Q. You don't even know that they did an optimization, right?
9 You just don't have any evidence.

10 And it's a yes-or-no question.

11 A. Right. I don't have the clinical trial that looked at
12 the other formulations or concentrations.

13 Q. Okay.

14 MR. ZIMMERMAN: Now, if we go to Slide 19.

15 BY MR. ZIMMERMAN:

16 Q. You talk about this comparison between 0.01 percent HP
17 and 0.05 percent HP with respect to potency and efficacy in
18 six weeks.

19 When you say "0.01 HP," are you talking specifically
20 about Bryhali®, or are you talking something broader?

21 A. Here I'm talking mainly about -- I'm talking about
22 Bryhali®.

23 Q. Okay. And only Bryhali®, right?

24 A. I'm talking about Bryhali®, yes.

25 Q. Okay. And only Bryhali®?

1 A. Yes.

2 Q. So when you talk about 0.01 percent HP has equal potency
3 to 0.05 HP, the 0.05 HP you're talking about is Bryhali®.

4 A. I'm talking about the potency of the superpotent steroid.

5 Q. Right.

6 A. Yes.

7 Q. But the 0.01 percent HP you're talking about at each
8 point on Slide 4-19 is Bryhali®?

9 A. Yes.

10 MR. ZIMMERMAN: Now, if you go to Slide 35.

11 BY MR. ZIMMERMAN:

12 Q. You talk about others hadn't achieved what Bryhali®
13 achieved, and you cite to a Padagis filing.

14 Do you know what that filing is actually for?

15 A. I believe it's for the generic versions of halobetasol.

16 Q. So it was a clinical trial to make a generic, right?

17 A. Yes.

18 Q. And when you make a generic product, it's got to be the
19 same strength as the one on the market, right?

20 A. Yes.

21 Q. Okay. So this doesn't evidence that Padagis was doing
22 research on other strengths of HP, does it?

23 A. It shows us that they were investigating the molecule of
24 halobetasol.

25 Q. Right. And trying to make a generic of the existing

1 product, correct?

2 A. I don't know what their thought process was. All I know
3 is what's presented here is that -- maybe they were doing
4 multiple things, but this shows that they were looking at the
5 generic of 0.05.

6 Q. Okay. And do you know -- the document you actually
7 looked at was about them making a generic version of the
8 0.05 percent, right?

9 A. Yes.

10 Q. It didn't have anything to do with exploring a different
11 concentration of halobetasol propionate other than the
12 marketed Ultravate® product, right?

13 A. Yes.

14 Q. Okay.

15 MR. ZIMMERMAN: Now, finally, I'd like to turn to
16 Slide 52 of your presentation. And I apologize, this is going
17 to take just a couple of minutes.

18 BY MR. ZIMMERMAN:

19 Q. So if we look at your Slide 52, you show some data from
20 the Gollnick reference, right?

21 A. Yes.

22 Q. And you say that Gollnick taught a preference for
23 tazarotene and a mid-potency corticosteroid as opposed to
24 tazarotene and a high-potency corticosteroid, right?

25 A. Yes.

1 Q. Okay. And on this chart, you see -- you take a portion
2 of Figure 1 and you box it in red and then you blow it up and
3 put it in yellow, right?

4 A. Yes.

5 Q. Okay. Now, the legend for this says that little diamonds
6 are tazarotene plus mid-potency corticosteroids, right?

7 A. The diamonds, yes.

8 Q. And the triangles are tazarotene plus high-potency
9 corticosteroid, right?

10 A. Yes.

11 Q. And your opinion that Gollnick prefers tazarotene and a
12 mid-potency corticosteroid over tazarotene and a high-potency
13 corticosteroid is that at week 12, the diamond is above the
14 triangle, right?

15 A. No.

16 Q. No?

17 A. No.

18 Q. Okay. What is your basis for that then?

19 A. There's a multitude of factors that go into it. The mid-
20 and the high-potency steroids are basically very equivalent,
21 but it goes more to when we look at the adverse event profile.
22 When you look at the high-potency steroid, the dropout rate is
23 quite high. When you look at the mid-potency steroid, the
24 dropout rate is much lower.

25 So taken in totality, anybody reading this article

1 would walk away and say I probably should use a mid potency.

2 Q. Okay. And can we agree that the graph that you put up is
3 actually incorrect?

4 A. That's the -- that's the post treatment period.

5 Q. The week 12 graph from Gollnick is actually wrong, isn't
6 it?

7 A. The graph is wrong...

8 Q. In the Gollnick reference -- you read the Gollnick
9 reference carefully in forming your opinions, right?

10 A. Yes. Sort of.

11 Q. And Gollnick's Figure 1 actually transcribes the data at
12 week 12 for the mid-potency and the high-potency
13 corticosteroid, doesn't it?

14 A. That, I really don't know. You'd have to show me in the
15 article.

16 MR. ZIMMERMAN: So if we could go to the Gollnick
17 article and look at Page 3.

18 And first we can bring up Figure 1.

19 BY MR. ZIMMERMAN:

20 Q. We can agree that at week 12, the diamond is shown as
21 above the triangle, right?

22 A. The diamond is above the triangle at week 12. Okay.

23 Q. And that means that the mid-potency corticosteroid was
24 more active than the high-potency corticosteroid, right?

25 A. So -- but it's not meaningful because they're both

1 basically the same.

2 Q. Right. But --

3 A. They're almost on top of each other.

4 Q. But what I'm saying is that the high potency has a lower
5 treatment success than the mid potency, right?

6 A. The high potency --

7 Q. The high potency is the --

8 A. -- has a lower potency success than the mid potency.

9 Q. Okay. So based on raw numbers, the graph says mid
10 potency --

11 A. Is better.

12 Q. -- is better.

13 A. Yes.

14 Q. And that's consistent with your conclusion on Slide 52;
15 that the mid potency is better, right?

16 A. Well, I'm not basing it just on this. These are
17 basically very, very -- all the lines are very, very similar.
18 There's not much of any difference between tazarotene by
19 itself, tazarotene plus -- well, they're all really, you know,
20 within -- not that big a major difference.

21 What I'm doing is looking at the totality of the
22 evidence, what is the efficacy and what is the safety, and
23 coming up with a bottom-line condition.

24 Q. Okay.

25 MR. ZIMMERMAN: And if we could go to the left-hand

1 column of Page 3 of Gollnick.

2 BY MR. ZIMMERMAN:

3 Q. You'll see that at week 12, the tazarotene high-potency
4 corticosteroid is 95 percent, and the Taz mid-potency
5 corticosteroid is 91, which is inconsistent with the graph in
6 Figure 1, right?

7 A. Yes. But these differences are not what I judged
8 anything by. I didn't really care if there was a 4 percent
9 difference in the study. That wasn't the basis of any of my
10 assessments.

11 Q. Okay.

12 MR. ZIMMERMAN: Let's bring back up your Slide 52.

13 BY MR. ZIMMERMAN:

14 Q. At the top of the slide, the piece you highlighted --

15 A. Yes.

16 Q. All three boxes --

17 A. Yes.

18 Q. -- are the data we just looked at.

19 A. Right.

20 Q. And in the highlighted boxes --

21 A. Yes.

22 Q. -- the pieces of the slide you chose to focus on and
23 highlight for everyone to look at --

24 A. Yeah.

25 Q. -- you picked the one at the top and said, oh, this

1 teaches tazarotene plus mid potency, right?

2 It's a yes-or-no question.

3 A. No.

4 Q. That's what you did.

5 A. No.

6 Q. No?

7 A. That's not what I'm showing here. What I'm showing here
8 is that the mid and the high are very, very similar. If
9 you're going to have a similar efficacy of mid and high, plus
10 looking then -- and you notice on my slide I have then the
11 safety right under it, taken in totality, by far the
12 mid-potency steroid is going to be the winner.

13 Q. Okay. And let's be clear. You look Figure 1 --

14 A. Yes.

15 Q. -- and you took the legend and you highlighted it, right?

16 A. Yes.

17 Q. And then you took the week 12 and week 16 data, correct?

18 A. Yes.

19 Q. And from that data you said tazarotene plus mid-potency
20 corticosteroid, right? That's what you put in the yellow box
21 right next to it.

22 A. Right. The high and mid are almost equivalent.

23 Q. And you didn't put on your slide, high and mid almost
24 equivalent, high and mid about the same, all of these are the
25 same. What you wrote is tazarotene plus mid-potency

1 corticosteroid, correct?

2 And it's a yes-or-no question.

3 A. I have to elaborate. I'm sorry.

4 Q. You didn't say they were all the same on your slide, did
5 you?

6 A. The slides are not to speak by themselves. The slides
7 are for me to explain. They're there as my guide. That
8 doesn't speak for itself. You can't just put up the slide and
9 have that comment for me. This is there for me to talk about.

10 Q. Okay. Can we agree that the actual numbers show that at
11 week 12, Gollnick's data in Figure 1 showed that tazarotene
12 and the high-potency corticosteroid had a higher number,
13 namely 95 percent?

14 A. That is shown on the slide. Yes, that's what's in the
15 paper.

16 Q. That's what's in the actual paper.

17 A. Yes.

18 Q. Thank you.

19 MR. ZIMMERMAN: Dr. Stein Gold, if we could look at
20 Slide 12.

21 You'll have to forgive me. I was a little confused
22 on this one.

23 BY MR. ZIMMERMAN:

24 Q. You wrote on the slide that dermatologists wanted the
25 strongest available treatments, correct?

1 A. Yes.

2 Q. But then you have a slide that shows the same drug as a
3 superpotent, potent, upper mid strength, lower mid strength,
4 right?

5 A. Right.

6 Q. So under your logic, the dermatologists would only want
7 the one at the top, right?

8 A. No.

9 Q. Okay. Why not?

10 A. Because this is a teaching point for vehicles. We're not
11 talking about treatment of psoriasis patients here. This was
12 a teaching point to explain that by changing the vehicle, you
13 change the potency.

14 What if you're treating seborrheic dermatitis?

15 Q. Correct. Okay.

16 So for plaque psoriasis, is it your testimony that
17 dermatologists always want the strongest available treatment?

18 A. Not a hundred percent of the time, but usually, yes.

19 Q. Isn't it true that dermatologists want a range of
20 treatments for patients with different severity?

21 A. I'm going to say no.

22 Q. Okay. But that's not why the drug we're looking at here
23 in Slide 4-12, the betamethasone, is offered in a range of
24 different classes?

25 A. So you need to understand that topical steroids are used

1 for a ton of -- it's the number one thing we use in
2 dermatology. The population, there's only seven to eight
3 million people walking around with psoriasis. Seborrheic
4 dermatides, eczema, poison ivy, there's a million different
5 reasons why people prescribe topical steroids. It's not all
6 psoriasis.

7 Q. Right. But we can agree dermatologists don't always want
8 the strongest treatment for psoriasis.

9 A. Generally, they do.

10 Q. Okay. Are the Bryhali® patents limited to treatment of
11 psoriasis?

12 A. No.

13 MR. ZIMMERMAN: Thank you. I have no further
14 questions and pass the witness, Your Honor.

15 THE COURT: Thank you.

16 Redirect.

17 MR. BRUNO: Yes, Your Honor.

18 REDIRECT EXAMINATION

19 MR. BRUNO: If we can bring up PDX-4-16.

20 BY MR. BRUNO:

21 Q. Dr. Stein Gold, do you remember being asked about this
22 slide?

23 A. I do.

24 Q. And you remember Mr. Zimmerman asking you about a
25 sentence that's not included on the slide?

1 A. Yes.

2 Q. What was that sentence about?

3 A. It was about whether or not the different arms of the
4 study showed statistical significance.

5 Q. Why didn't you include that sentence on the slide?

6 A. So just to give an understanding of what this is, when
7 you're conducting a clinical trial where all the arms are
8 actives, you need to have a very, very, very large study to
9 show statistically significant differences between all the
10 active arms. If it's active versus vehicle, where one arm is
11 active and one arm isn't, you don't necessarily need large
12 numbers.

13 This study was not powered appropriately to show a
14 statistically significant difference between the different
15 arms of the study. They potentially would have had to have
16 maybe hundreds of people in each arm. It's an underpowered
17 study.

18 Again, I said it wasn't a great study to begin with
19 but just because -- you know, and to be honest, if you're
20 running a clinical trial and you don't want to see a
21 difference between the different arms, you underpower it so
22 that it doesn't reach the statistical significance. So that's
23 what you would do to show no statistically significant
24 difference.

25 So it's not meaningful to me whether there was

1 statistical difference or not, it's just says that the study
2 was not powered to show a statistically significant
3 difference.

4 Q. And to be clear, Blum is one of the references that
5 Padagis is relying on for showing obviousness, right?

6 A. Right.

7 MR. BRUNO: Let's turn next to DX-127.

8 BY MR. BRUNO:

9 Q. I think this was on your slide inadvertently as DX-140.
10 Do you recognize this as the Kircik 2011 article?

11 A. I do.

12 Q. Let's focus in on the abstract. And, in particular,
13 let's look at the first two sentences.

14 Please let me know when you're done reading those.

15 A. Yes.

16 Q. Okay. So, first off, when you refer to the definition of
17 synergy, the one plus one equals three is the nuanced
18 definition, was that just your language?

19 A. It's in this particular Kircik article as well.

20 Q. Now, in the first sentence of this abstract, there's
21 reference to the word "synergy" as well, right?

22 A. Yes.

23 Q. And in this abstract, what contrast is Dr. Kircik drawing
24 between the use of synergy in the first sentence and use of
25 synergy in the second sentence?

1 A. So in the first sentence, he clearly defines synergy as
2 working together as opposed to not working together or
3 antagonistically.

4 In the second sentence, he calls out what he refers
5 to as the nuanced meaning, which is one plus one equals three.

6 Q. Approximately, how many pharmacological publications have
7 you read over the course of your career?

8 A. Too many to count.

9 Q. And would you agree, based on that experience -- actually
10 let me ask it a different way.

11 Based on that experience, what can you tell the Court
12 about how synergy is used in those publications?

13 A. So synergy, in the many times that the word is used, most
14 of the time, it's used the way he is saying, act
15 synergistically or together as opposed to being antagonistic.

16 Q. Personally, how do you differentiate between whether
17 synergy is the complimentary effect version versus the one
18 plus one equals three version?

19 A. The only way to understand that it's the one plus one
20 equals three, you have to have data there. If there's no data
21 explaining what you mean, then my interpretation would be that
22 it works in harmony.

23 MR. BRUNO: Now, let's turn to the summary portion of
24 the same article, and specifically, it's the page ending in
25 BAU 01199746.

1 BY MR. BRUNO:

2 Q. Let's focus in on the first paragraph and please read
3 that to yourself and let me know when you're done.

4 A. Yes.

5 Q. In this paragraph, in that first sentence, what is
6 Dr. Kircik teaching about the relevant -- I'm sorry, let me
7 ask that a different way.

8 What is Dr. Kircik teaching about the relative
9 availability of this complimentary synergy versus the one plus
10 one equals three synergy?

11 A. So I talked about the art of medicine or the art of
12 dermatology earlier. Part of our art is to take drugs that
13 work by different mechanisms of action or complimentary
14 mechanisms of action, lots and lots of drugs. In fact, most
15 of the topicals, you know, the different categories of
16 psoriasis, work by complimentary mechanisms of action.

17 Q. In the next sentence, Dr. Kircik refers to true
18 pharmacological synergy.

19 Do you know why he had to use the word "true" there?

20 A. Because, generally, the word "synergy" is not used that
21 way. He is just saying -- the exception really is to use it
22 as the one plus one equals three.

23 Q. In your own literature about Duobrii® -- actually, let's
24 do it this way.

25 MR. BRUNO: Let's turn to PTX-44. I'm sorry, PTX-44.

1 BY MR. BRUNO:

2 Q. You were asked about this article on cross-examination?

3 A. Yes.

4 Q. And this is the Kircik 2019 article that you're a
5 co-author on?

6 A. Yes.

7 Q. Now, in this article, you're reporting the synergy of
8 Duobrii®, correct?

9 A. We are.

10 MR. BRUNO: Let's turn to the next page. Let's blow
11 up those bullets there in the second column. Sorry, the one
12 that has synergy in bold.

13 BY MR. BRUNO:

14 Q. Why did you include this definition of synergy in your
15 article in 2019?

16 A. Because most people don't truly understand this
17 particular definition.

18 Q. Does this 2019 article include data supporting the
19 conclusion of synergy?

20 A. Yes.

21 Q. Okay. And without this definition and without the data,
22 how do you think that somebody would have read the article if
23 it had just said synergistic effects without anything more?

24 A. Again, you go back to the art of medicine, the art of
25 dermatology, synergy would have been -- used medicines that

1 work by complimentary mechanisms of action.

2 Q. Now, you were asked a lot about the Taclonex® suspension
3 on cross-examination.

4 Do you remember that?

5 A. Yes.

6 Q. Let's talk a little more broadly about synergy in the
7 dermatological arts.

8 Approximately, how many combination products exist in
9 the dermatological arts?

10 A. So I'm aware of many combinations for the treatment of
11 acne, I'm aware of the two fixed combinations that we talked
12 about for psoriasis, and I'm not aware of any other fixed
13 combinations for other disease states.

14 Q. Are you aware of any publications reporting the synergy
15 of the Taclonex® suspension prior to 2015?

16 A. No.

17 Q. Does Taclonex® suspension include a superpotent
18 corticosteroid?

19 A. No.

20 Q. Does Taclonex® suspension include a retinoid?

21 A. No.

22 Q. Does the fact that Taclonex® suspension may demonstrate
23 synergistic efficacy change any of your opinions?

24 A. No.

25 Q. Why not?

1 A. These are completely different drugs. We're talking
2 about a potent steroid with a vitamin D that was put together
3 in different formulations, and then we're talking about
4 completely different -- a superpotent steroid and a topical
5 vitamin A derivative. Completely different.

6 Q. Are you aware of any data that shows the Taclonex®
7 suppression shows the claimed synergistic reduction?

8 A. No.

9 Q. Are you aware of any literature in relation to your view
10 in this case that shows any combination demonstrating the
11 claimed synergistic reduction?

12 A. No.

13 Q. Now, I just want to clarify one bit of testimony. I
14 think you said on cross-examination that you haven't seen
15 clinical data for Bryhali® and Duobrii® for two to eight
16 weeks.

17 Just to clarify, were you referring to the patents or
18 just as a whole?

19 A. I'm sorry, can you say that again?

20 Q. Sure.

21 I believe on cross-examination you testified that you
22 hadn't seen clinical data for Bryhali® and Duobrii® for the
23 two- to eight-week period. I just want to clarify the record.

24 A. Yes.

25 Q. Were you referring to the patents or just in general?

1 A. Well, the clinical trials went that long. So I have seen
2 that data. I participated in those clinical trials.

3 So yeah -- I'm sorry, I probably misunderstood.

4 Q. Now, I want to talk to you a bit about the optimization
5 of Ultravate®.

6 Do you remember that testimony?

7 A. Yes.

8 Q. Why would a POSA have believed that Ultravate® was
9 optimized?

10 MR. ZIMMERMAN: Objection. Lacks foundation. She
11 testified that she had no evidence that it was or wasn't.

12 MR. BRUNO: Your Honor --

13 THE COURT: Overruled. She said that she was not
14 aware of any evidence. Let's find out what the basis for her
15 belief is.

16 THE WITNESS: Thank you.

17 So I run clinical trials and I understand Phase 2
18 clinical trials, especially with new drug entities, usually
19 are involved with looking at different concentrations, maybe
20 even different formulations; once a day, twice a day. There's
21 usually a lot of testing that goes on preclinical, and then
22 ultimately, you take your best two and you take it to the
23 Phase 2 clinical trials.

24 So there's a ton of work that goes up to that point.

25 And then Phase 2 you kind of figure out, okay, where

1 are we going to go, ideally, which concentration is going to
2 be best. Is it once a day, twice a day?

3 That's done, in my experience, with every drug that
4 I've done any kind of clinical testing for.

5 I wasn't around when halobetasol was doing their
6 Phase 2 clinical trials. I've actually looked to see if
7 there's a publication that specifically states the halobetasol
8 Phase 2 clinical trial. I haven't seen it.

9 But based on the art of running clinical trials, I
10 have to believe that that would not have been unique.

11 BY MR. BRUNO:

12 Q. Is it common to run dose finding studies as part of drug
13 development?

14 A. In my experience, always.

15 Q. And Blum is an article that compared the 0.02 percent
16 concentration of halobetasol against the 0.05 percent
17 concentration, right?

18 A. Yes.

19 Q. When did Blum publish in relation to when Ultravate® was
20 marketed?

21 A. Years in advance.

22 MR. BRUNO: Now, I'd like to put up PDX-4-52 which
23 talks about the Gollnick article.

24 BY MR. BRUNO:

25 Q. Do you remember that discussion with Mr. Zimmerman?

1 A. I do.

2 Q. What do you take away from the data at Week 16 that
3 you've presented here on your slide?

4 A. What I take away from this is that if you use tazarotene
5 as monotherapy, you see a really nice maintenance of effect
6 with -- you know, same thing as we saw with the phase -- with
7 the monotherapy studies.

8 But I also see that as you add more potent topical
9 steroids, we start to lose that benefit. There's not a
10 superpotent steroid here. So my guess, because we start to
11 see it decreasing as you get to higher concentrations, is we
12 probably lose it continued. But there's no study for
13 superpotent steroids.

14 Q. Thank you, Dr. Stein Gold.

15 MR. BRUNO: I have no further questions.

16 THE COURT: Any further cross?

17 MR. ZIMMERMAN: I'll be very brief, Your Honor.

18 RECROSS-EXAMINATION

19 BY MR. ZIMMERMAN:

20 Q. Dr. Stein Gold, I just want to be clear. You haven't
21 seen any Bristol-Myers Squibb documents that confirm
22 Ultravate® was optimized, right?

23 A. Correct.

24 Q. Okay. Now, were you involved in the clinical testing for
25 Duobrii®?

1 A. Yes.

2 Q. Okay. And your testimony just a moment ago was that
3 every single clinical trial you've been involved with the
4 product was optimized.

5 Would you like to change that testimony?

6 A. So with new chemical entities, yes.

7 Q. Okay. And, in fact, Duobrii® wasn't optimized with
8 respect to tazarotene and Dr. Pillai testified to that effect,
9 right?

10 A. That, I don't know.

11 Q. Okay. So you don't know if Duobrii® was optimized, do
12 you?

13 A. My -- for Duobrii® or for tazarotene?

14 Q. For the tazarotene piece of Duobrii®.

15 A. For the tazarotene piece of Duobrii® was that optimized?
16 I don't know.

17 Q. Okay. So you didn't listen to Dr. Pillai's testimony
18 that it wasn't?

19 A. That it wasn't optimized?

20 Q. Yes.

21 A. To be honest, it was a little -- I heard a lot of it, but
22 -- okay.

23 Q. Okay. So it wouldn't surprise you that not every
24 clinical product you've worked on has been optimized?

25 A. So as Dr. Pillai explained during his testimony, when

1 you're developing a new chemical entity and a new drug, you
2 make sure you have -- you do those trials.

3 He explained during -- with a fixed combination of
4 two drugs that are already there, you don't necessarily go
5 through those steps.

6 Q. Okay. So it's your understanding that the optimization
7 piece is for new chemical entities?

8 A. For new drugs.

9 Q. Okay.

10 MR. ZIMMERMAN: Thank you. I have no further
11 questions, Your Honor.

12 THE COURT: Any further redirect?

13 MR. BRUNO: No, Your Honor.

14 THE COURT: Thank you very much, Doctor.

15 (Witness excused.)

16 THE COURTROOM DEPUTY: Two minutes to set up.

17 MS. WEISBRUCH: We're also going to request that the
18 Court seal the courtroom at this time. Bausch intends to call
19 its commercial success expert.

20 THE COURTROOM DEPUTY: Anybody that should not be
21 here, please leave the courtroom.

22 Is there any press? Anybody from the press? Any
23 public?

24 Counsel, look around the room. Do you recognize all
25 the faces?

1 (Discussion held off the record.)

2 *** TESTIMONY UNDER SEAL ***

3 THE COURTROOM DEPUTY: The courtroom is sealed.

4 MS. WEISBRUCH: Your Honor, Bausch calls Dr. Sheridan
5 as a witness.

6 Before we begin with Dr. Sheridan, just in the
7 interest of expediency and saving time this afternoon, we are
8 offering Dr. Sheridan as an expert in the field of economics.
9 His credentials will be summarized on a slide that will be
10 shown, PDX-5-3 and his CV is PTX-333.

11 THE COURT: And there's no objection to him being so
12 qualified, correct?

13 MR. ZIMMERMAN: No objection, Your Honor.

14 THE COURT: All right. He is so deemed.

15 THE COURTROOM DEPUTY: Dr. Sheridan, please raise
16 your right hand.

17 DR. SEAN DAVID SHERIDAN, PLAINTIFF'S WITNESS,
18 having been duly sworn, testifies as follows:

19 THE COURTROOM DEPUTY: State your full name for the
20 record.

21 THE WITNESS: Sean David Sheridan.

22 THE COURTROOM DEPUTY: Thank you.

23 DIRECT EXAMINATION

24 BY MS. WEISBRUCH:

25 Q. Good afternoon, Dr. Sheridan.

1 Could you please introduce yourself to the Court?

2 A. Yes. As I said, I'm Sean Sheridan. I'm a principal in
3 the life sciences practice at Charles River Associates, which
4 is an economic consulting firm. And I'm based in the Chicago
5 office.

6 Q. And what is your role here today as a witness?

7 A. I'm here to testify regarding the commercial success of
8 Duobrii®.

9 Q. Could you please give us a summary of your opinions in
10 this case?

11 A. Sure. It's my opinion that Duobrii® is a commercial
12 successful product and that's demonstrated by the sales that
13 its achieved. [REDACTED] in less than three
14 years. That's the three years of -- less than three years of
15 data that I had available to me when I prepared my report.

16 The gross profits that it has earned are [REDACTED],
17 and those sales represent a market share in the -- or its
18 share of the relevant market of [REDACTED]

19 And I consider all of these indicators to be
20 significant given the brief period of time the product has
21 been on the market -- as I mentioned, it's less than three
22 years -- the number of established competitors that were
23 already in the market for a number of years before Duobrii®
24 was launched, and given the very significant, unexpected
25 challenge of COVID-19. So the pandemic hit less than a year

1 after Duobrii® had been launched.

2 There are other factors that indicate commercial
3 success, including the fact that Duobrii® received widespread
4 coverage by U.S. insurance companies.

5 And finally, I looked at a number of other economic
6 factors to see whether or not the demand for the product might
7 be due to those economic factors. And in particular, I looked
8 at marketing and pricing and concluded that those are not
9 driving demand for Duobrii®.

10 Q. Do you have an understanding of whether Duobrii® embodies
11 and is coextensive with the claimed features of the Duobrii®
12 patents?

13 A. Yes, it's my understanding based on a conversation that I
14 had with Dr. Stein Gold that Duobrii® does embody the
15 patents-in-suit and is coextensive with the claims of the
16 patents-in-suit. And it's also my understanding that, after I
17 submitted my report, the parties stipulated to the fact that
18 Duobrii® does embody the patents-in-suit.

19 Q. What did you conclude about Duobrii®'s sales and profits
20 since launch?

21 A. That is summarized on this slide, which is showing
22 Exhibit 5 to my report. And here what I've done is quantified
23 the net sales of the product from May 2019 through the end of
24 2021.

25 And as you can see in the highlighted figure up at

1 the top right, that's about [REDACTED] over that time
2 period. And over the same time period, the gross profits that
3 were earned were approximately [REDACTED]

4 Q. And why are those sales and profit numbers significant in
5 your opinion?

6 A. So there's a number of reasons that I mentioned before.
7 One of them is the brief period of time that we're looking at
8 here. So this is less than the first three years that the
9 product was on the market.

10 Industry study has shown that most pharmaceutical
11 products don't achieve peak sales even within the first five
12 years. And, in fact, many products can take as long as
13 12 years to achieve peak sales.

14 So we're really looking at just the initial kind of
15 launch period of the product.

16 With respect to competition in the marketplace, as I
17 mentioned before, there's a number of competitors that were
18 established in the market before Duobrii®'s launch. So it had
19 to differentiate itself with its own clinical benefits in
20 order to achieve sales given that environment.

21 And this is also a market that is very heavily
22 genericized; actually, 95 percent of the marketplace for
23 topical treatments is generic.

24 And finally, as I mentioned, a COVID-19 pandemic hit
25 the U.S. less than a year after the product was launched, so

1 that caused dermatology offices to close. They were no longer
2 having patients in 2020. Patients stopped coming in to see
3 the dermatologists, and there was also a disproportionate
4 impact on new product launches.

5 So the COVID-19 pandemic didn't -- it did lower all
6 dermatology sales, but it impacted new products more than
7 products that had been around for a while.

8 Q. And in reaching the opinions that you just discussed on
9 Duobrii® sales and profits, you considered Exhibits PTX-219
10 and PTX-224 as shown on your slide?

11 A. Yes, those were the Bausch financial documents that I
12 used in preparing this. That's correct.

13 Q. How do you know that the COVID-19 pandemic negatively
14 impacted dermatology treatments?

15 A. So there are internal Bausch presentations that were
16 prepared in the ordinary course of business that talk about
17 this, actually quite a few of them that talk about the
18 negative impact on dermatology overall and how it was forcing
19 dermatologists to kind of change how they were doing business
20 and try to switch over to telemedicine.

21 And there were third-party analyst reports that
22 discussed the same thing and how overall sales in dermatology
23 declined.

24 MS. WEISBRUCH: Can we please pull up PTX-73?

25 BY MS. WEISBRUCH:

1 Q. Dr. Sheridan, do you recognize PTX-73?

2 A. Yes. This is one of the documents that I reviewed. This
3 is a quarterly sort of management summary document. This is,
4 as you can see in the top left, "Q3 2020 in Review." And it's
5 looking at products in the ortho dermatologics segment at
6 Bausch Health.

7 And if you look over to the right, you'll see what
8 says, [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 So, you know, as I said, with the switch over to
16 telemedicine, that may have worked for -- at least for some
17 patients to interact with their doctors, but it's difficult to
18 reach physicians to educate them about the benefits of a new
19 product if you're not able to meet face-to-face. And there
20 are actually a number of other Bausch documents that talk
21 about that as well.

22 Q. Did you consider Duobrii®'s market share as part of your
23 analysis?

24 A. Yes, market share is important to consider when
25 evaluating the significance of the sales revenue.

1 Q. What did you conclude about Duobrii®'s market share in
2 your analysis?

3 A. So first, I considered, you know, what was the relevant
4 market to look at. And as I mentioned, 95 percent of volume
5 in the market are generic products. But, of course, generic
6 products are priced much lower than branded products. So most
7 of the value is actually in that 5 percent, you know, most of
8 the revenue to be captured is in that 5 percent of the market
9 that are not branded products.

10 So if you're going to look at the market share on the
11 following basis for a branded product, what's particularly
12 informative is how is it performing in the branded
13 significant? That's where the pharmaceutical companies are
14 going to make their money and their profits.

15 And then within that branded segment of the market,
16 not all products are competing with each product directly.

17 What's particularly relevant is, how is this product
18 performing compared to its key competitors? Those where we
19 know it's know it's competing head-to-head directly for
20 patients.

21 [REDACTED]
22 [REDACTED]
23 [REDACTED]

24 So within that segment, I calculated the share of the
25 market. And I just note that this figure, which comes -- is

1 Exhibit 3 from my report, the prescription that I had was in
2 Q2 2019 through Q2 2021, so just over two years of data.

3 So in just over two years on the market, Duobrii®
4 achieved over [REDACTED], most of which were made
5 during the pandemic; again, a very challenging time to be
6 getting new patients. And that represented, over fiscal time
7 period, [REDACTED]

8 [REDACTED]
9 [REDACTED]
10 Q. Does Bausch identify any other market as the relevant
11 market for measuring Duobrii®'s performance in the
12 marketplace, [REDACTED]

13 [REDACTED]
14 A. Yes. [REDACTED]

15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 And when we added the prescriptions for Otezla®, the
19 majority of the market is Otezla®. It's probably two thirds
20 of the overall market that are Otezla®. And that's due to a
21 number of factors, one of which is that this is a systemic --
22 a systemic oral.

23 And during the pandemic, Otezla® benefitted as a
24 result of the pandemic, unlike any other products, because
25 patients that were previously going in to receive injectable

1 biologics at clinics were no longer able to go into those
2 clinics, so they were switching over to Otezla® during the
3 pandemic.

4 Q. And what is Duobrii®'s market share in [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED] market share over this time period
8 as well.

9 Q. And to reach your conclusions about market, you relied on
10 Exhibits PTX-54, PTX-143 and PTX-216, as shown on your
11 Slide PDX-58.

12 Do I have that correct?

13 A. Yes.

14 MS. WEISBRUCH: Can we please pull up PTX-212?

15 BY MS. WEISBRUCH:

16 Q. Do you recognize this document, Dr. Sheridan?

17 A. Yes, this is one of the documents that I relied on in
18 preparing my report. This comes from the commercial analytics
19 group at Bausch Health.

20 MS. WEISBRUCH: If we can go to the third page of
21 PTX-212, which ends in Bates number 264.

22 BY MS. WEISBRUCH:

23 Q. What does Page 3 of PTX-212 show about [REDACTED]

24 [REDACTED]

25 [REDACTED]

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10 Q. Finally, Dr. Sheridan, do pricing and marketing drive
11 sales of Duobrii®?

12 A. No. In my opinion, they did not based on the data that I
13 analyzed, and that's summarized on this slide. Both of the
14 figures that you see here come from my report.

15 On the left, what we're looking at is the average
16 sales price. This is an actual price, realized revenue as
17 opposed to a list price for Duobrii®. And you can see on a
18 quarterly basis, it fluctuates up and down, but the trend has
19 been to increase over time.

20 Of course, if you're competing on price, you wouldn't
21 typically increase your prices. You might hold them constant
22 or even decrease them.

23 On the right-hand side, we're looking at another
24 figure from my report. And here I looked at advertising and
25 promotion, which is abbreviated as A&P, as a percentage of

1 revenue. And I also looking at direct selling expenses also
2 shown as a percentage of revenue, and I compared them to other
3 Bausch Health dermatology products.

4 And what you can see is that in the first couple of
5 years they are high because these expenses are high, and then
6 they decline.

7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]

15 So what this tells us is that the marketing expenses,
16 the selling expenses, they're very much in line.

17 And, in fact, it's in line with -- I think every
18 other commercial success case that I've worked on follows this
19 trend, where you expect these expenses to be high when a
20 product is first launched because it takes a lot of effort to
21 educate prescribers about a new product and the benefits of
22 the new product. But then they decline, and profits increase
23 as those expenses decline as well.

24 Q. Thank you.

25 And just for the record, in reaching your conclusions

1 about pricing and marketing, you relied on Exhibits DX-505,
2 506 and 507, and PTX-222, 223 and 224.

3 Do I have that right?

4 A. Yes, that's correct.

5 THE COURT: Any objections?

6 MR. ZIMMERMAN: No objections, Your Honor.

7 THE COURT: They're admitted into evidence.

8 MS. WEISBRUCH: Thank you, Your Honor.

9 I have no further questions and I pass the witness.

10 THE COURT: Your witness.

11 CROSS-EXAMINATION

12 BY MR. BARNES:

13 Q. Good afternoon, Dr. Sheridan. Can you hear me okay?

14 A. Yes, I can.

15 Q. Okay. My name is Brian Barnes. I'm one of the attorneys
16 for the Padagis defendants, and I'm going to be asking you
17 some questions about the opinions that you just offered in
18 your direct testimony.

19 Now, you are not offering an opinion that Bryhali® is
20 a commercially successful product, correct?

21 A. That's correct. I did not analyze the commercial
22 performance of Bryhali®.

23 Q. Okay. And on your direct, during your direct testimony,
24 I believe counsel asked you whether Duobrii® was commensurate
25 with the claims of the Duobrii® patents.

1 And I believe you responded that it's your
2 understanding that Duobrii® is commensurate with the claims of
3 the asserted patents. And so I just want to clarify that
4 answer.

5 Is it your understanding or are you offering an
6 opinion that Duobrii® is coextensive with the asserted claims
7 of what plaintiffs have referred to as the Bryhali® patents?

8 A. I am not providing any opinions regarding whether or not
9 the product is coextensive with any patents.

10 I have an understanding based on my discussion with
11 Dr. Stein Gold that the product Duobrii® is coextensive with
12 the four patents that I have listed in my report.

13 And it's also my understanding that that was a
14 stipulation between the parties, which occurred after I
15 submitted my report.

16 Q. So it's your understanding that there was a stipulation
17 between the parties that Duobrii® was coextensive with the
18 claims of all four patents in the case.

19 Is that what you're saying?

20 A. It sounds like this is a legal question you're asking me.

21 My report and my opinion when I was deposed in this
22 matter was based on my discussion with Dr. Stein Gold.

23 And I do understand that there was a stipulation that
24 occurred afterwards. I don't know the details.

25 I'm not quite sure what you're getting at.

1 Q. Okay. And then, again, just to clarify, your
2 understanding from your conversation with Dr. Stein Gold is
3 that Duobrii® is coextensive with the claims of all four
4 patents in this case.

5 Is that correct?

6 A. I believe that that's my understanding, yes. I can look
7 back at my report to see if there was anything different
8 there.

9 But again, this is a legal issue or a technical issue
10 that's outside the scope of my opinions. This is just my
11 understanding.

12 MR. BARNES: Okay. So I'd like to pull up your Slide
13 PDX-5-7.

14 BY MR. BARNES:

15 Q. And you gave some testimony about the gross profits for
16 Duobrii®.

17 Is that correct?

18 A. I did, amongst other things. That's correct.

19 Q. And the gross profits you calculated for Duobrii® only
20 account for the expenses relating to costs of goods sold.

21 Is that correct?

22 A. That's correct. But that --

23 Q. Okay. That -- that answers my question. That answered
24 my question.

25 And so your calculations for gross profits for

1 Duobrii® do not account for any marketing, advertising,
2 promotional, or selling expenses for Duobrii®, correct?

3 A. By definition, "gross profits" cannot account for those
4 expenses. That's why I also accounted for those expenses --

5 Q. Okay.

6 A. -- as you saw in my last slide.

7 Q. Okay. And so you're familiar with the concept of net
8 profit, correct?

9 A. Yes.

10 That would be profits -- typically, that's what would
11 be defined as profits after interest, tax, operating expenses,
12 all the other expenses that one might deduct.

13 Q. Okay. And so you would agree with me that one way to
14 define "net profits" is to deduct the advertising, promotional
15 and selling expenses related to that product from the gross
16 profits.

17 Can we agree on that?

18 A. Yes. That's what I just said.

19 You would deduct basically all the additional
20 expenses if we were calculating net profit.

21 Q. [REDACTED]

22 [REDACTED]

23 [REDACTED]

24 [REDACTED] So we would have to see what all the data is up
25 until this point.

1

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So it's not surprising that we see --

5

Q. And we'll get to that. My question was focused on

6

that -- Dr. Sheridan, my question --

7

A. -- that expenses --

8

THE COURT: Doctor, you answer the question that's

9

asked.

10

THE WITNESS: Yes, Your Honor.

11

THE COURT: We don't get into a shouting match

12

between you and counsel. If the question was a yes-or-no

13

question, you answer it that way.

14

Opposing counsel will be able to elicit any

15

additional information that he or she believes should be

16

brought to my attention on redirect.

17

Do not do that again.

18

Please proceed.

19

THE WITNESS: Yes, Your Honor.

20

MR. BARNES: Yes, Your Honor.

21

BY MR. BARNES:

22

Q. And so I'll ask again. For the period from when Duobrii®

23

was launched -- let me rephrase.

24

For the data that you considered in this case, based

25

on that data, [REDACTED]

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8 A. No, I do not. I didn't calculate that.

9 Q. And so it's your opinion that Duobrii® is a commercially
10 successful product, correct?

11 A. Yes, that is correct.

12 Q. [REDACTED]

13

14

15 Is that correct?

16 A. That's correct. I can explain, if you'd like --

17 THE COURT: Doctor, just answer the question.

18 BY MR. BARNES:

19 Q. And you also gave some opinion about Duobrii®'s net
20 sales.

21 Is that correct?

22 A. Yes, I did.

23 Q. And looking at this slide that's on the screen, PDX-5-7,
24 would you agree with me [REDACTED]

25

1 A. Annualized. So I didn't annualize the 2019, the partial
2 year of 2019 sales. But that is probably correct if you were
3 to do that.

4 Q. And you would agree with me that Duobrii®'s sales for the
5 year of 2019 did not begin until May of that year.

6 Is that correct?

7 A. That is correct.

8 Q. [REDACTED]
9 [REDACTED]
10 [REDACTED]

11 Is that correct?

12 A. That is correct.

13 Q. I'd like to turn to your market share analysis.

14 MR. BARNES: If we could bring up your slide -- I
15 believe it is Slide PX-5-8.

16 BY MR. BARNES:

17 Q. And I believe in your testimony you mentioned that there
18 were -- let me rephrase.

19 I believe in your direct testimony you testified that
20 there were a number of established competitors for Duobrii®
21 when Duobrii® entered the market.

22 Is that correct?

23 A. That's correct, yes.

24 Q. And can you explain what those competitors were?

25 A. Right. So there are generic competitor products.

1 95 percent of the market, as I said, are generics.

2 And then there are, in the branded combination
3 segment, which you look at here, there's Enstilar® and
4 Taclonex®, which consists of three separate products that I've
5 combined here into a single one. So I guess there's four of
6 the branded combination products that are here. And that's
7 within the topicals.

8 And, as I mentioned, Bausch Health also tracks what
9 it calls "Branded Combos Plus Otezla®," so it recognizes
10 Otezla® as a competitor as well.

11 Q. [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 Is that correct?

20 A. Yes, that is correct.

21 Q. Okay. And that market consists of Class 1
22 corticosteroids, Class 2 corticosteroids, systemic orals and
23 branded combinations, which Duobrii® would fall into that last
24 category.

25 Is that right?

1 A. Yes, that is correct.

2 Q. And you'd agree with me that in that broader dermatology
3 market, Duobrii®'s net share of the market [REDACTED]

4 [REDACTED]

5 A. Right. Because it's the generics that account for the
6 vast majority.

7 Q. And it's your testimony that what you have here as the
8 branded combination market is the relevant market when
9 assessing Duobrii®'s market share, correct?

10 A. Well, it's this, and I also think that branded combo plus
11 Otezla® is another relevant market, another way to look at the
12 relevant market.

13 Q. Okay. And so if we look on this slide, you highlighted
14 that [REDACTED]

15 [REDACTED]

16 A. Correct.

17 Q. And that [REDACTED]
18 [REDACTED] over that same period,

19 correct?

20 A. That's correct.

21 Q. So is it correct that in this market with only three
22 products, [REDACTED]

23 [REDACTED] from the period of Q2 2019 through Q2 2021?

24 A. That's correct, yes.

25 Q. And did you listen to Dr. Stein Gold's testimony earlier?

1 A. I did, yes.

2 Q. All right. And did you hear that Dr. Stein Gold
3 testified that Enstilar® and Taclonex® are both fixed-dose
4 combinations of the same ingredients at the same
5 concentrations?

6 A. I think -- I think I recall that.

7 Q. And do you recall Dr. Stein Gold testifying about how
8 really there's only two fixed-dose combinations for psoriasis,
9 Duobrii® and the combination that is in both Enstilar® and
10 Taclonex®?

11 Do you recall that?

12 A. Yeah. I didn't understand her to be saying products.
13 But in terms of what the active ingredients are, yes, that's
14 correct.

15 Q. And so actually, when you compare Duobrii®'s market share
16 in this market with the only other branded combination --
17 fixed-dose combination, Duobrii®'s market share is [REDACTED]
18 [REDACTED] of the only other fixed-dose combination for psoriasis.

19 Is that correct?

20 A. I'm not -- are you saying to add up the Enstilar® and
21 Taclonex® percentages together?

22 Q. Correct.

23 A. Okay. Yes. Then yes, I agree.

24 Q. And I believe you testified and mentioned earlier the
25 branded combo plus Otezla® market, correct?

1 A. I'm sorry. Can you repeat that?

2 Q. Yes.

3 So you had mentioned in your direct and both in your
4 answer earlier about the branded combo plus Otezla® market.

5 Do you recall that?

6 A. Yes, I do.

7 Q. And in that market, you testified that Duobrii® has
8 roughly [REDACTED]

9 Is that right?

10 A. It's maintained over [REDACTED].

11 Q. And that -- let me rephrase.

12 When you're referring to that branded combo plus
13 Otezla® market, that's not looking at total number of
14 prescriptions across all specialties, correct?

15 A. The data that I had available to me was looking at
16 dermatology as a specialty, which I think is where [REDACTED]

17 [REDACTED]

18 (Technical issues are encountered.)

19 Q. I think you may need to repeat that.

20 You broke up little bit, Dr. Sheridan.

21 A. Okay. I said that was looking at the dermatology
22 specialty, which, if I recall correctly, is where [REDACTED]
23 or more of Duobrii®'s sales are made, based on the data that I
24 saw.

25 Q. And so to clarify, when you referenced that [REDACTED]

1 market share figure, that was only based on prescriptions for
2 the dermatology specialty, correct?

3 A. That's correct.

4 The data that I had available to me.

5 Q. And you didn't mention that in your direct testimony to
6 this Court, correct? You just said it has [REDACTED] in the
7 market, correct?

8 A. That may be correct, yeah.

9 Q. And Duobrii® is priced lower than both Enstilar® and
10 Taclonex®.

11 Is that right?

12 A. Do you mean the list price?

13 Q. Do you agree that based on the wholesale acquisition cost
14 prices, Duobrii® is [REDACTED]

15 [REDACTED]

16 MS. WEISBRUCH: Objection. Outside the scope.

17 MR. BARNES: Your Honor, he testified --

18 THE COURT: Overruled.

19 BY MR. BARNES:

20 Q. Do you need me to ask the question again, Dr. Sheridan?

21 A. No. So wholesale acquisition cost, yes. That's what I
22 was referring to as list price.

23 [REDACTED]

24 [REDACTED]

25 [REDACTED]

1 [REDACTED]

2 [REDACTED]

3 A. It has -- for this time period, it has [REDACTED]

4 [REDACTED] That is correct. And its list price.

5 But we don't know about its average sales price of
6 the other products, whether or not it's lower.

7 MR. BARNES: Okay. And now I'd like to turn your
8 attention to a document with the Bates number BAU00563229,
9 which I will mark as DX-527 for the record.

10 (Exhibit No. DX-527, is introduced for
11 identification.)

12 BY MR. BARNES:

13 Q. Do you recognize this as one of the internal Bausch
14 presentations produced in the ordinary course of business that
15 you considered in forming your opinions in this case?

16 A. Yes, I did.

17 MR. BARNES: And if we can turn to the second page of
18 the presentation.

19 BY MR. BARNES:

20 Q. This presents an executive summary, correct?

21 A. That's correct. It looks like it's a draft. But yes,
22 that's correct.

23 Q. And under the heading [REDACTED]

24 [REDACTED]

25 [REDACTED]

1 Do you see that?

2 A. Yes, I do.

3 Q. So according to [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 A. I see that in this slide.

10 Q. Okay. And on that same page, under the heading [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 Do you see that?

14 A. I do.

15 Q. So [REDACTED]

16 [REDACTED] correct?

17 A. That's what this says, yes.

18 Q. And do you agree with me that the acronym of [REDACTED]

19 [REDACTED]

20 A. That's my understanding.

21 MR. BARNES: And if you turn to [REDACTED]

22 [REDACTED]

23 [REDACTED]

24 BY MR. BARNES:

25 Q. Do you see that?

1 Hold on.

2 A. Can you show me what you're --

3 Q. So the title [REDACTED]

4 [REDACTED] Correct?

5 A. I see that.

6 Q. Okay. And in the first bullet point, it states: [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 Do you see that?

10 A. I do.

11 Q. And so [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 A. You're paraphrasing that.

15 Yeah, I see that.

16 Q. And do you see [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 Do you see that?

20 A. I do.

21 Q. And so again [REDACTED]

22 [REDACTED], correct?

23 A. I guess if it's just [REDACTED]

24 [REDACTED], then yes. It's not entirely fair, but yes.

25 Q. Okay. The opinions that you offered in your report only

1 rely on sales data for -- or strike that.

2 The opinions you offered in your direct testimony
3 only rely on sales data for Duobrii® through 2021.

4 Is that correct?

5 A. Yeah. That's the only specs where the cutoff date was
6 for the sales data that I received.

7 Q. Okay. And you didn't ask Bausch for any sales data for
8 Duobrii® from 2022, correct?

9 A. That's correct.

10 Q. And it's your opinion that the COVID-19 pandemic
11 negatively affected the sales of Duobrii® for 2020 and 2021,
12 correct?

13 A. I wouldn't characterize that as my opinion. I'm just
14 relying on the documents, both Bausch documents and public
15 documents that I've reviewed.

16 Q. And you're not offering any opinion that the COVID-19
17 pandemic negatively impacted Duobrii®'s sales to a greater
18 extent in 2021 than 2020, correct?

19 A. That's correct.

20 I didn't say it was 2020 and 2021.

21 MR. BARNES: Okay. No further questions, Your Honor.

22 THE COURT: Redirect.

23 MS. WEISBRUCH: Brief redirect, Your Honor.

24 REDIRECT EXAMINATION

25 BY MS. WEISBRUCH:

1 Q. Dr. Sheridan, Mr. Barnes just asked you about the [REDACTED]
2 [REDACTED] sales between 2019 and 2021.

3 MS. WEISBRUCH: And can we actually put up
4 Dr. Sheridan's PDX-5-5?

5 Oh, I'm sorry. I have the wrong slide number. It
6 should be PDX-5-7.

7 BY MS. WEISBRUCH:

8 Q. Dr. Sheridan, why did sales [REDACTED]
9 between 2019 and 2021?

10 A. Well, one of the main things that was going on was the
11 start of the pandemic, which hit in March of 2020.

12 So I can't say exactly how much [REDACTED] is
13 due specifically to the pandemic, but that is a very major
14 factor that impacted sales.

15 Q. And Mr. Barnes also asked you about net sales.

16 Do you remember that?

17 A. Yes, that's correct.

18 Q. Is it uncommon for a new product to show [REDACTED]
19 [REDACTED] in its first three years on the market?

20 A. I think you may be referring to [REDACTED]

21 Q. Yes. Go ahead.

22 Sorry. I didn't mean to cut you off.

23 A. That's okay.

24 And no. In my experience, I think every commercial
25 success analysis that I've done right after launch, [REDACTED]

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[REDACTED]

[REDACTED] So that's very common.

MS. WEISBRUCH: No further questions. I pass the witness.

MR. BARNES: I don't have any further questions, Your Honor. But I have some exhibits we would like to admit. They are JTX-009-2, DX-151, PTX-380, and DX-527.

THE COURT: Any objections?

MS. WEISBRUCH: No objections, Your Honor.

THE COURT: They're admitted into evidence.

MR. BARNES: Thank you, Your Honor.

THE COURT: Are we finished with the doctor?

MS. WEISBRUCH: Yes, we are, Your Honor.

THE COURT: Thank you, Doctor.

MR. BARNES: Your Honor, I'm being told I missed a document. DX-156.

THE COURT: Any objection?

MS. WEISBRUCH: No objection.

THE COURT: Admitted into evidence.

MR. BARNES: Thank you, Your Honor.

(Exhibit Number JTX-009-2 is received in evidence.)

(Exhibit Number DX-151 is received in evidence.)

(Exhibit Number PTX-380 is received in evidence.)

(Exhibit Number DX-527 is received in evidence.)

(Exhibit Number DX-156 is received in evidence.)

1 MR. STEINDLER: With that, Your Honor, unless I'm
2 mistaken, Bausch rests its responsive case.

3 THE COURT: All right.

4 MR. STEINDLER: Thank you.

5 THE COURT: Does Padagis have anything further?

6 MS. CHEEK: Yes, Your Honor.

7 THE COURT: Let's go.

8 MS. CHEEK: Your Honor, Padagis calls our next
9 witness, Dr. Mickey Ferri.

10 MR. STEINDLER: And, for clarity, the record needs to
11 remain sealed while this -- this is their commercial success
12 expert, and the record will have to remain sealed while this
13 is being presented. Thank you.

14 MS. CHEEK: And if I could just quickly move exhibits
15 into evidence or I can do it after.

16 DX-135, DX-245, DX-288, DX-289, DX-290, DX-291,
17 DX-303, DX-304, DX-319, DX-350, DX-502, DX-503, DX-504,
18 DX-507, DX-508, and DX-509.

19 THE COURTROOM DEPUTY: Thank you.

20 MR. BRUNO: No objection, Your Honor.

21 THE COURT: They're admitted into evidence.

22 (Exhibit Number DX-135 is received in evidence.)

23 (Exhibit Number DX-245 is received in evidence.)

24 (Exhibit Number DX-288 is received in evidence.)

25 (Exhibit Number DX-289 is received in evidence.)

1 (Exhibit Number DX-290 is received in evidence.)

2 (Exhibit Number DX-291 is received in evidence.)

3 (Exhibit Number DX-303 is received in evidence.)

4 (Exhibit Number DX-304 is received in evidence.)

5 (Exhibit Number DX-319 is received in evidence.)

6 (Exhibit Number DX-350 is received in evidence.)

7 (Exhibit Number DX-502 is received in evidence.)

8 (Exhibit Number DX-503 is received in evidence.)

9 (Exhibit Number DX-504 is received in evidence.)

10 (Exhibit Number DX-507 is received in evidence.)

11 (Exhibit Number DX-508 is received in evidence.)

12 (Exhibit Number DX-509 is received in evidence.)

13 DR. MICKEY FERRI, DEFENSE WITNESS,

14 having been duly sworn, testifies as follows:

15 THE COURTROOM DEPUTY: Please state your full name
16 for the record.

17 THE WITNESS: My full name is Mickey Aron Ferri.

18 That's M-I-C-K-E-Y, A-R-O-N, F-E-R-R-I.

19 THE COURTROOM DEPUTY: Thank you.

20 MS. CHEEK: And, Your Honor, Padagis will be offering
21 Dr. Ferri as an expert in economics.

22 MR. BRUNO: No objection.

23 THE COURT: He's an expert.

24 MS. CHEEK: Thank you.

25 DIRECT EXAMINATION

1 BY MS. CHEEK:

2 Q. Good afternoon, Dr. Ferri.

3 A. Good afternoon.

4 Q. Dr. Ferri, can you briefly summarize the conclusions you
5 drew based on your analysis regarding the alleged commercial
6 success of Duobrii®?

7 A. Yes, I can.

8 And I'll break them out into four different
9 categories regarding Duobrii®'s purported profits.

10 [REDACTED] when
11 accounting for advertising and promotion and also selling
12 expenses, which indicates that while its been on the market,

13 [REDACTED]

14 Regarding sales, [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 When compared to Bausch's internal projections [REDACTED]

18 [REDACTED]

19 [REDACTED]

20 Compared to the competitors that Bausch recognizes
21 for Duobrii®, [REDACTED]

22 [REDACTED]

23 Regarding market share within the psoriasis market,

24 [REDACTED] It's actually less than

25 [REDACTED] over the time it's been on the market where we had

1 data available.

2 Dr. Sheridan offered some opinions regarding the
3 potential impact that COVID-19 may have had on Duobrii®'s
4 sales.

5 After my review of the data and of his opinions, I
6 view those as really speculative and not supported by the
7 actual data that we had available.

8 As a couple of examples, the dermatology market
9 overall grew in 2020 relative to 2019. And as you'll see
10 later on, [REDACTED]
11 [REDACTED] which further indicates that COVID-19 was not really the
12 driver of any lack of success.

13 Overall, taking all of this data into account, my
14 conclusion is that Duobrii® shows a lack of commercial
15 success.

16 Q. Dr. Ferri, let's first discuss your conclusions regarding
17 profits.

18 Please describe your analysis of Duobrii®'s profits.

19 A. So this is a chart for the three years of data that we
20 have available for when Duobrii® was on the market. The red
21 bar represents net sales each year, and it hovers right around
22 [REDACTED] each year. But to put those sales in context, you
23 have to also compare them to data on what Bausch was spending
24 to advertise and promote the product, [REDACTED]
25 [REDACTED], as well as what they were paying

1 salespeople to actually go out and sell the product.

2 And those numbers are represented by the light gray
3 bar.

4 Added together, advertising and promotion plus
5 selling expenses are represented each year by the taller black
6 bar. And what this indicates to me overall is that each year,
7 Duobrii® is making about [REDACTED]

8 (Reporter clarification.)

9 THE WITNESS: Bausch is making about [REDACTED] in
10 net sales while at the same time spending [REDACTED] and then
11 approximately [REDACTED] and then still over [REDACTED] just
12 on the advertising, promotion and selling. [REDACTED]

13 [REDACTED]

14 MS. CHEEK: And for the record, I'll just state that
15 this information on the slide is from DX-502, DX-503, DX-507,
16 DX-508 and DX-509.

17 BY MS. CHEEK:

18 Q. Dr. Ferri, given these facts, what does it show about
19 Duobrii®'s commercial success?

20 A. It's really showing a lack of commercial success for the
21 time period here.

22 Q. Let's move on to your opinions regarding sales.

23 Can you describe Duobrii®'s sales since its launch?

24 A. The red bars on the left represent the same data that
25 we've been looking at, and it's also the same data that

1 Dr. Sheridan presented.

2 What's important to recognize is that 2019 was a
3 truncated year. So Duobrii® was only on the market for about
4 eight months in that year. And when you annualize those
5 sales, it would have been on pace to make [REDACTED] in
6 2019. And that's really important to consider to put these
7 three years in context to each other. It actually -- when you
8 annualize the sales, Duobrii® [REDACTED] -- excuse me,
9 [REDACTED] from 2019 to 2020, and then it continued to
10 [REDACTED] in 2021.

11 Annualized sales [REDACTED]
12 [REDACTED]

13 MS. CHEEK: I'll just state for the record the
14 information on this slide came from DX-502 and DX-503.

15 BY MS. CHEEK:

16 Q. Dr. Ferri, you mentioned [REDACTED]

17 [REDACTED] Can you describe your analysis of those
18 projections?

19 A. Of course. So I was presented by Bausch with numerous
20 spreadsheets where they projected, as of where we are today,
21 what do we project or what do we expect Duobrii® to generate
22 during each year going forward.

23 And what this chart shows is three of those
24 projections in black and then in the dark gray and then in
25 light gray; and then the red represents the same actual sales

1 data when it same out.

2 So the first projection was from a document called a
3 2020 brand planning presentation in August 2019. At that
4 time -- already partway through 2019, when the product was
5 already on the market, [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 And then what happened was [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 But then the sales figures came in [REDACTED]

14 [REDACTED]. Projections were [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 Q. And, Dr. Ferri, how do these projections relate to the
19 commercial success analysis?

20 A. When companies make projections like they often do, I
21 view those as a really important metric because it really
22 represents what Bausch was expecting or anticipating or hoping
23 to make from the product. So the actual sales compared to the
24 projections is a really important metric for how Bausch would
25 evaluate the potential success of the product.

1 MS. CHEEK: I'll just state for the record these
2 projections come from DX-350 and DX-291.

3 BY MS. CHEEK:

4 Q. Dr. Ferri, you also mention that sales for Duobrii® are
5 small compared to other products.

6 How did you select products for comparison to
7 Duobrii®?

8 A. So as we've heard, there's a number of different products
9 that treat psoriasis and that treat plaque psoriasis, and
10 there were [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 So reading down this list, the products within this
16 category within this [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 [REDACTED]

20 [REDACTED]

21 [REDACTED]

22 MS. CHEEK: For the record, this document is DX-504.

23 BY MS. CHEEK:

24 Q. Dr. Ferri, did you evaluate any other information in
25 determining relevant competitors of Duobrii® to consider?

1 A. I did, yes. And I'll show more one example here.

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 Q. And, Dr. Ferri, you mentioned that some of these products
16 are injectables.

17 Was there any relevant discussion of injectables in
18 Bausch's documents?

19 A. There were.

20 There's another example here on the lower left-hand
21 corner from Exhibit Number DX-303.

22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

25 [REDACTED]

1 MS. CHEEK: And I'll just note for the record the
2 other slides on this that you discussed is from DX-288.

3 BY MS. CHEEK:

4 Q. Dr. Ferri, can you describe your analysis of Duobrii®
5 sales compared to its competitors?

6 A. I can.

7 THE WITNESS: If you turn to the next slide.

8 So what this chart represents is prescriptions over
9 time, and I'll recognize that 2019, the prescriptions only
10 begin partway through the year when Duobrii® launched. 2020
11 does represent a full year, and then 2021 represents also just
12 part of a year, it's about half of the year, and it's the same
13 data that Dr. Sheridan had available, as far as I understand.

14 The red represents Duobrii®'s number of -- total
15 number of prescriptions during each of these time periods.
16 And then Enstilar® and Taclonex®, as well as Otezla®, are the
17 next three gray bars. Notably, [REDACTED]
18 [REDACTED] including in 2021, Duobrii®'s third year on the
19 market. And Otezla® is just significantly [REDACTED]
20 [REDACTED] the other products on this list in terms of units sold.

21 Continuing down the list is Cosentyx®, Taltz®,
22 Tremfya®, Skyrizi® and Ilumya®. And these would all be the
23 injectables that were highlighted as competitive on Bausch's
24 previous slide. And what's interesting here, especially in
25 2021, is [REDACTED]

1 [REDACTED] for all of these
2 injectables except for Ilumya®, and that's especially
3 important considering the injectables' higher prices.

4 BY MS. CHEEK:

5 Q. Dr. Ferri, how does Duobrii®'s price compare to some of
6 these competitors?

7 A. So generally compared to these specific ones, Duobrii® is
8 the [REDACTED] And you can see that on the table on
9 the right where I had the 2021 WAC highlighted. Duobrii® is
10 just [REDACTED] while Enstilar® and Taclonex®, the branded
11 combos, are each in the [REDACTED] range, and Otezla® is [REDACTED]
12 [REDACTED] It's significantly higher priced, and it's
13 significantly outperforming in terms of number of
14 prescriptions.

15 Q. Can you give an example of why it's important to consider
16 pricing in addition to the number of units sold?

17 A. I can.

18 So especially in 2021 -- I'll give this example --
19 Duobrii®'s number of units was [REDACTED] and Skyrizi®, which is the
20 second to the right, had [REDACTED] And that's an
21 injectable, as I've mentioned before.

22 The number of units is comparable so it might only
23 look like Skyrizi® is slightly overperforming [REDACTED]
24 [REDACTED] but Skyrizi® is significantly higher priced, and
25 Skyrizi®'s reported 2021 net sales were actually \$2.5 billion

1 compared to Duobrii®'s just [REDACTED] So in that context,
2 Skyrizi® is generating [REDACTED] that Duobrii®
3 generated during that time period.

4 MS. CHEEK: And I'll state for the record that this
5 information comes from DX-304, DX-319, DX-289 and DX-290.

6 BY MS. CHEEK:

7 Q. Dr. Ferri, let's turn to your opinions regarding market
8 share.

9 Can you describe the results of your analysis?

10 A. I can.

11 So based on the TRx data, these are generally the
12 same data that I was using in the previous slide, just
13 considering now all psoriasis treatments in the left pie
14 graph. Duobrii®'s share in this market is just [REDACTED]
15 And when we look at the right chart, where I remove
16 injectables and I also remove the systemic orals and the
17 vitamin D, so now we're just down to Duobrii®, Bryhali®, the
18 branded combos and all other topicals, even within just the
19 topicals' psoriasis treatment market, Duobrii®'s share is [REDACTED]
20 [REDACTED]

21 Q. Is this market share typical of a commercially successful
22 product?

23 A. I wouldn't say typical. It's possible for a product to
24 have a [REDACTED]

25 [REDACTED]

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So taken all together, it really is looking like a lack of commercial success.

MS. CHEEK: And I'll state for the record the information on this slide comes from DX-304.

BY MS. CHEEK:

Q. Dr. Ferri, let's turn now to your analysis of COVID-19's impact on Duobrii®.

When Dr. Sheridan was testifying, he said that he cannot say exactly how much of Duobrii®'s [REDACTED] is due specifically to the pandemic.

Would you agree with that?

A. I would agree with that.

Q. And was there any other information that you considered with respect to the COVID-19 pandemic and its impact on Duobrii®?

A. I did, yes.

THE WITNESS: If you could turn back to the previous slide.

This is a Fortune Business Insights' article from 2002 about the psoriasis treatment market size, share and COVID-19 impact analysis. And notably, this article is

1 written in 2022, so you had the 2020 and 2021 data available.

2 And at this point, even then the article was
3 indicating that, highlighted in yellow, the total -- the
4 global COVID-19 pandemic has been unprecedented and staggering
5 with psoriasis treatment experiencing higher than anticipated
6 demand across all regions compared to pre-pandemic levels.

7 Based on the analysis in this article, the global
8 market -- and that would be for psoriasis -- exhibited a
9 higher growth of 11.1 percent in 2020 as compared to 2021.

10 So this market is indicating that overall, the
11 psoriasis market was growing even during 2020.

12 MS. CHEEK: For the record, this article is DX-135.

13 THE WITNESS: In the second excerpt here, which also
14 jumped out to me during the analysis, was that telemedicine
15 services played a major part in the market growth even though
16 hospital visits were restricted. With telemedicine services,
17 the psoriasis management showed higher success rates than
18 normal care.

19 BY MS. CHEEK:

20 Q. Dr. Ferri, was there anything else you considered in
21 evaluating COVID-19's impact on Duobrii®'s sales?

22 A. Yes, there were. And I'll point to another here, which
23 is the same chart I showed earlier.

24 [REDACTED]
25 [REDACTED]

1 [REDACTED] indicates to me that
2 any -- that Duobrii®'s lack of success would have been due
3 other factors than COVID.

4 Q. Dr. Ferri, can you summarize your findings regarding the
5 alleged commercial success of Duobrii®?

6 A. I can, yes. This is the same summary as before and I'll
7 restate it for the record.

8 In terms of Duobrii®'s profit, [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]

17 Within the market, Duobrii® has a [REDACTED] in the
18 psoriasis market.

19 And then regarding COVID-19, any potential impact of
20 COVID-19 strikes me as speculative, especially in the context
21 of the dermatology market growing overall in 2020 and in terms
22 of Duobrii®'s sales [REDACTED]

23 So overall, my conclusion is that Duobrii® shows a
24 lack of commercial success.

25 Q. And, Dr. Ferri, having looked at the sales of Duobrii®

1 and the expenses incurred since its launch, [REDACTED]
2 [REDACTED]
3 [REDACTED] [REDACTED]
4 MS. CHEEK: Thank you, Dr. Ferri. I have no further
5 questions.
6 I pass the witness.
7 THE COURT: Please proceed with cross.
8 MR. BRUNO: Your Honor, I would like to take a break,
9 our afternoon break now, if we can.
10 THE COURT: I'm sorry?
11 MR. BRUNO: If we can, if now's a good time, we'd
12 like to take the afternoon break.
13 THE COURT: We'll take our afternoon break.
14 How long do you think your cross is going to be?
15 MR. BRUNO: Somewhere between, I'd say, 10 to
16 15 minutes.
17 THE COURT: And are there any witnesses after this
18 witness?
19 MR. BRUNO: Not from Bausch, Your Honor.
20 MR. ZIMMERMAN: Your Honor, we have one witness by
21 deposition whose testimony is four or five minutes.
22 THE COURT: We'll take a 10-minute break.
23 THE COURTROOM DEPUTY: All rise.
24 (Recess taken from 3:27 p.m. to 3:39 p.m.)
25 THE COURTROOM DEPUTY: All rise.

1 THE COURT: Be seated. We only do that to make sure
2 you get some exercise.

3 THE COURTROOM DEPUTY: The courtroom is sealed.

4 MR. BRUNO: May I proceed, Your Honor?

5 THE COURT: Proceed.

6 MR. BRUNO: Thank you.

7 CROSS-EXAMINATION

8 BY MR. BRUNO:

9 Q. Dr. Ferri, good afternoon.

10 A. Good afternoon.

11 Q. You may remember we met the first time during your
12 deposition.

13 A. I do.

14 Q. Now, the goal of a pharmaceutical company is to make
15 money over the life of a product, correct?

16 A. Not necessarily.

17 Q. So you think the goal of a pharmaceutical company is to
18 lose money over the life of a product.

19 A. Yeah, I'd say that's definitely not true.

20 Q. Okay. So -- but you won't agree with me that the goal of
21 a pharmaceutical company is to make money over the life span
22 of a product that it commercializes?

23 A. I would say that could be one goal, and it could also be
24 important to make money over a particular time period.

25 Q. A generic company commercializing a product wants to make

1 money too, right?

2 A. Generally speaking, yes.

3 Q. A generic company wouldn't want to commercialize a
4 product that it didn't think it was going to make money on,
5 right?

6 A. I think in most cases that would be fair.

7 Q. Now, I would like to talk to you about -- actually,
8 before I ask that next question.

9 Padagis is trying, in this case, to commercialize a
10 generic version of Duobrii®, right?

11 A. I understand that's true.

12 Q. Now, I would like to talk about your understanding of
13 what it means for a product to be commercially successful.

14 You agree that a product is commercially successful
15 so long as it captures significant sales in a relevant market,
16 right?

17 A. That could be one factor that you would look at.

18 Q. There's no specific threshold of sales, right?

19 A. Not that I'm aware of.

20 Q. But you think there are factors other than whether a
21 product captures significant sales in a relevant market that
22 determine commercial success?

23 A. I would say yes, and both Dr. Sheridan and I evaluated
24 other factors.

25 Q. But you agree there's no specific threshold of sales

1 required.

2 A. Yes, as far as I'm aware.

3 Q. No specific market share required for commercial success,
4 right?

5 A. As far as I'm aware.

6 Q. Certainly a product doesn't have to achieve equal market
7 share with its competitors. Isn't that true?

8 A. I'd agree that's true.

9 Q. In fact, even a product with the lowest market share can
10 still be commercially successful, correct?

11 A. In some cases, correct.

12 Q. And you agree that a product obtaining a 1 percent market
13 share could represent commercial success, correct?

14 A. In some cases, that could be correct.

15 Q. In fact, don't you agree that a product does not even
16 have to be profitable to be commercially successful?

17 A. I would say correct, and that's why you look at many
18 factors and evaluate it in the context of lots of factors.

19 Q. But you agree that a product doesn't have to be
20 commercially successful -- to be commercially successful. I'm
21 sorry.

22 A product does not have to be profitable to be
23 commercially successful, correct?

24 A. Being more profitable definitely helps, but I agree it
25 does not have to be.

1 Q. It's your view that the relevant market is every
2 psoriasis treatment under the sun. Isn't that true?

3 A. No, I disagree with that.

4 Q. You're aware that one market that Bausch tracks is the
5 branded combo plus Otezla® market, correct?

6 A. I agree with that, correct.

7 Q. You're aware that one market Bausch tracks is the branded
8 combo market?

9 A. I agree with that.

10 Q. Besides these two markets, you include biologics in your
11 market analysis, right?

12 A. In some of my market analyses, yes, those are included.

13 Q. You include all generic products to treat psoriasis in
14 your definition of the market?

15 A. In some of my market definitions, yes.

16 Q. You include UV therapy in your definition of the
17 psoriasis, ultraviolet?

18 A. In some of them, I believe that's included.

19 Q. But you agree that Bausch has more direct experience with
20 evaluating Duobrii® than anyone else would, right?

21 A. I think generally they have a significant amount of
22 experience, yes.

23 Q. Bausch has direct experience with marketing Duobrii®,
24 right?

25 A. Yes, I agree with that.

1 Q. Bausch has direct experience with evaluating the markets
2 that Bausch engages in, right?

3 A. Yes, I agree with that.

4 Q. Now, I'd like to turn your attention to the market that
5 existed before Duobrii® launched.

6 It's your position that the '847 patent
7 disincentivized companies from developing a product like
8 Duobrii®, right?

9 A. That was not part of my testimony today.

10 Q. Now, let's talk about what happened when Duobrii®
11 launched.

12 When Duobrii® hit the market, it was a product on the
13 rise, wasn't it?

14 A. I wouldn't classify it that way, necessarily.

15 Q. By the fourth quarter of 2019, Duobrii® had garnered a
16 [REDACTED] market share in the branded combo products market,
17 correct?

18 A. I'm not sure if that's exactly right, but if you could
19 point me to the number, I could verify it for you.

20 Q. Absolutely.

21 MR. BRUNO: Let's pull up Figure 11 from your report.

22 THE WITNESS: It's going to be way down.

23 BY MR. BRUNO:

24 Q. What's shown on the screen right now is Figure 11 from
25 your report, correct?

1 A. That looks correct, yes.

2 Q. I want to focus your attention to the fourth quarter of
3 2019.

4 Do you see that chart on the screen?

5 A. I do, yes.

6 Q. Duobrii® garnered a [REDACTED] market share in the
7 branded combos market by the fourth quarter of 2019, right?

8 A. Yes, that's what the chart says.

9 Q. And to be clear, that's the [REDACTED] of the
10 three-product market, right?

11 A. During that quarter, yes, it is.

12 Q. Now, Otezla® was by and far away the most prescribed
13 treatment in the branded plus Otezla® market since Duobrii®'s
14 launch, correct?

15 A. Among those four products, yes, Otezla® has been the
16 highest prescribed.

17 Q. But even if you account for Otezla®, Duobrii® still had a
18 [REDACTED] market share in the fourth quarter of 2019, right?

19 A. If you can point me to the figure that has the
20 [REDACTED], I'd appreciate it.

21 Q. Sure.

22 MR. BRUNO: Let's blow up Figure 12 from your report.
23 I'll ask the question again.

24 BY MR. BRUNO:

25 Q. Even if you account for Otezla®, Duobrii® still had a

1 [REDACTED] market share in the fourth quarter of 2019,
2 correct?

3 A. Yes, that's correct.

4 Q. And that's the [REDACTED] for a product in the
5 branded combo plus Otezla® market, right?

6 A. During that quarter, yes, it is.

7 MR. BRUNO: Now let's pull up DDX-416.

8 BY MR. BRUNO:

9 Q. This is a slide you presented during your direct
10 examination.

11 A. Yes.

12 Q. And it's your opinion that COVID did not
13 disproportionately affect Duobrii® sales, correct?

14 A. I think you'd have to be specific about a time period or
15 what you mean by "disproportionately affect."

16 Q. Do you offer an opinion that Duobrii® was
17 disproportionally affected by COVID?

18 A. I don't recall one way or the other over specific months
19 it may have been, but over the long-term, in terms of total
20 prescriptions, which is what I view as what is more meaningful
21 than one particular point in time, that wouldn't be -- that
22 would not be my opinion.

23 Q. I don't think that answers my question.

24 Do you have an opinion that COVID disproportionately
25 affected Duobrii®'s sales?

1 A. Not that I recall.

2 Q. Would you agree with me that Duobrii® was
3 disproportionately affected by COVID?

4 A. Not necessarily.

5 Q. Would you disagree with me that Duobrii® was
6 disproportionately affected by COVID?

7 A. You would have to be specific about a time period in --
8 something specific.

9 Q. Okay. The article that you're showing on this slide is
10 discussing global COVID-19 pandemic as well as global
11 psoriasis market size, right?

12 A. The specific highlighted sentence, yes, discusses the
13 global COVID-19 pandemic and the global market.

14 Q. So this article isn't specific at all to the U.S. market,
15 right?

16 A. If I recall, there were other parts of the article that
17 did discuss the U.S. specifically.

18 Q. You didn't highlight to the Court during your direct
19 examination anything relating specifically to the U.S. market,
20 correct?

21 A. That looks correct, yes.

22 Q. And isn't it true that third-party analyses around the
23 time of COVID identified Duobrii® as being disproportionately
24 impacted by COVID?

25 A. I do recall there was some analyses that did indicate

1 that at specific points in time.

2 Q. But you're not offering an opinion on whether COVID
3 was -- actually affected Duobrii®'s sales, right?

4 A. My opinion is more that the overall impact that COVID may
5 have had on Duobrii®'s sales would be speculative and has not
6 been quantified.

7 MR. BRUNO: Let's turn to PTX-75 at page BAU01200034.

8 BY MR. BRUNO:

9 Q. This article is a summary report from a third-party
10 analyst about Bausch Health, correct?

11 A. I would say this is a summary -- correct, among other
12 things. Because this report is very long, and it addresses
13 things other than just Bausch Health.

14 Q. Okay. And this is a report dated in April 2020?

15 A. It looks like it's April 6, 2020, yes.

16 MR. BRUNO: Okay. Now let's focus in on the third
17 bullet under "Earnings." The one that starts "for recent
18 launches."

19 BY MR. BRUNO:

20 Q. Do you see that bullet?

21 A. I do, yes.

22 Q. Okay. And this bullet refers to Duobrii® as a recent
23 launch, correct?

24 A. It looks like Duobrii® is listed among other products,
25 including Bryhali®, Siliq, Lumify and Trulance.

1 Q. And this report is stating that the greatest impact from
2 COVID-19 is that dermatologists are no longer seeing patients,
3 right?

4 A. Part of the highlighted sentence indicates that, it looks
5 like it, yes.

6 Q. Okay. And that was hindering new launches in psoriasis,
7 correct?

8 A. Can you repeat the question? I didn't understand the
9 question.

10 Q. Absolutely. Isn't this article stating that COVID-19 was
11 hindering new launches in psoriasis?

12 A. The highlighted sentence doesn't include COVID-19,
13 although it does include Bryhali® and Duobrii®. And I
14 understand parts of this page relate to COVID-19.

15 Q. Okay. So this analysis is stating that COVID-19 was
16 disproportionately impacting new launches in psoriasis,
17 including the launch of Duobrii®, right?

18 A. I agree one could interpret the article in that way.

19 Q. By September 2020, Duobrii® was again -- was obtaining
20 [REDACTED] than Enstilar®, wasn't it?

21 A. It might be helpful to pull the figure up again.

22 MR. BRUNO: Let's turn to Figure 6 of Dr. Ferri's
23 report.

24 BY MR. BRUNO:

25 Q. And Figure 6 reports new prescription data, correct?

1 A. Yes. Figure 6 would be the NBRx, which would be the
2 new-to-brand prescription data for Duobrii®, Otezla® and
3 Enstilar® in this particular figure.

4 Q. And in this figure, you're drawing the baseline as COVID,
5 right? The beginning of COVID?

6 A. The baseline, I believe, was defined to be the week of
7 March 13, 2020. And that would have been the baseline before
8 sales started -- before the new-to-brand started to
9 significantly drop, for example, for Duobrii®.

10 Q. And you picked that as the baseline because that was
11 when, in your analysis, COVID had started to have an effect in
12 the United States?

13 A. Yes, approximately.

14 Q. Okay. And at the time that COVID first started, Duobrii®
15 was receiving [REDACTED] than Otezla® and
16 Enstilar®, correct?

17 A. At that time, yes, it was.

18 Q. And then COVID happens through 2020, right?

19 A. Generally, yes.

20 Q. Okay. And in September 2020, Duobrii® is [REDACTED]
21 [REDACTED] against Otezla® and
22 Enstilar®.

23 Isn't that true?

24 A. It's true that the red line fell by the most and then
25 recovered by a bit to be, by the end of that time period,

1 towards the top. And at the same time, it has recovered the
2 least to its previous baseline level.

3 Q. Yes or no, Duobrii® was obtaining the [REDACTED]
4 [REDACTED] as of September 11, 2020?

5 A. Compared to these two other drugs, yes.

6 MR. BRUNO: Let's put Figure 11 of your report back
7 up.

8 BY MR. BRUNO:

9 Q. Isn't it true that by the first quarter of 2021, Duobrii®
10 had recaptured [REDACTED] of the branded combos market share?

11 A. I don't know if I'd use the word "recaptured." I can
12 agree it's true that during that specific quarter, it
13 registered a [REDACTED] market share.

14 Q. So you agree that in a three-product market, Duobrii® had
15 [REDACTED] market share as of the second quarter of 2021,
16 right?

17 A. During that one quarter, yes, I agree.

18 Q. Now, it's your position that Duobrii® did not achieve
19 significant market sales, right?

20 A. Compared to other meaningful metrics, that's my opinion,
21 yes.

22 Q. Yes or no, is it your opinion that Duobrii® did not
23 achieve significant market sales?

24 A. Yes.

25 Q. Okay. Duobrii® obtained [REDACTED] prescriptions in the

1 first two years on the market, correct?

2 A. I believe that's correct, yes.

3 Q. Duobrii® achieved gross profits of [REDACTED] over three
4 years, correct?

5 A. I believe that's correct, yes.

6 Q. [REDACTED] in
7 its first two and a half years on the market, right?

8 A. Can you just repeat it? I just missed the number.

9 Q. Duobrii® achieved a total net sales of [REDACTED] in
10 its first two and a half years on the market?

11 A. I can agree with that, yes.

12 MR. BRUNO: Thank you. No further questions.

13 THE COURT: Redirect.

14 MS. CHEEK: Very brief redirect, Your Honor.

15 REDIRECT EXAMINATION

16 BY MS. CHEEK:

17 Q. Dr. Ferri, counsel was asking you about some NBRx data
18 regarding products in the marketplace.

19 Can you explain the difference between TRx and NBRx
20 data?

21 A. Yes. So TRx represents the total amount of prescriptions
22 that are being prescribed. And those data were on a weekly
23 basis, so that would be total number of prescriptions during
24 the week. NBRx is only the new-to-brand prescriptions during
25 that week.

1 And if you look at the difference in the magnitudes,
2 the NBRx numbers in new prescriptions are significantly lower
3 than total prescriptions. They represent a very small part of
4 what's happening overall.

5 Q. And why did you focus on TRx data for your analysis today
6 rather than NBRx data?

7 A. Well, one reason, among other ones, but one reason is
8 that the TRx does represent the entire market. So that would
9 be the most indicative of how the overall market is doing.

10 Q. And, Dr. Ferri, do you recall counsel suggesting that
11 Bausch has the most information regarding Duobrii®'s
12 performance in the marketplace?

13 A. I do, yes.

14 MS. CHEEK: And can we turn to your Slide DDX-4.9.

15 BY MS. CHEEK:

16 Q. So despite Bausch having the most information on Duobrii®
17 in the marketplace, [REDACTED]

18 [REDACTED]

19 A. Well, what I'd say is [REDACTED]

20 [REDACTED]

21 [REDACTED]

22 [REDACTED]

23 MS. CHEEK: No further questions.

24 THE COURT: Any further recross?

25 MR. BRUNO: Your Honor, a very brief recross.

1 RE CROSS-EXAMINATION

2 BY MR. BRUNO:

3 Q. When Bausch made its projections in 2019, could it have
4 predicted COVID?

5 A. For the 2019 ones, I wouldn't think it would be fair that
6 it could have predicted COVID.

7 MR. BRUNO: No further questions, Your Honor.

8 THE COURT: Anything further?

9 MS. CHEEK: Very briefly, Your Honor.

10 FURTHER REDIRECT EXAMINATION

11 MS. CHEEK: Can we go back to DDX-4.9?

12 BY MS. CHEEK:

13 Q. Dr. Ferri, what's your understanding of when [REDACTED]

14 [REDACTED]

15 A. My understanding is the [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 [REDACTED]

20 [REDACTED]

21 [REDACTED]

22 Q. And why do you make that presumption?

23 A. I make that presumption because [REDACTED]

24 [REDACTED]

25 [REDACTED]

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MS. CHEEK: Thank you. No further questions, Your Honor.

THE COURT: Anything further?

MR. BRUNO: No re-recross, Your Honor.

THE COURT: Thank you.

Doctor, thank you very much. You're excused.

THE WITNESS: Thank you, Your Honor.

(Witness is excused.)

MR. BRUNO: At this time, though, we would like to move in Exhibit PTX-75.

MS. CHEEK: No objection.

(Exhibit Number PTX-75 is received in evidence.)

MS. CHEEK: We're very close to the end, Your Honor. Padagis has one further witness by deposition. It's just about five minutes. The testimony is from Arturo Angel, Bausch's 30(b)(6) witness, and a named inventor on the halobetasol patent.

THE COURT: Let's proceed.

THE COURTROOM DEPUTY: The courtroom is going to be opened.

*** SEALED PORTION CONCLUDED ***

THE COURT: Folks, to the extent that you assert that

1 particular exhibits or particular portions of the testimony
2 should remain sealed, I'm going to require you within one week
3 to submit to me the designations and the reason that you are
4 proffering to have that particular information sealed.

5 So, for example, the testimony of our two economists
6 doesn't have to be fully sealed and there may be exhibits
7 which, in fact, show specific sales, projections, sales
8 information and so on, and it's certain rational for me to
9 seal them.

10 But their general opinions, for example, to the
11 extent they are disclosing non-confidential information should
12 not be sealed.

13 MR. STEINDLER: Entirely understood, Your Honor.

14 THE COURT: Okay.

15 MR. STEINDLER: Yes.

16 MR. ZIMMERMAN: May we proceed, Your Honor?

17 (Video played.)

18 ARTURO ANGEL, DEFENSE WITNESS,
19 having been duly sworn, testifies
20 through his videotaped deposition as follows:

21 DIRECT EXAMINATION

22 BY MS. PITZEL CRUZ:

23 "QUESTION: Good morning, Mr. Angel. My name is
24 Carol Pitzel Cruz. I'll be asking you questions throughout
25 today. If you could please state your name for the record.

1 "ANSWER: Good morning, Carol. My name is Arturo
2 Javier Angel.

3 "QUESTION: Thank you. And you -- are you currently
4 employed?

5 "ANSWER: Yes, I'm currently employed.

6 "QUESTION: Okay. And by whom?

7 "ANSWER: I'm currently employed by Bausch Health
8 Pharma.

9 "QUESTION: And what is your current title?

10 "ANSWER: My current title is that of executive
11 director.

12 "QUESTION: And you mention "preformulation data,"
13 what type of data would that encompass?

14 "ANSWER: We -- we typically do literature search
15 on -- on the compounds of interest. We assess the solubility
16 properties of compounds of interest in different ingredients,
17 their physical and chemical integrity in those ingredients.

18 "That's generally the essence of what we call
19 preformulation.

20 "QUESTION: Okay. But it would be routine at the
21 beginning of a development product to test the solubility of
22 the active ingredients?

23 "ANSWER: It would be routine to us.

24 "QUESTION: And do you know why you would want to
25 minimize the systemic absorption of corticosteroid?

1 "ANSWER: It -- it has its side effects.

2 "QUESTION: Okay. So if you reduce the systemic
3 absorption, you can potentially reduce the side effects?

4 "ANSWER: Correct.

5 "QUESTION: Okay. And I think the low irritation
6 potential from tazarotene you referenced earlier, that was
7 Gordon's idea, but can you explain to me what the lower
8 irritation potential from tazarotene is referencing?

9 "ANSWER: So in general, retinoids are considered to
10 induce irritation. So if you were to combine a compound that
11 is known to cause an irritation with a compound that is known
12 to mitigate that, that that would be beneficial.

13 "QUESTION: And if we look at diisopropyl adipate,
14 why was diisopropyl adipate chosen for solubility testing of
15 halobetasol propionate?

16 "ANSWER: For the same reason that we selected the
17 diethyl sebacate: lipophilic nature.

18 "QUESTION: Okay. And if we look at isopropyl
19 myristate, why was isopropyl myristate chosen for solubility
20 testing of halobetasol propionate?

21 "ANSWER: Lipophilic in nature as well.

22 "QUESTION: So it was based on confirmatory visual
23 observations and the comparable chemical results, diethyl
24 sebacate and isopropyl myristate were identified as lead
25 ingredients/solvent systems.

1 "Do you see that?

2 "ANSWER: I see that.

3 "QUESTION: And it describes their history of use in
4 the pharmaceutical industry, coupled with their solubility,
5 and hydrophobic properties provided several options in
6 developing emulsion systems in which both drug substances
7 would be present in their soluble form.

8 "Do you see that?

9 "ANSWER: I see that.

10 "QUESTION: And what is -- what is meant by their
11 history of use in the pharmaceutical industry?

12 "ANSWER: The -- the -- there is a document that the
13 FDA releases. It's called 'Inactive Ingredient Guidance.'
14 There they depict the use of ingredient in pharmaceutical
15 products, and there they use -- and -- and the levels used of
16 it.

17 "QUESTION: So it was decided to reduce the
18 tazarotene concentration from 0.09 percent to 0.045 percent
19 at -- at some point during the development of the Duobrii®
20 product, correct?

21 "ANSWER: Yes.

22 "QUESTION: Okay. And do you have any reason to
23 disagree with the statement here that: The concentration of
24 tazarotene was reduced to 0.045 percent, with the objective of
25 further lowering the prototype's irritation potential?

1 "ANSWER: I would agree with that.

2 "QUESTION: And is it fair to say that the only
3 difference between IDP-122 and IDP-118 is that IDP-118 adds in
4 0.045 percent tazarotene to the formulation?

5 "ANSWER: The differences between the formula under
6 IDP-118 versus IDP-122 is the presence or absence of
7 tazarotene."

8 (Video ends.)

9 MS. CHEEK: Just one document to move into evidence,
10 JTX-11-9 that was referenced in the deposition.

11 MR. STEINDLER: No objection.

12 THE COURT: Admitted into evidence.

13 (Exhibit Number JTX-11-9 is received in evidence.)

14 MS. CHEEK: And with that, defendants rest.

15 THE COURT: All right.

16 MR. STEINDLER: I think with that the case is
17 submitted, and I'm sure my colleague, Mr. Zimmerman, joins me
18 in wanting to thank publicly the Court, the court personnel
19 for your time and attention in this case. I know people
20 sometimes take that for granted, but none of us do.

21 MR. ZIMMERMAN: We appreciate it.

22 THE COURT: And I want to thank you, folks, and I
23 also want to thank both sides for giving their more junior
24 attorneys the opportunity to make presentations here and to,
25 in fact, hone their courtroom skills.

1 So congratulations to you and your associates.

2 MR. ZIMMERMAN: Thank you.

3 THE COURT: And we've agreed upon a briefing
4 schedule, correct?

5 MR. ZIMMERMAN: Yes, we have.

6 MR. STEINDLER: We have a few internal things to work
7 out, but we have agreed on when we're going to get it to you,
8 which is the --

9 THE COURT: Great.

10 MR. ZIMMERMAN: Thank you.

11 THE COURT: Thank you. It's been a pleasure. Have a
12 wonderful weekend. Hopefully it will be as nice tomorrow as
13 it is today.

14 MR. STEINDLER: Thank you, Your Honor.

15 MR. ZIMMERMAN: Thank you, Your Honor.

16 THE COURT: Have a good evening, everyone. Thank
17 you.

18 THE COURTROOM DEPUTY: All rise.

19 Counsel should submit the updated exhibit list in
20 addition to the sealed document.

21 (Proceedings concluded at 4:10 p.m.)

22 FEDERAL OFFICIAL COURT REPORTER'S CERTIFICATE

23 I certify that the foregoing is a correct transcript
24 from the record of proceedings in the above-entitled matter.

25 /S/ Mary Jo Monteleone, RMR, CCR, CRCR
Official Court Reporter

10/07/2022
Date

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