

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 I)

Pages 1 - 268

10 Frank Lautenberg Post Office & U.S. Courthouse
11 2 Federal Square
12 Newark, New Jersey 07102
13 Tuesday, October 4, 2022
14 Commencing at 9:23 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.

United States District Court
District of New Jersey

A P P E A R A N C E S:

GIBBONS P.C.
 BY: WILLIAM P. DENI JR., ESQUIRE
 J. BRUGH LOWER, ESQUIRE (remotely)
 One Gateway Center
 Newark, New Jersey 07102-5310
 Counsel for the Plaintiff

MCDERMOTT WILL & EMERY LLP
 BY: THOMAS P. STEINDLER, ESQUIRE
 CHRISTOPHER M. BRUNO, ESQUIRE
 APRIL E. WEISBRUCH, ESQUIRE
 The McDermott Building
 500 North Capitol Street, NW
 Washington, DC 20001-1531
 Counsel for the Plaintiff

FOX ROTHSCHILD LLP
 BY: KAREN A. CONFOY, ESQUIRE
 997 Lenox Drive
 Lawrenceville, New Jersey 08648-2311
 Counsel for the Defendant

KNOBBE MARTENS
 BY: CAROL PITZEL CRUZ, ESQUIRE
 925 4th Ave #2500
 Seattle, Washington 98104
 Counsel for the Defendant

KNOBBE MARTENS
 BY: WILLIAM ZIMMERMAN, ESQUIRE
 ANDREA CHEEK, ESQUIRE
 1717 Pennsylvania Avenue N.W.
 Washington, DC 20006
 Counsel for the Defendant

KNOBBE MARTENS
 BY: BRIAN C. BARNES, ESQUIRE (remotely)
 2040 Main Street
 Irvine, California 92614
 Counsel for the Defendant

A L S O P R E S E N T:

THOMAS SAVITSKY, Legal Director, Bausch Health Companies
 LANDON CLARK, Vice President Legal Affairs, Padagis, LLC

INDEX

OPENING STATEMENTS

BY MS. WEISBRUCH	9
BY MS. PITZEL CRUZ	19

	<u>DIRECT</u>	<u>CROSS</u>	<u>REDIRECT</u>	<u>RECROSS</u>
--	---------------	--------------	-----------------	----------------

WITNESSES FOR THE PLAINTIFFS

DR. LINDA STEIN GOLD		48		
DR. RADHAKRISHNAN PILLAI	56	103	143	

	<u>DIRECT</u>	<u>CROSS</u>	<u>REDIRECT</u>	<u>RECROSS</u>
--	---------------	--------------	-----------------	----------------

WITNESSES FOR THE DEFENSE:

DR. ROBERT STERN	149	195		
------------------	-----	-----	--	--

E X H I B I T S

<u>NO.</u>	<u>MARKED</u>	<u>RECEIVED</u>
------------	---------------	-----------------

JTX-1		33
JTX-2		33
JTX-3		33
JTX-4		33
JTX-5		33
JTX-6		33
JTX-7		33
JTX-8		33
JTX-12		33
JTX-12-9		33
JTX-12-10		33
JTX-19		33
JTX-20		33
JTX-21		33

1	PTX-37	33
	PTX-67	33
2	PTX-243	33
	PTX-301	33
3	PTX-341	33
	PTX-358	34
4	PTX-395	34
	JTX-009-3	146
5	JTX-011-3	146
	JTX-011-6	146
6	DX-64	146
	JTX-009-5	148
7	DX-009	148
	DX-142	148
8	DX-184	148
	DX-196	148
9	DX-201	148
	DX-203	148
10	DX-208	148
	DX-140	148
11	DX-141	148
	DX-10	148
12	DX-61	149
	DX-98	149
13	DX-104	149
	DX-443	149
14	DX-444	149
	DX-445	149
15		
16		
17		
18		
19		
20		
21		
22		
23		
24		
25		

United States District Court
District of New Jersey

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
10:56:55AM 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.

10:57:40AM 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
10:58:50AM 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
10:59:28AM 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
11:00:31AM 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
11:01:38AM 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
11:02:45AM 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,
11:03:45AM 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
11:04:54AM 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
11:05:52AM 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?

11:06:48AM 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
11:07:38AM 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
11:08:39AM 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
11:09:23AM 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.

11:10:22AM 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
11:11:02AM 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?

11:12:16AM 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.

11:12:50AM 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.

11:14:05AM 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
11:14:58AM 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
11:16:10AM 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?

11:16:40AM 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.

11:17:50AM 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
11:18:26AM 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
11:19:35AM 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
11:20:31AM 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:

11:21:31AM 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,
11:22:28AM 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
11:23:35AM 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.

11:24:19AM 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?

11:25:18AM 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
11:26:05AM 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
11:27:17AM 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
11:28:07AM 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?

11:28:56AM

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.

11:29:42AM

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.

11:30:49AM 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?

11:31:25AM 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

11:32:52AM 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.

11:33:27AM 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.

11:34:30AM 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?

11:35:04AM 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
11:36:13AM 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.

11:36:58AM 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
11:38:10AM 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?

11:38:56AM 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.

11:40:10AM 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.

11:40:42AM 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
11:42:00AM 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
11:42:52AM 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
11:44:10AM 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
11:44:50AM 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
11:45:50AM 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.

11:46:36AM 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.

11:47:33AM 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
11:48:25AM 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?

11:49:17AM 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?

11:50:01AM 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
11:51:02AM 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
11:51:48AM 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.

11:52:47AM 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
11:53:23AM 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.

11:54:30AM 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
11:55:16AM 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
11:56:19AM 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.

11:57:10AM 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
11:58:13AM 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
11:59:10AM 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?

12:00:15PM

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 --
12:00:50PM 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
12:01:56PM 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
12:02:50PM 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
12:04:19PM 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?

12:04:59PM 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
12:06:06PM 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®.

12:06:57PM 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
12:08:02PM 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.

12:08:45PM 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.

12:09:41PM 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
12:10:24PM 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
12:11:23PM 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.

12:12:10PM 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?

12:12:58PM 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.

12:13:30PM 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?

12:50:09PM 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.

12:50:54PM 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
12:52:08PM 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
12:52:49PM 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?

12:53:54PM 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.

12:54:33PM 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?

12:55:42PM 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.

12:56:29PM 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?

12:57:37PM 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
12:58:20PM 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?

12:59:32PM

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.

01:00:37PM

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.

01:01:29PM 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 --

01:01:53PM 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:

01:02:44PM 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.

01:03:16PM 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:

01:03:49PM 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.

01:04:34PM 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?

01:05:26PM 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?

01:05:53PM 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,
01:06:43PM 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?

01:07:17PM 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
01:08:09PM 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.

01:08:37PM 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?

01:09:36PM 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
01:10:15PM 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.

01:11:15PM 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.

01:12:05PM 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
01:13:21PM 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
01:13:58PM 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?

01:14:44PM 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?

01:15:11PM 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?

01:16:07PM 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
01:16:44PM 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
01:17:47PM 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
01:18:46PM 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...

01:19:47PM 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
01:20:26PM 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.

01:21:30PM 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
01:22:13PM 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
01:23:05PM 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
01:23:46PM 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
01:24:47PM 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
01:25:22PM 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
01:26:18PM 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
01:27:00PM 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.

01:27:52PM 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.

01:28:26PM 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
01:29:37PM 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®
01:30:25PM 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
01:31:20PM 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?

01:32:15PM 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
01:33:25PM 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.

01:33:56PM 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
01:34:44PM 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,
01:35:24PM 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?

01:36:25PM 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?

01:37:02PM 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.

01:37:42PM 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
01:38:29PM 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.

01:39:23PM 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
01:40:01PM 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.

01:41:04PM 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?

01:41:38PM 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 --

01:42:25PM 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?

01:42:59PM 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
01:43:50PM 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
01:44:39PM 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?

01:46:00PM 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
01:46:40PM 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?

01:47:20PM 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.

01:47:54PM 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
01:48:49PM 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
01:49:17PM 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?

01:50:15PM 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
01:50:50PM 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.

01:51:54PM 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.

01:52:29PM 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?

01:53:22PM 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.

01:54:01PM 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
01:54:59PM 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.

01:55:28PM 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 --

01:56:37PM 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
01:57:25PM 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.

01:58:18PM 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:

01:58:53PM 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:

01:59:51PM 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
02:00:31PM 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.

02:01:23PM 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.

02:01:48PM 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
02:02:31PM 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.

02:03:22PM 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.

02:03:58PM 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
02:04:26PM 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 --
02:05:30PM 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?

02:06:05PM 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 (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
12 Date

13
14
15
16
17
18
19
20
21
22
23
24
25

United States District Court
District of New Jersey