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UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

-----X

INTAS PHARMACEUTICALS LTD,
Petitioner,

-against-

ATOSSA THERAPEUTICS, INC.
Patent Owner.

-----X

Case IPR2025-00799
Patent 11,261,151

-----X

DEPOSITION OF
WILLIAM MAYO, PH.D.
REMOTE LOCATION
January 9, 2026

REPORTED BY: KIARA MILLER
FILE NO.: 614360

1 UNITED STATES PATENT AND TRADEMARK OFFICE
2 BEFORE THE PATENT TRIAL AND APPEAL BOARD
3 -----X
4 INTAS PHARMACEUTICALS LTD,
5 Petitioner,
6
7 -against-
8
9 ATOSSA THERAPEUTICS, INC.
10 Patent Owner.
11 -----X
12 Case IPR2025-00799
13 Patent 11,261,151
14 -----X
15
16 Deposition of WILLIAM MAYO, PH.D., taken on
17 behalf of PATENT OWNER, at REMOTE LOCATION
18 commencing at 9:57 AM, January 9, 2026,
19 before Kiara Miller.
20
21
22

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

2

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20

21

22

ALSO PRESENT:

ZOOM TECH, SEDRICK LAMPKINS

1 TECHNICIAN LAMPKINS: I understand the
2 objections, and I will not record
3 today's proceeding; however, since this
4 proceeding is being held remotely, I
5 will only need to record the
6 administration of the oath for notary
7 purposes. I will stop the recording
8 immediately after the witness is sworn
9 in. Thank you.

10 W I L L I A M M A Y O, PH.D., after having first
11 been duly sworn by a Notary Public of the State of
12 New York, was examined and testified as follows:

13 COURT REPORTER: Please state your name
14 and address for the record.

15 THE WITNESS: William Edward Mayo,
16 spelled M-A-Y-O. My address is
17 648 Kensington Place. That is in Wilton
18 Manors, Florida, zip code 33305

19 EXAMINATION BY

20 MR. BERMAN:

21 Q Good morning, Dr. Mayo.

22 A Good morning.

1 Q Where do you work?

2 A I don't. I'm retired.

3 Q Have you been retained by Intas to
4 provide an expert testimony in this
5 case?

6 A Yes, I have.

7 Q And before you retired, where did you
8 work?

9 A I was working as a consultant with my
10 own business, which was called Polymorph
11 Experts.

12 Q And what did you do as a consultant for
13 Polymorph Experts?

14 A I was an expert witness working on
15 pharmaceutical-related cases, such as
16 cases before the patent office and also
17 in litigation.

18 Q So you have been an expert witness
19 before?

20 A Yes. I have.

21 Q Approximately, how many times have you
22 been an expert witness?

1 A Today will be, I believe, the 18th
2 deposition, and I've also testified 6
3 times at a court.

4 Q Okay. I'd like to start off by
5 directing you to what I believe to be
6 your expert declaration in this action.
7 I'll represent to you that has been
8 marked as Intas Exhibit 1038. I believe
9 the copy that you have in the front of
10 you is not stamped.

11 Dr. Mayo, is this, in fact, your
12 expert declaration?

13 (Whereupon, Expert Declaration
14 of William Mayo, Ph.D. was
15 marked as Exhibit 1038 for
16 identification as of this
17 date.)

18 A I'll open the package. I did not open
19 it.

20 Q Okay. Please open the package.

21 A In the past they've asked me to wait.
22 Yes. My declaration and the

1 exhibits were attached to it.

2 Q All right. And then on Page 38 of the
3 declaration, is that your signature?

4 A Well, the copy that I have, this set,
5 doesn't have my signature on it, it's on
6 Page 39.

7 Q Okay. So Page 39, that's your
8 signature?

9 A Well, there is no signature on this
10 copy.

11 In fact, what you sent appears to
12 be a review copy.

13 I'm sorry, that's my mistake. I
14 turned to the appendix. It was the
15 redline version of the document.

16 Q Okay.

17 A There are too many pages, 38 pages.

18 Yes. That's my signature on
19 Page 38 of the declaration.

20 Q Great.

21 So it sounds like you have given a
22 number of depositions before. I'll just

1 quickly go through some ground rules for
2 today, just to make sure we're on the
3 same page.

4 I'll be asking you a series of
5 questions, and please do your best to
6 answer them truthfully and completely.
7 If you don't understand my question,
8 please let me know, and I'll do my best
9 to either clarify or rephrase it.
10 Everything we say today is being
11 transcribed by a court reporter, so it's
12 very important that we give clear,
13 verbal answers; not just head nods or
14 something like that. And that we don't
15 speak over each other. If we need a
16 break at any point, just let me know,
17 and I'll be happy to take one, as long
18 as I'm not in the middle of one of my
19 questions.

20 Do you understand the basic ground
21 rules for today?

22 A Yes.

1 Q How did it come about that you were
2 retained by the petitioner, Intas, to be
3 an expert witness in this case?

4 A I received an email from someone at H&M
5 Analytical Services. They told me that
6 Dr. Miller, who had been retained
7 originally was no longer available. So
8 they asked me if I would be interested
9 in substituting for Dr. Miller. And I
10 told them that I would help them out,
11 they, then, passed that message to
12 counsel, who then contacted me.

13 Q And were you familiar with Dr. Steven
14 Miller before that outreach?

15 A Yes.

16 Q And Dr. Miller purchased H&M Analytical
17 Services from you in or around mid-2012,
18 right?

19 A Yeah, so it was a long transition
20 period, but the document was signed in
21 2012.

22 Q How did that transaction come about?

1 A Well, I had known Dr. Miller from his
2 days at Rutgers. We were two ships
3 passing in the night at Rutgers. And I
4 was impressed by him. So when I was
5 looking to -- or thinking about
6 retirement, I contacted him to see if he
7 might be interested. So I hired him on
8 a temporary basis, and he joined H&M for
9 a year and he was interested in
10 purchasing the business, so we
11 negotiated the contract.

12 And the contract calls for an
13 amount, in addition to which, I would
14 stay on for the period of time so that
15 Dr. Miller could become completely
16 familiar with the business, and also
17 have some time to expand the business
18 into a new area. And I finally left the
19 business on or around mid-2016.

20 Q And how much did Dr. Miller -- you said
21 it was a set dollar amount -- how much
22 did Dr. Miller pay for the H&M Services?

1 A I believe it was 700,000.

2 Q To move onto to just some more general
3 questions.

4 So you mentioned you were doing
5 consulting on Polymorphism earlier.

6 What is a polymorph?

7 A Materials frequently can adopt multiple
8 structures, and we sometimes refer to
9 that as morphology. And many materials
10 can adopt different structures depending
11 upon the conditions. So the classic
12 example is steel; steel can be magnetic
13 or nonmagnetic depending upon the
14 crystal structure. Hybrid is another
15 example, where -- sorry -- where one
16 structure is diamond, another structure
17 is graphite.

18 And so the properties of a material
19 are frequently related to its structure.
20 When we talk about polymorphism, we're
21 simply referring to which crystal
22 structure the material has.

1 Q Can substances change polymorphs after
2 they've been synthesized?

3 A Well, there are many ways that a
4 material may change its structure. It
5 depends on the material. There is no
6 universal rule.

7 Q So what are some examples of how some
8 structures might change in different
9 materials?

10 A Well, let's go back to the simplest one,
11 which is carbon. Graphite is actually
12 the stable form of carbon, but if you
13 put the carbon under extreme pressure,
14 it has millions of atmospheres at high
15 temperature, you can convert it into
16 diamond. But then a reverse process
17 will also happen, and over a geological
18 time scales, temperatures and pressures,
19 diamond will convert back to graphite,
20 the stable form. So in that case,
21 pressure and temperatures are the
22 controlling factors.

1 Q Do you agree that physical
2 manipulations, like, scratching or
3 stirring or grinding something could
4 also cause a change in polymorphs?

5 A Well, that's a very hypothetical kind of
6 question. It would solely depend upon
7 the particular material, there are no
8 general rules.

9 Q So you're saying -- sorry, please
10 continue.

11 A I'm sorry. I missed that?

12 Q I said, so you're saying that there are
13 no general principles. What you mean is
14 that in theory, anything can precipitate
15 a change in structure from one form to
16 another.

17 MR. MENCHACA: Objection to form.

18 A No, what I'm saying is that what may
19 cause a polymorphic transformation in
20 one material, may not cause a
21 transformation in a different material.
22 Again, every material is different, and

1 you would need to study the particular
2 system.

3 Q Okay. Is x-ray pattern fraction one way
4 to know which polymorph of a substance
5 is present in a composition?

6 A It's one of the most common ways.

7 Q And could experimental conditions of
8 that XRPD analysis affect which
9 polymorph is present?

10 MR. MENCHACA: Objection, form.

11 A X-ray diffraction is an observations
12 technique, and simply observing a
13 material would not cause a structural
14 change.

15 Q All right. So, for example, could
16 sample preparation, the way the sample
17 is prepared for the analysis, affect
18 which polymorph is present?

19 A Well, the sample preparation has nothing
20 to do with the x-ray diffraction testing
21 itself. The sample preparation is
22 completely separate from the diffraction

1 testing. I'm going to repeat what I
2 just said. The x-ray observation would
3 not change the crystalline structure.

4 Q Okay. Prior to that observation, you
5 need to prepare the sample, right?

6 A Sometimes.

7 Q And could, in those situations where a
8 sample needs to be prepared in some way,
9 could this process affect what polymorph
10 is present?

11 A Well, that's an extremely wide
12 hypothetical question. There may be
13 some materials where it does, there may
14 be other materials where it doesn't. It
15 would simply be determined on a case by
16 case basis. In the case with the
17 material that we're looking at, won't
18 see any evidence of that has occurred.

19 Q In addition to sample preparation,
20 there's also experimental conditions,
21 right, like what temperature range you
22 run the experiment across, correct?

1 A I'm not sure I understand your question.
2 Can you try rephrasing it, please?

3 Q In addition to sample preparation, when
4 you run the experiment there are
5 different variables that you can --
6 there are different variables in the
7 experiment, right, like the temperature
8 range? Right?

9 A The temperature is fixed. And the
10 temperature is usually room temperature.
11 It is very rare that the temperature is
12 elevated for a diffraction.

13 Q Right, but do you agree with me that
14 there is a temperature and that's one
15 variable, yes?

16 A It's fixed. It's not a variable. And
17 again, room temperature is a fixed
18 temperature, but I would not consider it
19 a test variable.

20 Q So if the samples were not room
21 temperature, would that potentially
22 impact the results?

1 A For the particular case that we're
2 dealing with, everything was done at
3 room temperature. So you're asking
4 about a hypothetical situation.

5 In the case of a hypothetical
6 situation, the temperature which a test
7 is done may or may not change the XRD
8 test results. In this case that's not
9 an issue.

10 Q Thanks and I appreciate that. And for
11 now I'm just asking sort of general
12 questions about XRD and then I promise
13 we'll get to the specifics of your
14 declaration as well. I generally
15 understand when somebody's setting up an
16 experiment, or reviewing results sort of
17 what things they'd be looking for to
18 say, hey, this might change from
19 experiment to experiment. This might be
20 something that I need to look out for to
21 see if it was performed correctly or
22 that wasn't an issue here?

1 A Temperature is not an issue. In my
2 life, I have analyzed approximately
3 250,000 x-ray diffraction patterns and I
4 don't believe a single one was elevated
5 with low temperatures. But it's
6 extremely rare that anyone changes
7 temperature for x-ray diffraction.

8 Q When you're reviewing some of these XRP
9 results, what types of factors -- what
10 information would you want to know to be
11 sure they did it correctly?

12 A Well, the -- at H&M, for example, we
13 have a standard operating procedure,
14 which is required by the FDA to maintain
15 GMP status and to maintain the FDA
16 certification. And if the standard
17 operating procedure was followed, then
18 the test is well-controlled. So the
19 first thing you look for are the test
20 conditions of whether it follows a
21 standard operating procedure.

22 Q And where in your declaration does it

1 discuss H&M's standard operating
2 procedures?

3 A Well, if you look at the last page of
4 Dr. Miller's letter to Dr. Bihovsky, he
5 list's the test conditions and those are
6 all from the H&M standard operating
7 procedure.

8 Q Right, but that's not part of your
9 declaration, I don't think?

10 A Let me look.

11 Q Okay.

12 A I will have to look at Dr. Miller's
13 report and see if he referenced it,
14 because he did send a letter to
15 Dr. Bihovsky that included the test
16 conditions and those were the standard
17 operating procedure, the conditions
18 contained within the SOP.

19 Q I appreciate that and my question is
20 where is that letter or that discussion
21 in the declaration?

22 A I would have to take a more careful look

1 to see if Dr. Miller referred to it.

2 Q I think, let's go ahead and do that
3 then.

4 A Okay.

5 No. It's not included in any of
6 those.

7 Q Okay. So -- and do you personally know
8 whether Dr. Miller followed those
9 conditions in his report?

10 A Well, the day that Dr. Miller generated
11 was generated following the conditions
12 outlined in his letter report to
13 Dr. Bihovsky, and I did review that
14 letter and that did outline all of the
15 testing conditions and those were the
16 standard operating procedure.

17 I know that they were the standard
18 operating procedures from the laboratory
19 because I was the one who wrote the SOP.

20 Q How do you know that Dr. Miller followed
21 those conditions at the time that he did
22 the experiment?

1 A He's required to by the FDA. As in the
2 FDA certification you're required to
3 follow good manufacturing practice. And
4 part of the requirements of GMP is that
5 you follow various SOPs. H&M has
6 approximately 175 SOPs that are on file
7 that are viewed periodically by the FDA
8 by on-site inspections. And the FDA
9 inspection bases whether people follow
10 the SOPs or not. And if a company does
11 not follow the SOP they risk losing the
12 FDA certification and if you lose the
13 FDA certification you're out of the
14 business.

15 So H&M would be foolish not to
16 follow the SOP. So I'm certain that H&M
17 followed the conditions that are
18 outlined in the SOP.

19 Q But those SOPs aren't anywhere in your
20 declaration, right?

21 A No. They're not.

22 Q And there's no mention of H&M's FDA

1 certification in your declaration?

2 A No. There isn't.

3 Q And did you personally check whether
4 Dr. Miller followed the FDA SOPs here?

5 A Again, the last page of Dr. Miller's
6 letter report to Dr. Bihovsky clearly
7 indicates that they followed the SOP.
8 The instrument that they used is the one
9 that is used for GMP testing and it
10 follows a protocol known as 21 CFR
11 Part 11 that controls electronic data
12 and electronic signatures and all of
13 that is part of the SOP. So that
14 particular machine requires that you
15 follow the SOPs.

16 Q If you're reviewing somebody's
17 experimental results who wasn't from
18 H&M, would you want to know, for
19 example, how they prepared the sample
20 before doing the analysis?

21 A Usually it's not a concern. Only in
22 rare occasions is sample preparation

1 considered. So, for example, I was a
2 consultant to the ICDD, which is the
3 International Center for Diffraction
4 Data and I was an editor for 18 years,
5 when you collected data from the open
6 literature and we included it in the
7 x-ray diffraction database and there is
8 an information box in the database for
9 sample preparation techniques. And
10 information that goes into there is
11 optional. So the ICDD said that it's
12 nice if the originator included sample
13 preparation, but it was not required and
14 we did not press the office for that
15 information.

16 Q So do you agree that the way that the
17 sample is made into a powder and put
18 into the sample holder can affect the
19 quality of the data?

20 A We're talking about the present case or
21 in general?

22 Q In general.

1 A In general, in most cases, no. In some
2 cases, yes. It all depends upon the
3 details of the material, and the
4 particular sample holder and the
5 instrument.

6 Q And do you agree that another error that
7 is possible at least, is to fill the
8 sample holder with too much or too
9 little sample and that that can cause a
10 shift in peak positions?

11 A Current situation they -- the sample
12 holder that was used is a zero
13 background holder, which has a
14 depression which is only 50-microns deep
15 and it's not possible to put too much
16 sample into the sample holder. And in
17 fact, it is impossible to put too much
18 material into the sample holder. So in
19 the current case the issue you just
20 phrased is not possible.

21 Q And where is that description of the
22 sample holder in your declaration?

1 A That's in the testing procedure that
2 Dr. Miller described in his letter
3 report to Dr. Bihovsky.

4 Q And we discussed that earlier, right,
5 that's not part of your declaration,
6 correct?

7 A That's correct.

8 Q So in general, stepping outside of this
9 case, is it possible to have a situation
10 where you overfill or under fill the
11 sample holder and that can cause a shift
12 in the peaks?

13 A The x-ray diffraction literature is
14 filled with advice on how to load
15 samples, so that that situation that you
16 just described doesn't occur, right. So
17 in fact, the recommended method is to
18 use a method known as backfilling, and
19 that prevents both overloading and
20 underloading a sample. So for anyone
21 who's -- where even the basic advice on
22 how to load a sample doesn't run into

1 that problem.

2 So only someone who doesn't know
3 what they're doing would run into the
4 problem. And I think someone who has a
5 Ph.D. or a person of -- who knows the --
6 skilled in the art would certainly know
7 how to load a sample properly.

8 Q You said there's a lot been written on
9 sample loading, right?

10 A Sure.

11 Q One inference for why people are writing
12 so much about it is because people were
13 doing it wrong in many cases; is that
14 fair?

15 A Perhaps 35 years ago that was true, but
16 the first textbook that I know of that
17 talked about that was a book by Cullity,
18 which I think was published back in the
19 late '60s, early '70s, and that's gone
20 through a couple of revisions. And
21 every textbook since then includes a
22 brief discussion of it, along with how

1 x-rays are generated.

2 And that's all intended for a
3 novice audience just to be sure that
4 they're brought up to speed. The older
5 textbooks may have spent more time on
6 it. The more recent textbooks spend a
7 lot less time on it.

8 Q What is preferred orientation when we're
9 discussing a sample for XRPD testing?

10 A Grains tend to have a nonspherical
11 morphology. It means grains tend to be
12 tubes, rectangles, needles, plates,
13 different morphologies. And when you
14 put them into a sample holder, the
15 grains may preferentially align, since
16 then all the plates are parallel to each
17 other, all the needles are parallel to
18 each other.

19 When that happens, the x-ray
20 diffraction pattern is skewed, and the
21 few peak reflections will become more
22 intense, while other peak reflections

1 are -- become less intense. And when
2 that happens, it's relatively easy to
3 observe. And any person who's skilled
4 in the art would immediately see what is
5 happening, and then they would take
6 steps to mitigate the preferred
7 orientation.

8 Q How would you -- you said a person of
9 ordinary skill in the art -- would
10 automatically see this happening. How
11 would they know it's happening?

12 A Well, if you see two peaks that are at,
13 let's say, 100 percent and 90 percent
14 and all the other peaks are at 1 percent
15 intensity, that's obvious that you have
16 preferred orientation. No real
17 materials would have a diffraction
18 pattern that looked like that. So in
19 that case, you would have to take
20 additional steps to avoid that problem.

21 Q What kind of additional steps would you
22 need to take?

1 A One method would be to grind the sample
2 so that you break up the needles or the
3 plates into something that is closer to
4 spherical particles or, let's say,
5 cubes. Another method would be to use
6 what is called spray drying, where the
7 material is passed through a nozzle,
8 right, and carried by a liquid which
9 evaporates during the spraying process,
10 and that weighs down a randomly oriented
11 arrangement of the crystals.

12 There are a number of techniques
13 that are used. Some people use Vaseline
14 on a glass slide, and they just sprinkle
15 the powder on the Vaseline. Some people
16 use Scotch tape to do the same thing.
17 So there's fairly simple techniques to
18 get rid of preferred orientation.

19 Q So if you're reviewing somebody else's
20 XRPD results who wasn't from H&M, would
21 you also want to know about the changes
22 in temperature of the compound

1 throughout the process, starting from,
2 you know, when the lab received it until
3 when the experiment was finished?

4 A No --

5 (Reporter clarification.)

6 A I believe what I said was my job is to
7 analyze the material that I've received
8 and to report the results that I find.
9 And so what happens before I received
10 the material is not really my concern.
11 That is really the investigator who
12 prepared the sample, so that's the
13 concern of the investigator who prepared
14 the sample.

15 Q Right. And my question is: From when
16 you receive the sample until the
17 experiment's finished, would you want to
18 know the temperature that the sample was
19 kept at?

20 A Well, if the temperature is important to
21 the investigator, they will take steps
22 to ship the sample under controlled

1 conditions. So for example, if --
2 especially with pharmaceuticals, the
3 sample was sent in a low temperature box
4 usually by special courier in a
5 refrigerated box.

6 And when that happens, we will
7 immediately take the sample out and put
8 it into an FDA-approved refrigerator
9 under controlled conditions to duplicate
10 the conditions that the investigator had
11 used to ship the sample. If the sample
12 might have been shipped at room
13 temperature, we will store it at room
14 temperature. So we attempt to duplicate
15 the test conditions that the sample was
16 shipped in.

17 Q And why do you do that?

18 A Because we do not want to introduce any
19 changes to the sample.

20 Q What kind of changes could be introduced
21 to the sample by changes in temperature?

22 A I have no idea. We just are extremely

1 cautious in storing the sample with the
2 same temperature because the
3 investigator felt that it was important
4 to ship the sample at a particular
5 temperature. And so we simply follow
6 their guidelines.

7 Q Okay. Similar to temperature, do you
8 sometimes receive samples that might
9 have humidity controls?

10 MR. MENCHACA: Objection. Form.

11 A I don't believe I've ever received a
12 sample where we were requested to
13 control the humidity.

14 Q Earlier, we discussed the instruments
15 that are used for this kind of analysis.
16 When you're reviewing someone else's
17 experimental results, would you want to
18 know what type of instrument they
19 used -- or instruments?

20 A Yes.

21 Q And would you want to know how that
22 instrument was calibrated?

1 A No.

2 Q Why "no"?

3 A Because it's usually the water
4 diffractometers are extremely rugged
5 instruments. For example, the samples
6 stage typically weighs 500 to a
7 thousand pounds, and you're controlling
8 a sample that weighs milligrams. So the
9 system is extraordinarily rugged, and
10 history has shown that the instruments
11 drift very, very slowly. And so the
12 recommended practice by the manufacturer
13 is that the calibration be checked on an
14 entry point basis.

15 And my experience has shown that
16 the calibration of an instrument's,
17 that's only over a period of years, not
18 on a daily basis. And in fact, under
19 good manufacturing practice, which is
20 done at H&M labs, we test the
21 calibration typically on a -- I believe
22 it's a bimonthly basis, and the drift is

1 usually imperceptible.

2 Q And do you discuss H&M's calibration
3 procedures in your declaration?

4 A No.

5 Q And earlier you said you would want to
6 know why -- sorry. Withdrawn.
7 Earlier, you said you would want to know
8 which instrument was used in the XRD
9 analysis.
10 Why would you want to know that?

11 A I would want to know which type of
12 instrument is used. For example, they
13 might have used a synchrotron. They
14 might have used what's known as the
15 Guinier camera. They may have used a
16 Debye-Scherrer camera. They may have
17 used a diffractometer.

18 And the reason we would want to
19 know which of those four is used is that
20 a Debye-Scherrer camera dates back to
21 the 1930s, and it is notoriously
22 inaccurate. Therefore, we would not

1 rely upon the results taken with that
2 sort of instrument.

3 I haven't seen a Debye-Scherrer
4 camera probably in about 30 years. A
5 diffractometer is the most common
6 laboratory instrument, and that gives
7 high-quality, accurate data. The
8 Guinier camera is a specialty instrument
9 that frequently operates under special
10 environmental conditions. And a
11 synchrotron is a billion-dollar
12 instrument that is used for research
13 purposes that gives superb accuracy and
14 is a very uncommon instrument.

15 So therefore, we would like to know
16 in general what kind of instrument is
17 used because that helps us decide the
18 reliability of the data that comes from
19 it.

20 Q To perform a XRPD analysis, the
21 composition being tested needs to be in
22 a powder form, right?

1 A No.

2 Q It doesn't?

3 A No. Metals, for example, are solids.

4 Q XRPD stands for x-ray powder
5 diffraction, right?

6 A Yes. But people frequently -- the real
7 name is x-ray diffraction, and that is
8 the generic name, like, where you can
9 use liquids, solids, or powders.
10 Sometimes when people are testing
11 powders, they will talk about x-ray
12 powder diffraction. But the instrument
13 is the same, whether you're testing
14 powders or solids.

15 (Reporter clarification.)

16 Q Do you agree that if you are going to
17 analyze a powder using XRPD, that
18 requires that the powder is very fine
19 grain to achieve good signal-to-noise
20 ratio and avoid fluctuation intensity?

21 A No, that's really a compound question.
22 There are several things in there to

1 discuss. But let's talk about the size
2 first.

3 The powder size is recommended to
4 be less than 50 microns. If the powder
5 size is less than 50 microns, then you
6 have good counting statistics. And you
7 get good intensity, and you get a good
8 representation of all of the grain
9 orientations in the material.

10 Pharmaceuticals tend to have
11 particle sizes which are much smaller,
12 if you're down in the single micron
13 range; typically, half a micron to
14 10 microns, those actually are ideal for
15 the x-ray diffraction testing. And in
16 that case, we don't worry about the
17 powder size, we don't need to reduce the
18 powder size.

19 The second issue is the
20 signal-to-noise ratio. And the
21 signal-to-noise ratio is controlled by
22 the counting time, and the intensity of

1 the XRPD, and so therefore, they are two
2 separate issues.

3 Powder size and x-ray intensity are
4 two separate things.

5 Q And if you were reviewing somebody
6 else's XRPD results, would you want to
7 know what counting time they used?

8 A No, in fact, typically the counting time
9 is not reported. What matters is the
10 intensity of the peak. So what I look
11 at when I see someone else's diffraction
12 pattern, is I look for the quality of
13 the pattern and I look for how intense
14 the strongest peaks are, and I also look
15 for how much noise is in the background
16 between the peaks. If there's a lot of
17 noise in the background, then I'm
18 concerned that the signal-to-noise ratio
19 is too high and I may be missing small
20 peaks that may be important in the
21 analysis.

22 So, therefore, you can tell by just

1 looking at the pattern itself whether it
2 is a good quality or low quality
3 pattern. The counting time really is
4 not that important.

5 Q If you were analyzing the results of
6 XRPD analysis and you understood the
7 composition had been made into a powder
8 from a previously solid form, would you
9 want to know how that process of
10 creating the powder was done?

11 A No.

12 Q Why not?

13 A My job is to take a sample that is
14 provided by somebody else and to report
15 back what peaks I see in the diffraction
16 pattern. So it's simply to provide the
17 peak list and the intensity of each
18 peak. If the investigator asked me to
19 compare the peak intensities of the
20 solid verses the powder, then I would
21 report, independently, the results of
22 two separate tests, and let the

1 investigator draw their conclusions.

2 Q Do you agree that the way a substance is
3 turned into a powder could cause
4 specimen contamination by particles
5 abrading from the milling instrument?

6 MR. MENCHACA: Objection, form.

7 A It's a very broad question. Again, it's
8 a hypothetical situation. And in the
9 present case, my belief is that the
10 materials that Dr. Bihovsky produced,
11 were by precipitation. And that usually
12 produces a fine powder, would not
13 involve in any grinding, whatsoever.

14 So in some hypothetical situation
15 where a solid is produced and you need
16 to reduce it to a powder, then
17 contamination might become an issue, but
18 it would depend upon what sort of
19 material is used to reduce a solid to a
20 powder. Again, it would depend upon the
21 material that you were working on.

22 Q And, in general, do you agree that the

1 process of turning a substance into a
2 powder could also cause a solid state
3 transition from one polymorph to
4 another?

5 MR. MENCHACA: Objection, form.

6 A Again, it's a hypothetical question and
7 it would depend upon the particular
8 system.

9 Q But at least in some systems it is
10 possible that grinding from a solid to a
11 powder could cause a solid state
12 transition from one polymorph to
13 another?

14 MR. MENCHACA: Objection, form.

15 A In my experience, that's extremely rare.

16 Q And then we touched on this a little bit
17 already, but just quickly, discussing
18 the results of an XRPD analysis, those
19 are typically reported as what you're
20 calling peaks, right?

21 A Would you repeat that, please?

22 Q I just want to discuss the results of

1 the XRPD analysis. So the results are
2 typically reported as peak intensities,
3 correct?

4 A It's recorded as peak positions, then
5 the corresponding spacing from the
6 crystal is calculated from those peak
7 positions, then the relative intensity
8 of peaks are reported. So usually three
9 pieces of data are recorded for each
10 peak. But only for peaks that are
11 typically above 1 percent relative
12 intensity.

13 Q And how do you determine when a sample
14 that you're testing is a known
15 polymorph, like a reference that you're
16 looking for, for example?

17 A In order to identify what a material is,
18 you need some sort of database. The
19 database may consist of one standard
20 that you may have prepared yourself in
21 the past, or you may refer to the open
22 literature, which may give diffraction

1 patterns for various materials.

2 An example of the database is the
3 powder diffraction file produced by ICDD
4 that I worked on. And that has
5 1.1 million diffraction patterns listed
6 there. And by using that database, you
7 could identify a material if it's within
8 that database.

9 Q I think now what I want to do is direct
10 you to what's marked in this preceding
11 as Intas Exhibit 1031. If we can get
12 that up on the screen, as well, please.

13 TECHNICIAN LAMPKINS: Stand by.

14 (Whereupon, USP 941 was marked
15 as Exhibit 1031 for
16 identification as of this
17 date.)

18 Q Dr. Mayo, do you have Intas Exhibit 1031
19 in front of you?

20 A Yes, I do.

21 Q Do you recognize this document?

22 A Almost by heart.

1 Q What is it?

2 A It's the -- USP 941 is the controlling
3 document for XRPD testing of various
4 materials, as a matter of fact, it has
5 particular relevance to testing a
6 pharmaceutical material.

7 Q And why is that?

8 A By law, the USP -- let me back up.

9 Pharmaceutical companies are
10 required to follow USP protocols, when
11 such a protocol is available. So in
12 this case, by, let's say it's the FDA
13 Modernization Act that was published in
14 1997, it says that pharmaceutical
15 companies have to follow these
16 regulations; so therefore, this is the
17 regulation that governs on how to run
18 and analyze x-ray diffraction tests for
19 pharmaceuticals.

20 Q I'd like to turn your attention --

21 A Pardon me.

22 Q Were you finished, I'm sorry?

1 A Yeah, it's Section 503, by the way, in
2 the FDA Modernization Act.

3 Q I'd like to turn your attention to
4 Page 7, and there's a header there
5 that's called "Specimen Preparation and
6 Mounting."

7 A Yeah.

8 Q And the first sentence of that reads:

9 "Preparation of the powdered
10 material and the mounting of the
11 specimen in a suitable holder are
12 critical steps in the many analytical
13 methods, particularly for x-ray powder
14 diffraction analysis, since they can
15 greatly affect the quality of the data
16 to be collected."

17 Do you see that?

18 A Which line is that?

19 Q So the heading, "Specimen Preparation
20 and Mounting," and then it's the first
21 sentence following that.

22 A Yeah.

1 Sure. Okay. What about it?

2 Q Do you agree that preparation of the
3 powdered material and the mounting of
4 the specimen in a suitable holder can
5 greatly affect the quality of the data
6 to be collected in the XRPD analysis?

7 A Sure. And that's why textbooks warn
8 novices that they have to be careful and
9 here's how to do it, so that you don't
10 run into problems. So, again, for
11 people who are experienced, this is not
12 an issue.

13 Q And then in the next heading, it's
14 "Specimen Preparation."

15 Do you see that?

16 A Yes.

17 Q The last sentence on this page going
18 over into the next page, reads:

19 "Preferred orientation in the
20 specimen influences the intensities
21 of various reflections so that some
22 are more intense, and others less

1 intense, compared to what would be
2 expected from a completely random
3 specimen."

4 Do you see that?

5 A Yes.

6 Q And do you agree that a preferred
7 orientation in the specimen can
8 influence the intensities of various
9 reflections in XRPD analysis?

10 A I believe I described the situation
11 before, but in the present case that is
12 not an issue because it's obvious from
13 the diffraction patterns of the current
14 materials, that there is no preferred
15 orientation. Preferred orientation is
16 an occasional problem, but in many
17 materials it's a nonissue.

18 And as I indicated, when you start
19 getting to very small particle size,
20 other problems begin to come in and
21 preferred orientation goes away.

22 Q And then Page 8 there's a heading

1 called, "Specimen Mounting: Effect of
2 Specimen Displacement."

3 Do you see that?

4 And it says:

5 "A specimen surface that is offset
6 by D with reference to the
7 diffractometer rotation axis causes
8 systematic errors that are very
9 difficult to avoid entirely."

10 Do you see that?

11 A I see it.

12 Q And do you agree that a specimen that is
13 offset or not mounted correctly with
14 reference to diffractometer rotation
15 axis causes systemic errors in the
16 results?

17 A If the sample is very thick that may
18 become an issue, but if the sample is
19 very thin, as in the current case, it's
20 not an issue.

21 In the current case, Dr. Miller
22 used the zero background holder, which

1 has a very thin well in which the sample
2 is placed, so that minimizes any
3 sampling displacement issues.

4 Q Right. And as we discussed earlier,
5 that information is not in your
6 declaration, right, that's in a separate
7 letter you reviewed?

8 A That's correct.

9 Q On the bottom of Page 8, there's another
10 section called "Control of the
11 instrument performance" and the second
12 sentence there says:

13 "The degree of alignment or
14 misalignment directly influences the
15 quality of the results of an XRPD
16 investigation."

17 Do you see that?

18 A Yes.

19 Q Do you agree that the degree of
20 alignment or misalignment of the
21 instrument during the analysis directly
22 influences the quality of the results of

1 an XRPD investigation?

2 MR. MENCHACA: Objection. Form.

3 A In general, the alignment of the
4 instrument has to be considered, but as
5 I described previously, the modern
6 instruments are extremely rugged and
7 once aligned to factory specs, the drift
8 in the instrument is extremely small.
9 In case of the instruments at H&M, the
10 typical misalignment using a standard
11 produced by NIST, the observed error is
12 of the order of 0.002 degrees. So the
13 error in the H&M instruments is
14 extremely small and it certainly would
15 not impact the current samples.

16 Q Which instrument Dr. Miller uses is not
17 in your declaration, correct?

18 A Yes. The instrument that Dr. Miller
19 described in his letter report, he
20 indicates the serial number of the
21 instrument, and that is the one that is
22 used for FDA compliant testing under

1 both GMP and 21 CFR Part 11 with
2 controls.

3 Q I appreciate that. Just to be clear for
4 the record, that information about which
5 instrument Dr. Miller used is not in the
6 declaration you provided in this
7 proceeding, right?

8 A That's correct.

9 Q I want to jump back up to the middle of
10 Page 8 or maybe the top even, earlier we
11 were talking about preferred orientation
12 and then it says, it's about half way
13 through the top paragraph there.

14 "In some cases particle sizes as
15 large as 50-micrometers will provide
16 satisfactory results in phase
17 identification. However, excessive
18 milling particle sizes less than
19 approximately 0.5-micrometers may cause
20 line broadening and significant changes
21 to the sample itself, such as specimen
22 contamination by particles abraded from

1 the milling instrument."

2 Do you see that?

3 A Yes.

4 Q Do you agree that one potential issue
5 from excessive milling would be specimen
6 contamination?

7 A The key word there is "excessive." If
8 one mills a material under normal
9 conditions and using a careful
10 procedure, contamination is extremely
11 limited. In the case of excessive
12 milling then there is a possibility of
13 contamination, but it would depend upon
14 what milling materials we used, whether
15 it's done by hand or by machine, and in
16 my experience using a mortar and pestle
17 will not introduce a contamination.

18 Q And continuing on with this list of
19 potential issues arising from excessive
20 milling. The next one is, reduced
21 degree of crystallinity.

22 Do you agree that's another

1 potential issue of excessive milling?

2 A Again, if it's excessive, that is a
3 possibility, yes.

4 Q The next one on the list from potential
5 issues from excessive milling is, a
6 solid state transition from another
7 polymorph.

8 Do you agree that's a potential
9 issue from excessive milling?

10 A It's a rare situation. So it's
11 theoretically possible in rare
12 situations and it strongly depends on
13 the particular material. In general
14 though, it doesn't happen.

15 Q The next issue on this list of potential
16 issues from excessive milling is,
17 chemical decomposition.

18 Is that another potential issue
19 from excessive milling?

20 A Well, again, excessive milling may raise
21 the temperature and that in turn may
22 cause the decomposition, but again, you

1 have to be careful when milling
2 materials. And anyone in x-ray
3 diffractions knows you have to be
4 careful when milling materials to avoid
5 these problems.

6 Q The next one on the list from excessive
7 milling potential problems is,
8 introduction of internal stress. Do you
9 agree that's a potential problem from
10 excessive milling?

11 A In my career, stretching almost
12 60 years, I've never seen that happen.

13 Q Do you agree in theory, it's a potential
14 problem, though?

15 A In theory, possible. But in practice,
16 I've never seen it.

17 Q And the last potential issue on the list
18 from excessive milling is, inducing a
19 solid state reaction. Do you agree
20 that's another potential issue from
21 excessive milling?

22 A I don't know what they mean by solid

1 state reaction. It's an unclear
2 statement. Solid state reaction
3 generally implies that two different
4 phases react with each other. And I'm
5 not sure what they are talking about.

6 MR. MENCHACA: We've been going for
7 almost an hour, is this a good stop for
8 maybe 10-minute break.

9 THE WITNESS: Sure.

10 (Whereupon, a recess was taken
11 from 10:59 AM until 11:10 AM.)

12 THE WITNESS: So I'd like to make a
13 correction if everybody's ready.

14 The correction that I would like to
15 make is that the document that I
16 referred to as the letter report by
17 Dr. Miller to Dr. Bihovsky technically
18 is in your possession. If you turn to
19 Page 13 of my declaration, you'll see
20 that the letter that I've been referring
21 to is actually Appendix B of
22 Dr. Miller's report. So I do refer to

1 it in my declaration and Dr. Miller also
2 referred to it.

3 BY MR. MENCHACA:

4 Q Let's go there for a second. You said
5 Paragraph 23 of your declaration?

6 A That's right.

7 Q And the last sentence there it says, I
8 understand that the experimental test
9 and analysis conditions used for the
10 XRPD testing was intended to be attached
11 to Dr. Miller's declaration as
12 Appendix B?

13 A Right. I received an email that
14 indicated that Appendix B had been
15 inadvertently omitted from the first
16 submission of Dr. Miller's declaration
17 and then they sent Appendix B
18 independently.

19 Q But there's nothing in your report that
20 says we have it, just to be clear. That
21 just says that Dr. Miller intended to
22 attach Appendix B?

1 A No, but as I recall, it is a part of the
2 record, at least the electronic email
3 record, he had supplied a copy of
4 Appendix B.

5 Q Right, but just to be clear, nothing in
6 your report says that.

7 A Well, my report on Page 13, says the
8 data is in Dr. Miller's Appendix B.

9 Q Well, it says, was intended to be
10 attached as Appendix B, right, that's a
11 little bit different than in Appendix B?

12 A Well, I think that's up to the board to
13 interpret, to parse the words.

14 Q Fair enough. During the break did you
15 have any discussions with your counsel
16 at all?

17 A No.

18 Q No, okay.

19 Just to put one final clear point
20 on that, Appendix B is not in your
21 declaration, correct, there's no
22 Appendix B there?

1 A I don't know whether -- I think that --
2 I think that error may have been
3 repeated that in -- also put all the
4 documents together they apparently
5 omitted Appendix B again. Again, you've
6 received Appendix B via email.

7 Q Just move on to some general questions
8 about your declaration which I
9 represented earlier, is Intas
10 Exhibit 1038, I don't believe you have
11 the stamped copy.

12 So you weren't present for
13 Dr. Miller's testing, right?

14 A No. I wasn't.

15 Q And you don't have knowledge about
16 Dr. Miller's testing beyond what's in
17 your declaration, correct?

18 A I'm sorry. (Indiscernible.) I read what
19 was in that Appendix B and the test
20 conditions and what testings conditions
21 he would have used.

22 Q So what you did was you reviewed

1 Dr. Miller's declaration regarding his
2 tests and then you provided your
3 opinions about that, that declaration,
4 essentially, right?

5 A That's correct.

6 Q So sort of that other information that
7 you referenced is not in your report,
8 meaning the letter and the prior
9 knowledge that you have of H&M's SOPs
10 was not in your report?

11 A The reference I made to Dr. Miller's
12 Appendix B, that was part of the record.
13 That the information about H&M's SOP was
14 inferred from Dr. Miller's SOP
15 information. I inferred that
16 Dr. Miller's followed the SOP.

17 Q What was your basis for that inference?

18 A Well, knowing that H&M is an FDA
19 certified laboratory, and they are
20 required to follow SOPs. And the fact
21 the data contained in Dr. Miller's
22 Appendix B follows the SOP to the

1 letter. That tells me that he followed
2 the SOP. There's no reason for him not
3 to follow the SOP. The penalties for
4 not following the SOP are severe.

5 Q Where is that outlined in your
6 declaration?

7 A It's not.

8 Q So I'd like to point you now to
9 Paragraph 1 of your declaration. And
10 here you discuss US patent 11,261,151,
11 which is the patent at issue in this
12 proceeding.

13 Have you reviewed the '151 Patent?

14 A Yes, I have.

15 Q And then I'd like to move to Paragraph 9
16 of your declaration. And there you say
17 that you understand that Dr. Miller was
18 asked to perform certain experiments to
19 determine the x-ray pattern diffraction
20 patterns of crystals synthesized by
21 Dr. Ron Bihovsky, right?

22 A Correct.

1 Q How many samples did Dr. Miller test?

2 A As far as I know, he tested two samples.

3 Q Do you know if he tested all the samples
4 Dr. Bihovsky sent him?

5 A I don't know how many samples
6 Dr. Bihovsky sent.

7 Q How do you know that Dr. Miller tested
8 two samples?

9 A The infamous Appendix B that we've been
10 talking about describes test results of
11 two samples.

12 Q Did Dr. Miller report results from every
13 sample that he received from
14 Dr. Bihovsky? In other words, did
15 Dr. Miller test any samples that are not
16 discussed in the report?

17 A The report only describes the test
18 results of two samples. There is no
19 mention of other samples.

20 Q So you don't know whether Dr. Miller
21 tested other samples that are not
22 described in the report?

1 A There's no indication that there were
2 other samples.

3 Q But there's also no indication that
4 there were not other samples, correct?
5 MR. MENCHACA: Objection. Form.

6 A I have no reason to believe that there
7 were other samples. There's nothing in
8 record to indicate that.

9 Q So you don't know whether Dr. Miller
10 tested all the samples that he received
11 from Dr. Bihovsky?

12 MR. MENCHACA: Objection. Form.

13 A Again, what I noticed, that Dr. Miller
14 tested two samples. That's all I know.

15 Q Have you reviewed Dr. Bihovsky's
16 declaration in forming your opinions?

17 A Briefly I reviewed Dr. Bihovsky's
18 declaration.

19 Q I'd like to move now to Paragraph 16 in
20 your report. This is where you start
21 reciting the patent claims. And these
22 are also -- the patent claims are also

1 in Intas Exhibit 1001 beginning on
2 Page 66. You're welcome to look at
3 them, either in the patent or on the
4 report.

5 A The original '151 Patent?

6 Q Yeah. And when you get there, I want to
7 talk about --

8 A Yes.

9 Q Okay. Claim 1 is directed to a
10 composition of endoxifen where at least
11 90 percent of the weight of the compound
12 is (Z)-isomer; is that right?

13 MR. MENCHACA: Objection. Form.

14 Q I'll repeat the question. Claim 1 is
15 directed to a composition of endoxifen
16 where at least 90 percent of the weight
17 of the compound is the (Z)-isomer,
18 right?

19 MR. MENCHACA: Objection. Form.

20 A (No verbal response given.)

21 Q And Claim 1 also requires that the
22 composition be the crystalline form of

1 the (Z)-isomer, which is called Form I
2 in the claim, which is characterized by
3 an x-ray powder diffraction pattern
4 comprising major peaks at 16.8 plus or
5 minus 3 degrees, 17.1 plus or minus 3
6 degrees, and 21.8 plus or minus 3
7 degrees two theta; is that right?

8 MR. MENCHACA: Objection. Form.

9 A Yes, that's how it reads.

10 Q Did you review Dr. Miller's results to
11 determine whether the samples produced
12 by Dr. Bihovsky had an x-ray powder
13 diffraction pattern comprising the major
14 peaks at 16.8 plus or minus 3 degrees,
15 17.1 plus or minus 3 degrees, and 21.8
16 plus or minus 3 degrees two theta?

17 A Yes, I did.

18 Q What was the results of that analysis?

19 A The match was essentially perfect for
20 both samples that Dr. Miller tested.

21 Q And then let's move to Claim 16. And
22 Claim 16 also requires a composition of

1 endoxifen wherein at least 90 percent of
2 the weight of the compound is the
3 (Z)-isomer, right?

4 A Yes, that's what it says.

5 Q And Claim 16 requires the same major
6 peaks that Claim 1 requires, right?

7 A That's correct.

8 Q And did Dr. Miller perform the same
9 analyses for Claim 1 and for Claim 16 to
10 determine whether the samples produced
11 by Dr. Bihovsky had the claimed major
12 peaks?

13 A Let me double-check.

14 Yeah, what Dr. Miller says is -- he
15 says that the -- he refers -- when
16 discussing Claim 16 in Paragraph 38, he
17 says that, as discussed with respect to
18 Claim 1, the Liu's materials exhibit the
19 claimed XRPD patterns. So he basically
20 states the conclusion. He did not state
21 it line by line. He just simply refers
22 back to Claim 1.

1 Q Then let's move to Paragraph 20 of your
2 declaration. There, you discuss
3 International Patent Application No. WO
4 2017/070651, which we have been
5 referring to as Liu in this proceeding.
6 Have you reviewed Liu?

7 A Yes.

8 Q And that's also Intas Exhibit 1003, for
9 reference.

10 In Paragraph 21 of your
11 declaration, you state that Liu does not
12 report any XRP data for any of the
13 compounds that Liu synthesized; is that
14 right?

15 A Correct.

16 Q And without the XRP data, is there a way
17 for one skilled in the art to determine
18 whether the compounds Liu synthesized
19 have the same major peaks as those that
20 are required by the claims of the
21 '151 Patent?

22 A Well, by following the recipe that Liu

1 used, Dr. Bihovsky created material
2 which is the same as that described in
3 Liu, and the x-ray diffraction work was
4 done independently of the WO patent.
5 And that was called the defendant's
6 '151 Patent.

7 Q And that x-ray diffraction data is not
8 in Liu, correct?

9 A That's correct.

10 Q So in order to know whether the process
11 of Liu creates something that matches
12 the claims of the '151 Patent, one of
13 ordinary skill in the art would need to
14 have some x-ray or other structural
15 comparison data, correct?

16 A It's really what this whole thing is
17 about. It's up to the board to make
18 that decision, what would be required.
19 It's simply Liu describes how to make
20 the material. Then, someone comes along
21 and makes that material and runs the
22 tests and finds it's identical to what

1 is in the '151 Patent. That is what has
2 happened here.

3 And of course, the testing was done
4 at a level that someone with skill in
5 the art would have known certainly at
6 the time. So it certainly seems that --
7 certainly, I think it's been proven that
8 the material described in Liu is the
9 same as the material Form I in the
10 '151 Patent.

11 Q Is it your position that without the
12 XRPD testing, one of ordinary skill
13 would have been able to tell that what
14 Dr. Bihovsky produced is allegedly the
15 same as what's in the '151 Patent?

16 A The '151 Patent uses the x-ray
17 diffraction work to characterize the
18 material that is produced in --
19 characterized as Form I. So therefore,
20 in order to compare oranges to apples,
21 one would need to take the old material
22 from the x-ray diffraction pattern on

1 those and then compare that to the
2 '151 Patent, and that is what was done.

3 Q Thanks.

4 And then in Paragraph 21, you state
5 that Liu discloses two different methods
6 for preparing highly pure (Z)-endoxifen,
7 what's called Liu's Recrystallization
8 Procedure and Liu's Isomerization and
9 Recrystallization Procedure, right?

10 A Yes.

11 Q And what is your understanding of the
12 difference between those two procedures?

13 A Well, in the simple recrystallization
14 process is a sequential operation where
15 there are multiple steps where the
16 powder is dissolved in solvents in which
17 one of the isomers is preferentially
18 dissolved and the other one is not. And
19 then the material is filtered to remove
20 the solvents, and then the liquor that
21 remains is then purified in the
22 (Z)-isomer. And that is repeated a

1 couple of times to -- this is at
2 99 percent purity.

3 The other method produces a second
4 step where the liquor that was produced
5 by the first -- the solution step is
6 then modified to convert the E
7 (E)-isomer to (Z)-isomer and thus
8 improve the overall yield. So that
9 second process is refers to as the --
10 it's referred to as the isomerization
11 and recrystallization process.

12 Q At the end of Paragraph 21, you state
13 that Liu's "procedure provides
14 (Z)-endoxifen that exhibits the claimed
15 XRPD pattern."

16 Do you see that?

17 A Yes.

18 Q Was it Liu's Recrystallization Procedure
19 or Liu's Isomerization and
20 Recrystallization Procedure that
21 resulted in the claimed XRPD pattern?

22 A Would you mind repeating that? Sorry.

1 My mind drifted.

2 Q Yeah. Which was it, Liu's
3 Recrystallization Procedure or Liu's
4 Isomerization and Recrystallization
5 Procedure that resulted in the claimed
6 XRPD pattern?

7 A Well, it actually should be the plural.
8 It should be "procedures." Blame it on
9 public school education.

10 Q All right. Quickly, I just want to jump
11 back to something. Earlier, we were
12 looking at the USP on XRPD, and I was
13 wondering if there are any, like,
14 standard textbooks or, like, you know,
15 the main treatise that you would
16 recommend to somebody about proper XRPD
17 analysis and procedure?

18 A Most of the modern textbooks are
19 advanced. They deal with techniques
20 that are way beyond on the scope of what
21 we're looking at. You have to go back
22 to some of the older textbooks. And the

1 classic one is Cullity, C-U-L-L-I-T-Y.
2 I think it's the B.D. And the most
3 recent version is Cullity and -- I
4 forget who the new coauthor is. But
5 there is a third edition floating
6 around.

7 There also is a book by Smith. You
8 know, we're talking about books that go
9 back to the '70s. I used to have half a
10 dozen books in that era. I simply have
11 forgotten the names of most of them. I
12 simply don't use them very often.

13 Q I appreciate that.

14 Now, what I want to do is turn to
15 Dr. Bihovsky's declaration, which is
16 marked as Intas Exhibit 1033 in this
17 proceeding. Maybe we can get that up on
18 the screen to Paragraph 74.

19 Paragraph 74, which is Page 46.

20 All right. Dr. Mayo, so we're at
21 Dr. Bihovsky's declaration, Intas
22 Exhibit 1033, Paragraph 74, and there,

1 Dr. Bihovsky says:

2 "I followed the procedures outlined
3 in Liu to obtain highly pure
4 (Z)-endoxifen. I sent the
5 resulting crystalline solids of the
6 (Z)-endoxifen to Dr. Steve Miller
7 at H&M Analytical Services for XRPD
8 testing."

9 Do you see that?

10 A Yeah.

11 Q Does Dr. Bihovsky describe how he
12 prepared and isolated the samples of
13 shipment to Dr. Miller?

14 A No, not in this document.

15 Q Do you know, personally, how the samples
16 were isolated and prepared for the
17 shipment to Dr. Miller?

18 A No.

19 Q Does Dr. Bihovsky explain whether those
20 samples were temperature controlled
21 during shipment?

22 A Not in this document, no.

1 Q Does Dr. Bihovsky explain whether the
2 samples were controlled for humidity
3 during the shipment?

4 A Again, not in this document, no.

5 Q You're saying "not in this document."
6 Is there some other document you're
7 aware of where this is described?

8 A I don't know. I don't know about all
9 the documents in this case, so there may
10 be others.

11 Q But you're not aware of any other?

12 A I'm not aware of any, no.

13 Q So in this paragraph, Dr. Bihovsky says
14 what he sent to Dr. Miller were, "the
15 resulting crystalline solids," right?

16 A That's correct.

17 Q So what Dr. Bihovsky is saying here is
18 what he sent Dr. Miller was something in
19 solid form, right?

20 A A crystal liquid. Solid may have two
21 meanings. Solid may mean that all the
22 individual grains are compacted together

1 into a single entity, but solids may
2 also mean a state of the matter. A
3 solid versus liquid versus gas. And I
4 think in this context, it simply means
5 that it's a nonliquid, nongaseous.

6 Q What's your basis for going with that
7 interruption as opposed to the other one
8 that you posited?

9 A It's obviously not a liquid, because the
10 diffraction pattern would not have been
11 like it appeared. It would have been
12 very different if it were a liquid.

13 Q You described another possible
14 interpretation as, you know, one compact
15 unit, one form. Why? What's your basis
16 for saying that's not the correct
17 interpretation here?

18 A Because used the words solids, so I
19 assume what he is sending are powders.

20 Q And what's your basis for that
21 assumption?

22 A Because I know that the materials were

1 prepared by precipitation and
2 precipitation always produces powders.

3 Q Okay. Let's go back to your
4 declaration.

5 A Okay. I've got it.

6 Q Okay. And here, in Paragraph 23, does
7 Dr. Miller explain the packaging or
8 manner in which he received the samples
9 from Dr. Bihovsky?

10 A It's a question from memory, since I
11 don't have the document here.

12 Q We're in your declaration, Paragraph 23.

13 A Yeah, you're referring to -- you're
14 asking me whether Miller's Appendix B --

15 Q No, I'm asking you -- you go.

16 A I answered the question from memory, and
17 the answer would be that there was
18 nothing in Dr. Miller's letter report
19 that would indicate how the samples were
20 received.

21 Q Thank you. And there's nothing in your
22 declaration either, that provides that

1 information, correct?

2 A Other than a reference to Dr. Miller
3 Appendix B.

4 Q Similarly, there's nothing in your
5 declaration that describes how the
6 samples were stored in between when
7 Dr. Miller received them to when he
8 performed the analysis?

9 A Well, as I described before, H&M would
10 reproduce the shipping conditions. So
11 if the samples were sent in a cold box,
12 they would be put into the refrigerator.
13 If they were sent at room temperature,
14 they would be stored at room
15 temperature.

16 Q And where in your declaration does it
17 say that H&M reproduced shipping
18 conditions?

19 A It doesn't, but I know the standard
20 operating procedure.

21 Q Do you know whether Dr. Miller and
22 Dr. Bihovsky had any discussions about

1 the preparation or shipment of the
2 samples that are not outlined in your
3 declaration or Dr. Bihovsky's
4 declaration?

5 A No. I don't know about any
6 communication they had.

7 Q Earlier you said you knew that the
8 experiments that Dr. Miller performed
9 were done at room temperature.

10 Do you recall that?

11 A Yes.

12 Q Where in this declaration does it
13 discuss the temperature that the
14 experiments were performed at?

15 A It doesn't describe the temperature in
16 which it was done, but I know that it
17 was done at room temperature because H&M
18 does not have high temperature
19 capability.

20 Q And where is that in your report?

21 A It's not. High temperature capability
22 on diffractometers, it's very rare. So

1 it's basically standard procedure.

2 Q Then, earlier we also discussed things
3 that could cause shifts in the
4 polymorphs and one of them was grinding
5 or excessive grinding of the material.
6 And you said that you were -- you didn't
7 see any evidence that that has occurred
8 in this case.

9 And what evidence is there that
10 that hasn't occurred?

11 MR. MENCHACA: Objection, form.

12 A I think you're misquoting what I said.
13 What I said previously is that, yes,
14 maybe due to things like sample
15 displacement errors, but that's not the
16 case in the H&M equipment, using a zero
17 background holder, so that problem is
18 eliminated. Shifts may also be caused
19 by things like strains or stresses in
20 the material, but I don't see that
21 either. Because if there were strains
22 in the material, the peaks would be

1 broaden. And I don't see a broadening
2 in the diffraction piece. So there is
3 no evidence whatsoever that any of the
4 causes of peak shifts were present.

5 Q Circling back just a little bit, I just
6 want to make sure we are clear on this.
7 What do you know about what was done to
8 the sample between when Dr. Miller
9 received it and when he tested it in
10 this case?

11 A If Dr. Miller had done anything to the
12 sample between receiving it and testing
13 it, it would have been described in his
14 report with Dr. Bihovsky. In standard
15 practice, that is required. So since
16 his report does not discuss any
17 processing of the sampling, I'm
18 convinced that he did not do anything.

19 Q So it's your understanding that
20 Dr. Miller received the sample and
21 immediately tested it?

22 A Yes. For example, I can tell from the

1 shape of the diffraction peaks that the
2 materials were not milled in any way.
3 If the materials had been milled, the
4 diffraction peaks would have been rather
5 broad. In diffraction patterns that he
6 obtained, there was a good separation
7 between closely spaced peaks, and that
8 would not have happened if the material
9 had been milled either by bone milling
10 or mortar and pestle.

11 Q Then circling back to Paragraph 23, we
12 touched on this a little bit already.
13 The last sentence says that you
14 understand that the experimental test
15 and analysis conditions used for the
16 XRPD testing was intended to be attached
17 to Dr. Miller's declaration as
18 Appendix B, but was not actually
19 attached.

20 Do you understand that?

21 A Again, I received a copy of an email
22 between the two law offices that

1 indicated that Appendix B had been
2 inadvertently omitted and that email was
3 transmitting the Appendix B that would
4 correct the record.

5 Q When did you receive that email?

6 A At the beginning of my work with
7 counsel.

8 Q Approximately what month?

9 A In the past month, I've only been
10 working this a month.

11 Q Okay.

12 Aside from Appendix B, your
13 declaration doesn't report the
14 experimental analysis conditions used in
15 Dr. Miller's experiments, right?

16 A The experimental conditions can be
17 gleaned from the diffraction experiments
18 themselves. And my knowledge of the
19 equipment. So for example, in the graph
20 showing the diffraction patterns, I can
21 see what the range is and I also know
22 what the step size is, it's always

1 .0167-degrees. And I can tell from the
2 intensity that the intensity was very
3 good, they probably used 250-seconds
4 counting time. So I have a pretty good
5 idea of what the testing conditions
6 were. So I was not surprised when I
7 actually saw the table.

8 Q And none of that is specified in your
9 declaration, correct?

10 A No. Excuse me. My -- referring to
11 Appendix B and Miller's report covers
12 that. There's no need for me to
13 duplicate it. Excuse me.

14 Q Right, but just to be clear, that that
15 separate analysis that you just gave
16 about, you know, I can tell from the
17 peaks the experimental conditions,
18 that's not in your declaration, right?

19 A Right, that would be redundant.

20 Q You mentioned this earlier, you work or
21 you have worked in the past as an editor
22 for a journal or a publication, right?

1 A Yes.

2 Q And what was your experience there?

3 A Well, a couple of positions. One is I
4 was an associate editor for the journal
5 Powdered Diffraction. I did that for
6 several years, I don't remember exactly
7 how many, and there reviewed papers that
8 were submitted for analysis, I'm sorry
9 for publication, and my job was to
10 review the work that was submitted for
11 accuracy or things like preferred
12 orientation to determine the reliability
13 of the data and so forth. My major job
14 was an editor for the Polymer
15 Diffraction file, which is the database
16 that I referred to. And in that job, I
17 analyzed 1,000 papers per year, where I
18 extracted information, such as the type
19 of machine used to test conditions, the
20 materials were processed. And then I
21 analyzed the patterns for the quality of
22 the data, I looked for mistakes,

1 referred orientation and I assigned a
2 quality rating to each of the patterns,
3 which then carried through to the
4 database to try to improve the quality
5 of those. I also had several other side
6 jobs with the ICDD dealing with various
7 publications. So I did a lot of work
8 over a lot of years dealing with how
9 other people do x-ray diffraction work.

10 Q When you're reviewing other people's
11 work, what information would you want to
12 see to determine whether it was reliable
13 and accurate?

14 A Well, relied upon the authors to supply
15 some of the basic information. If that
16 was not supplied in the paper then we
17 would write to the authors and ask for
18 the information and they usually
19 provided it. I then developed computer
20 programs which numerically analyzed the
21 patterns, you would test the validity of
22 the data, you would look for things like

1 systematic errors, to test the data
2 against models of the crystal structure
3 that was being proposed. So there was a
4 lot of added value in the published data
5 for any particular material.

6 So basically it was trying to
7 really beef up the database and try and
8 provide a more enhanced scientific
9 basis.

10 Q And you said you would need the basic
11 information from the paper and if not
12 you would get it from the author, what
13 basic information are you referring to
14 there?

15 A The type of diffractometer, for example,
16 Debye-Scherrer versus Guinier, versus
17 diffractometer versus synchrotron. The
18 radiation that was used, if there was
19 copper, chrome, or lithium, the step
20 size that sort of information. That was
21 the important stuff.

22 Q When you're peer reviewing a paper,

1 would you accept a paper into a journal
2 if you didn't have that information?

3 A No.

4 Q Why not?

5 A Because the computer programs that I
6 developed would then independently
7 determine a lot of that information
8 based upon prior knowledge.

9 And then we would test numerically
10 the quality of the data. And we would
11 go through each of the peaks and compare
12 the peak position to a calculated peak
13 position and look for the difference
14 between the two. And then based upon
15 the average difference between -- the
16 average difference of all the peaks, we
17 would then assign what's called the
18 quality mark. Which would give a reader
19 of the database, an instant analysis of
20 whether the data is reliable or not. We
21 would use something like a star to
22 indicate that it's high quality data, an

1 R value would indicate that there's a
2 lot of additional information that was
3 supplied by the author. So we had
4 several quality marks that were used to
5 give a visual indication of whether the
6 data is reliable or not.

7 Q And if you were missing that information
8 from the author and you had to generate
9 it yourself, would that be more likely
10 to result in an unreliable score?

11 A Possibly. It would depend upon the
12 data. If the data was good and there
13 was information missing like the x-ray
14 radiation wavelength, that would not be
15 a pillar, you could certainly live
16 without it.

17 Q What would be --

18 A Sometimes the author would supply all
19 that information, but the data was
20 garbage, I would reject the pattern
21 (Indiscernible.) So the criteria was a
22 bit flexible and that was my job to put

1 some human eyes on the data rather than
2 to rely solely on the authors or solely
3 on number crunching by computer.

4 Q And you said that you could live without
5 that radiation type, for example, is
6 there a certain data you couldn't live
7 without?

8 A Yes. The reason is that there were
9 typically only three radiation
10 wavelengths that are used in x-ray
11 diffraction and I can easily determine
12 by observation which wavelength was
13 used.

14 Q Right. So now you gave us an example of
15 something you could live without. My
16 question is, conversely, is there
17 information you couldn't live without
18 and still make a reliability
19 determination?

20 A Sure. Sometimes the authors would only
21 report the intensity -- I'm sorry, the
22 peak positions, but not report the

1 intensities. And I cannot live without
2 the intensity values, because that's
3 important for phase identification. But
4 that's an example of something I could
5 not live without. Also, if the author
6 did not indicate that material was phase
7 pure I could not live without that piece
8 of information.

9 Q Are there any other sort of things you
10 couldn't live without?

11 A Those are the two big ones. Those are
12 ones I can think of.

13 Q Okay.

14 A To summarize, my job was to be the
15 gatekeeper trying to keep the quality of
16 the database reliable.

17 Q Moving away from the database, you said
18 you also did like publications, too,
19 like journal publications; is that
20 correct?

21 A Based on my research.

22 Q You edited journal publications as well?

1 A Oh, yeah, I was an editor for the
2 journal Powder Diffraction and I was the
3 editor for new data.

4 Q When you were peer reviewing submissions
5 to that journal, what types of
6 information were you looking for in peer
7 review to determine whether the data was
8 reliable and could be published in the
9 journal?

10 A Well, the papers that were submitted
11 were identical to the type of paper that
12 I would receive when reviewing the
13 database. I would perform the same sort
14 of analysis on the review of the paper
15 submissions that I would do for the
16 database. I would look for the
17 information about how the testing was
18 performed, I would look for information
19 about how the sample was prepared, I
20 would then look for the numerical data
21 reported, peak positions and
22 intensities, then I would do the

1 computer analysis of all that data and
2 so forth. So this analysis was
3 essentially identical to what I would do
4 for the database.

5 Q What would do you in the publication
6 context if you were missing some or all
7 of that information?

8 A Well, when someone submits a paper for
9 publication there's always communication
10 back and forth between the author and
11 editor and we frequently send the papers
12 back to the authors with my comments and
13 requests for data, along with reviews
14 that other people have submitted of the
15 paper. Normally a paper submitted for
16 publication has two or three additional
17 reviews beyond my review. So I submit
18 all that information to the authors and
19 they will in turn return all the new
20 information I requested.

21 Q Would it be typical to publish a paper
22 without information about how the sample

1 was prepared?

2 A No.

3 Q Why not?

4 A Because when someone writes up a paper,
5 they usually are talking about a new
6 material that they are creating. An
7 x-ray diffraction is simply a tool to
8 evaluate that material. The focus of
9 the paper is not the x-ray diffraction
10 side of it, but instead the focus of the
11 paper is the synthesis of the material.
12 So as a result, their emphasis is
13 step-by-step sample preparation. And if
14 they don't supply that information, we
15 would require them to supplement.

16 Q And for other -- just if the -- somebody
17 submitted a paper to the journal
18 publication without a list of
19 experimental conditions, would you
20 similarly follow up for that
21 information?

22 A Normally, experimental conditions would

1 be included in the sample preparation.
2 And by "sample preparation," we mean a
3 synthesis method, not the preparation
4 for the x-ray diffraction. Normally,
5 the sample preparation for XRPD is
6 simple; therefore, only if it required
7 special preparation would they talk
8 about that in the paper.

9 Q How would you know whether it requires
10 special preparation?

11 A They would say so.

12 Q So you wouldn't know ahead of time,
13 though?

14 A No. For example, they might say we have
15 produced a thin film of a material, and
16 we then took the sample, a thin film,
17 and we removed it from the substrate and
18 we used an adhesive to attach it to
19 (indiscernible).

20 (Reporter clarification.)

21 A Let me repeat the last paragraph or so.
22 When they talked about special

1 preparation for XRD testing, they would,
2 say, remove the thin film from the
3 substrate and then glue the thin film
4 onto a plate of silicon and insert it
5 into a special molding. That would be
6 an example of the preparation for XRD.
7 Normally, they did not describe the
8 preparation of XRD because they used
9 standard procedures.

10 Q They will say something, though, like,
11 we used standard procedures, for
12 example? Would you expect to see
13 something like that?

14 A No. If they produced a powder, for
15 example, everyone skilled in the art
16 knows how they prepared the sample.
17 There's no point in wasting space in
18 describing when there's a routine
19 process.

20 Q Is there information in your declaration
21 about whether Dr. Miller used the same
22 experimental conditions for all the

1 analyses that he did?

2 A Well, Appendix B says that he --
3 Dr. Miller's Appendix B says that he
4 used a certain set of conditions to run
5 the samples.

6 Q And apart from Appendix B, is there
7 information about the experimental
8 conditions that he used for both
9 samples --

10 A No. What is in Appendix B is more than
11 sufficient.

12 MR. BERMAN: We'll take a break here.
13 Been going for about another hour.

14 THE WITNESS: I prefer to continue on
15 after a short break, if you don't mind.

16 (Whereupon, a recess was taken
17 from 12:03 PM until 12:12 PM.)

18 BY MR. BERMAN:

19 Q Dr. Mayo, did you have any discussions
20 with your counsel during the break?

21 A No.

22 Q All right. Let's move to Paragraph 24

1 of your declaration, please. And in
2 Paragraph 24 you recite the results that
3 Dr. Miller received from his XRPD
4 analyses in table form, right?

5 A Correct.

6 Q And then in Paragraph 25, you're
7 presenting those same results in
8 graphical form?

9 A Correct.

10 Q And then if you could please leave that
11 open but also turn to Figure 9 in
12 Exhibit 1001, the '151 Patent.

13 Now, on the one hand we have
14 Dr. Miller's experimental results in
15 Paragraphs 24 and 25, and on the other
16 hand we have Figure 9 of the
17 '151 Patent, which shows a list of XRPD
18 peaks, right?

19 A Yes.

20 Q And have you compared each of the peaks
21 of Figure 9 to Dr. Miller's results to
22 determine whether they match?

1 MR. MENCHACA: Objection. Form.

2 A Each and every peak?

3 Q Each and every peak.

4 A Yes, I have.

5 Q And do they?

6 A Up to a range of 30 degrees.

7 Q I'm sorry. You compared them up to a
8 range of -- you said 30 degrees?

9 A 30 degrees. The range on that is
10 limited to 30 degrees. It's that it's
11 custom in the x-ray diffraction field
12 for organic materials to deem a
13 diffraction pattern above 30 degrees
14 useless. Therefore, no one uses peaks
15 beyond that point.

16 Q Why is that?

17 A Because there was so many peaks, and
18 they are all weak, and a lot of the
19 peaks will overlap. You get no useful
20 information from those regions. The
21 important information comes from the
22 strong peaks at the lower angles.

1 Q So focusing your attention on
2 Paragraph 24, the table for Liu's
3 Recrystallization Procedure. About
4 halfway down it lists three peaks at
5 21 degrees, right?

6 A You're referring to the table on
7 Page 14?

8 Q Yeah.

9 A What peak is that?

10 Q So we see three peaks at 21 degrees or
11 thereabout, right?

12 A Yep.

13 Q And then if we go to Figure 9 of the
14 patent, that only has two peaks around
15 21, right?

16 A No, diffraction patterns have three
17 peaks between 21 and 22 degrees.
18 Figure 9 of the '151 Patent, that is
19 three peaks.

20 Q What are they?

21 A 20.951, 21.320, 21.745 in Figure 9.

22 Q Isn't the 20.9.1 over 2 degrees away

1 from -- withdrawn.

2 Isn't the 20.9.1 over 0.2 degrees
3 away from the value in Dr. Miller's
4 table, which is 21.133?

5 A Actually, I would refer you to Table 8
6 of the '151 Patent, which is around
7 Column 79. The author himself records
8 three peaks very close to the 21-degree
9 region: 20.9, 21.3, and 21.7.

10 Q I only you see two peaks around 21 in
11 Table 8. When I'm looking at
12 Paragraph 24, I see 20.848, 21.133,
13 21.315, 21.735. And when I look at
14 Table 8, I see 20.9, 21.3, 22.1, and
15 then it goes 22.5.

16 So do you agree --

17 A You missed a peak at 21.7.

18 Q 20.9, 21.3, 21.7, 22.5. So that's
19 three --

20 A You're talking about the difference
21 between 20.9 that comes from the
22 '151 Patent and 20 point -- 21.13 from

1 Miller's data. The difference is
2 0.23 degrees, and '151 Patent allows
3 peaks to be within plus or minus
4 3 degrees. So according to the
5 '151 Patent, two peaks match.

6 Q So you don't agree that there's an extra
7 peak here?

8 A No.

9 Q I'm going to circle back to something
10 you said sort of towards the beginning
11 of this discussion, Dr. Mayo, which is
12 that you don't consider peaks beyond
13 30 degrees in organic materials; is that
14 right?

15 A Yes.

16 Q So if there were additional peaks,
17 either in Dr. Bihovsky's samples or in
18 the figures in the '151 Patent beyond
19 30 degrees that didn't match, that
20 wouldn't affect your opinion?

21 A A single extra peak or an extra couple
22 of peaks would not change the overall

1 impression. The phase identification is
2 based upon the strongest peaks in the
3 pattern. And so therefore, all of the
4 strong peaks in the '151 Patent
5 Figures 9 and 10 are present in the two
6 Bihovsky samples.

7 And not only do the peak positions
8 match to within both the USP standard
9 and '151 allowable error, but the
10 intensities match also, within a
11 reasonable number.

12 Q What do you consider a reasonable number
13 for the intensities matching?

14 A Well, first of all, USP 941 says that
15 intensities tend to be unreliable. In
16 the old days, USB 941 would just say
17 plus or minus 20 percent. And we're
18 certainly within the plus or minus
19 20 percent, not a perfect match. For
20 example, one peak is 47 percent in one
21 pattern and 35 percent in the other
22 pattern, that would be considered a good

1 match. But we're talking about
2 10 percent difference.

3 Q You said that the current version of the
4 USP says that intensities are
5 unreliable; is that right?

6 A Yeah, I think -- if I can find it. I
7 don't see it right away, but you'll have
8 to take my word for it. I'll find it
9 somewhere.

10 They have eliminated that as a
11 potential matching source.

12 Q Earlier, you said that you wouldn't rely
13 on data if you didn't have the
14 intensities. How do you kind of
15 reconcile that with the USP saying that
16 they're unreliable?

17 A Well, they're unreliable as the primary
18 source of identification. But as
19 secondary measures of identification are
20 useful. For example, the phase of
21 identification is done by virtue of a
22 search engine, and the search engine

1 will look for the strongest three peaks
2 or the strongest five peaks, sometimes
3 take permutations of the five strongest
4 peaks and even up to the strongest eight
5 peak and compare them between the known
6 and the unknown samples.

7 So it does use the intensities
8 indirectly. It doesn't compare the
9 exact values of the intensities. That's
10 an example of the secondary use of the
11 intensity values.

12 MR. BERMAN: I have no further
13 questions, but I do want to state for
14 the record that we object to Appendix B
15 and to any testimony about Appendix B.
16 It's not in the record, as we've
17 discussed with counsel, and we reserve
18 our rights to move to strike at the
19 appropriate time.

20 MR. MENCHACA: I'm going to have about a
21 half hour of questions. Dr. Mayo,
22 should we proceed now, or would you like

1 to take a break?

2 THE WITNESS: If it's up to me, I would
3 say let's plow ahead.

4 EXAMINATION BY

5 MR. MENCHACA:

6 Q I'll go ahead and start then.

7 Earlier, counsel asked you whether
8 you had an understanding that Dr. Miller
9 had performed his analysis according to
10 the standard operating procedures of
11 H&M.

12 Do you recall that?

13 A Yeah.

14 Q And your answer was yes?

15 A Yes.

16 Q You also indicated that you had reviewed
17 a document that enabled you to make that
18 conclusion.

19 What document was that?

20 A I reviewed both the report by
21 Dr. Bihovsky, and I also reviewed
22 Dr. Miller's declaration.

1 Q Do you remember the specific details
2 that were in the report from Dr. Miller
3 to Dr. Bihovsky, that enabled you to
4 make the conclusion that Dr. Miller
5 followed the standard operation
6 procedures of H&M?

7 A Yeah, so Dr. Miller reported the
8 identification number of the
9 diffractometer, which immediately told
10 me that is the machine that is under the
11 FDA control. And then he also described
12 the angular range of the scan, the step
13 size, the counting time. He specified
14 the type of radiation. The standard
15 holder. He also described the various
16 kinds of slits that we used, both for
17 the incident and the diffractive beam
18 side and the columnation. And all of
19 that is in the standard operating
20 procedure. And all of those varied for
21 other types of testing.

22 So the specific use of that set of

1 combinations of variables is what is
2 used for testings pharmaceutical.

3 Q Do you remember those specific
4 details -- do you remember those
5 specific details that you just
6 mentioned, for example, the machine, the
7 type of radiation, the angle, and things
8 of that nature?

9 MR. BERMAN: Objection, form.

10 A He mentioned a serial number, which I
11 believe ended in 776. He used copper
12 radiation. He used a pixel detector
13 with a step size of 0.1667 degrees. He
14 used a range of 3 degrees to 50 degrees,
15 mounting time of 250 seconds. The
16 incident slip was .02 degrees, the
17 receiving slip was double that. He used
18 a nickel filter, I think I said copper
19 radiation. And then he used a zero
20 background holder.

21 And then for the analysis, he used
22 a computer program called JADE Version

1 9, so I think that's -- those are all
2 the details in the work.

3 Q Was there any other information that you
4 felt was helpful in you coming to the
5 conclusion that Dr. Miller followed the
6 standard operating procedures of H&M
7 when he performed the experiments that
8 he reported to Dr. Bihovsky?

9 MR. BERMAN: Objection.

10 A Well, the key thing is what is not
11 included in the cover letter. If
12 Dr. Miller had changed the standard
13 operating procedure, he is required to
14 notify the customer of that. And the
15 fact that there is no such description
16 in the cover letter, tells me that he
17 followed the standard operating
18 procedures to the letter. And since
19 you're dealing with product from a
20 pharmaceutical process, which involved
21 precipitation, there is no reason to
22 change the standard operating procedure.

1 So I had set up the SOP years ago for
2 exactly that kind of situation.

3 Q Other than the information that you just
4 provided, is there any additional
5 information that you believe was
6 reflected in that letter from Dr. Miller
7 to Dr. Bihovsky, that would support your
8 conclusion that Dr. Miller followed the
9 standard operating procedures of H&M?
10 MR. BERMAN: Objection. Outside the
11 scope.

12 A No. I think that was it. He described
13 the details perfectly, the SOP. He did
14 not indicate any deviation from the SOP.
15 And according to the GMP requirements,
16 he's not allowed to deviate from the SOP
17 without writing up some sort of
18 deviation report; so therefore, I'm
19 confident that no deviations were done.

20 Q Dr. Mayo, throughout today's deposition
21 counsel asked you many, many questions
22 about Appendix B and the fact that it's

1 not included in the report.

2 Is there any, to your recollection,
3 any testimony that counsel asked you
4 about related to Appendix B that you
5 were not able to answer because you
6 could not remember what was in
7 Appendix B?

8 MR. BERMAN: Objection, form.

9 Objection, scope. Foundation.

10 A When I saw the email between the two law
11 firms, there was an explanation that
12 Appendix B had been inadvertently
13 admitted when Dr. Miller's declaration
14 was submitted. So the Appendix B was
15 attached, and as a result, I was able to
16 obtain a copy of Appendix B. I was
17 simply downloading it from that email. I
18 don't remember who sent or who received
19 the emails, but I do have a copy of the
20 emails somewhere in my records.

21 Q My question is really more directed not
22 to emails, but the Appendix B.

1 And earlier in your testimony,
2 counsel asked you many questions
3 regarding Appendix B and whether that
4 information was in your report or not.

5 Were there, to your recollection in
6 your testimony today, any questions that
7 counsel asked you that you were not able
8 to answer because you did not have
9 immediate access to Appendix B?

10 MR. BERMAN: Same objections.

11 A No. Appendix B is quite short. It
12 consists of two tables and two graphs,
13 and it had a couple of paragraphs and a
14 cover letter. So I remembered it
15 explicitly, I have a copy of it in my
16 records. So when I was discussing
17 Appendix B with counsel, I had full
18 recollection of what was in there. So I
19 did not have any problem of being
20 up-to-date with what was in there.

21 Q In today's earlier testimony, you
22 didn't --

1 A That's correct. Yeah, I didn't have any
2 problems. I remembered it explicitly.

3 Q Other than the details that you provided
4 to us regarding your understanding of
5 Dr. Miller's -- strike that.

6 Is there any other information of
7 which you are aware that supports your
8 understanding that Dr. Miller followed
9 the standard operating procedures of H&M
10 when he performed the testing that he
11 reported to Dr. Bihovsky?

12 MR. BERMAN: Objection, scope.

13 A No. I think I covered that.

14 MR. MENCHACA: I have no further
15 questions.

16 MR. BERMAN: I have a few additional
17 questions based on counsel's redirect.

18 EXAMINATION BY

19 MR. BERMAN:

20 BY MR. BERMAN:

21 Q Dr. Mayo, when you were speaking to
22 counsel just now, you provided a list of

1 experimental conditions from Appendix B
2 or what counsel has represented as
3 Appendix B, right?

4 A (Indiscernible.)

5 Q Were you reading those from a list
6 somewhere or did you have those
7 memorized.

8 A I have them memorized.

9 Q Okay.

10 MR. BERMAN: I have no further
11 questions. Thank you for your time,
12 Dr. Mayo.

13 MR. MENCHACA: I have one further
14 question.

15 EXAMINATION BY

16 MR. MENCHACA:

17 BY MR. MENCHACA:

18 Q Dr. Mayo, you commented that the list
19 that you recited was from your memory.

20 Why do you have such a good memory
21 of all those details?

22 A When I wrote the SOP years ago I also

1 built the diffractometer and I purchased
2 the detector. And I personally had run
3 thousands of the experiments on that
4 machine, testing various forms of
5 pharmaceuticals always using the same
6 test conditions. And I had to reenter
7 that information into various reports
8 that I wrote, so just think of it as
9 muscle memory more than anything else.

10 MR. MENCHACA: I have no further
11 questions.

12 MR. BERMAN: Same.

13 THE WITNESS: Okay. Thank you very
14 much.

15 MR. MENCHACA: Yes, we'll reserve
16 signature.

17 MR. BERMAN: I'll just note for the
18 record that our understanding is there's
19 no errata as of right, but it's
20 something we can discuss at a later
21 time.

22 (Whereupon, this examination

1 was concluded at 12:39 PM)

2

3

4

5 WILLIAM MAYO PH.D.

6

7

8 Subscribed and sworn to
9 before me on this ____ day
10 of _____, _____.

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Notary Public

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I N D E X

WITNESS: WILLIAM MAYO, PH.D.

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1 CERTIFICATE OF SHORTHAND REPORTER - NOTARY PUBLIC

2
3 I, KIARA MILLER,
4 a Shorthand Reporter and Notary Public of the
5 State of New York, do hereby certify:

6
7 That WILLIAM MAYO, PH.D., the
8 witness whose deposition is hereinbefore set
9 forth, was duly sworn by me before the
10 commencement of such deposition and that such
11 deposition was taken before me and is a true
12 record of the testimony given by such witness.

13
14 I further certify that the adverse
15 party, PETITIONER, was represented
16 by counsel at the deposition.

17
18 I further certify that the deposition
19 of WILLIAM MAYO, PH.D., occurred via Zoom
20 videoconference, on the 9th day of January, 2026,
21 commencing at 9:57 a.m. to 12:39 p.m.

22

1 I further certify that I am not related to
2 any of the parties to this action by blood or
3 marriage, and that I am in no way interested
4 in the outcome of this matter.

5
6 *Kiara Miller*
7 _____

8 KIARA MILLER
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