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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NOVARTIS PHARMACEUTICALS CORPORATION,

Petitioner,

v.

REGENTS OF THE UNIVERSITY OF MICHIGAN

and UNIVERSITY OF SOUTH FLORIDA,

Patent Owners.

Case IPR2023-01346

U.S. Patent No. 10,633,344

- - -

DEPOSITION OF

ROBIN D. ROGERS, Ph.D.

May 23, 2024

9:00 a.m. EDT

4 Times Square

151 West 42nd Street

New York, New York

REPORTED BY: MARIE FOLEY, RMR CRR

DIGITAL EVIDENCE GROUP

1730 M Street, NW, Suite 812

Washington, D.C. 20036

(202) 232-0646

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Deposition of ROBIN D. ROGERS,

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Ph.D., held at 4 Times Square, 151 West

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42nd Street, New York, New York,

6

commencing at 9:00 a.m. EDT, on the above

7

date, before Marie Foley, a Registered

8

Merit Reporter, Certified Realtime

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Reporter and Notary Public.

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

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3 ON BEHALF OF PLAINTIFF:

4 VENABLE, LLP

5 BY: CHRISTINA SCHWARZ, ESQUIRE

6 LAURA FISHWICK, ESQUIRE

7 ALEXIS M. McJOYNT, ESQUIRE

8 151 West 42nd Street, 49th Floor

9 New York, New York 10036

10 PHONE: 212.307.5500

11 EMAIL: Cschwarz@venable.com

12

13

14 ON BEHALF OF DEFENDANT:

15 FISH & RICHARDSON P.C.

16 BY: KELLY A. DEL DOTTO, ESQUIRE

17 AHMED DAVIS, ESQUIRE (via Zoom)

18 222 Delaware Avenue

19 17th Floor

20 Wilmington, Delaware 19899

21 PHONE: 302.778.8403

22

23 VIDEOGRAPHER:

24 Ingrid Rodriguez

25

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3 EXAMINATION OF ROBIN D. ROGERS, Ph.D.:

4 BY: MS. DEL DOTTO..... 7

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9 E X H I B I T S

10 NO. DESCRIPTION PAGE

11 Rogers Notice of Deposition of 11

12 Exhibit 2003 Dr. Robin D. Rogers in

13 IPR2023-01346

14 Rogers Notice of Deposition of 11

15 Exhibit 2004 Dr. Robin D. Rogers in

16 IPR2023-01347

17 Rogers Etter article, 1990 36

18 Exhibit 2005

19 Rogers Peterson article, 2002 42

20 Exhibit 2006

21 (REPORTER'S NOTE: All quotations from

22 exhibits are reflected in the manner

23 in which they were read into the

24 record and do not necessarily denote

25 an exact quote from the document.)

1 - - -

2 9:00 a.m. EDT

3 - - -

4 THE VIDEOGRAPHER: This is file
5 number 1 of the videotaped deposition
6 of Robin Rogers in the matter of
7 Novartis Pharmaceuticals Corporation,
8 Petitioner, versus Regents of the
9 University of Michigan and University
10 of South Florida, Patent Owners, in
11 the United States Patent and Trademark
12 Office Before the Patent Trial and
13 Appeal Board.

14 This deposition is being held at
15 Venable, LLP, New York, New York on
16 May 23rd, 2024. The time on the video
17 screen is 9:00 a.m.

18 My name is Ingrid Rodriguez. I
19 am the legal videographer from Digital
20 Evidence Group. The court reporter is
21 Marie Foley in association with
22 Digital Evidence Group.

23 Will counsel please introduce
24 themselves for the record.

25 MS. DEL DOTTO: Kelly Del Dotto

1 of Fish and Richardson on behalf of
2 the patent owners.

3 MS. SCHWARZ: Christina Schwarz,
4 Laura Fishwick, and Alexis McJoynt
5 from Venable on behalf of Novartis.

6 MR. DAVIS: This is also Ahmed
7 Davis from Fish and Richardson, I'm on
8 the Zoom.

9 THE VIDEOGRAPHER: Will the
10 court reporter please swear in the
11 witness.

12 THE STENOGRAPHER: If I could
13 ask you to raise your right hand,
14 please.

15 Do you swear or affirm the
16 testimony you give will be the truth,
17 the whole truth, and nothing but the
18 truth today?

19 THE WITNESS: I do.

20 THE STENOGRAPHER: Thank you.

21 - - -

22

23

24 ROBIN D. ROGERS, Ph.D., the Witness herein,

25 having been first duly sworn by a

1 Notary Public in and of the State of
2 New York, was examined and testified
3 as follows:

4 EXAMINATION BY

5 MS. DEL DOTTO:

6 Q. Good morning, Dr. Rogers.

7 A. Good morning.

8 Q. It's nice to meet you.

9 Can you please state your full
10 name and residential address for the
11 record?

12 A. My name is Robin Don Rogers, and
13 my address is 9 Oakwood Court in
14 Tuscaloosa, Alabama.

15 Q. I understand you were deposed in
16 this case, or relating to this case in a
17 district court litigation prior to this
18 IPR deposition, but prior to the
19 deposition regarding claim construction in
20 the district court litigation between the
21 parties, how many times have you been
22 deposed before?

23 A. I would not be able to give you
24 an exact number. It has been several.

25 Q. Is several more than ten?

1 A. It would be more than ten, but I
2 can't give you an exact number.

3 Q. And have all of those instances
4 where you have been deposed, were you
5 deposed as an expert witness?

6 A. Yes.

7 Q. And did any of those cases
8 involve pharmaceutical formulations of
9 co-crystals?

10 A. I don't believe so, no.
11 You said other cases, right?

12 Q. Correct.
13 And how many times in the cases
14 that you've been deposed have you -- has
15 the subject matter dealt with co-crystals
16 outside of pharmaceutical formulations?

17 A. Crystals in general, I don't
18 remember specifically co-crystals.

19 Q. So approximately how many times
20 have you been deposed as an expert related
21 to crystals in general?

22 A. That would be the majority of
23 the -- the depositions.

24 Oh, I do remember -- no, I'm
25 sorry. I forgot your question.

1 Q. My question was how many times
2 have you been deposed as an expert witness
3 as -- in the context of crystals aside
4 from co-crystals.

5 A. That, again, that would be the
6 majority of them.

7 Q. Do you understand that you're
8 under oath today and that you've sworn to
9 tell the truth?

10 A. I do.

11 Q. And your attorney may make
12 objections, but do you understand that
13 unless instructed to and you choose not to
14 answer, you're obligated to answer the
15 question to the extent you are able?

16 A. That's my understanding.

17 Q. You may ask me to clarify a
18 question, but if you answer it, I will
19 take that as an indication that you
20 understand the question.

21 Is that fair?

22 A. I understand you.

23 Q. If you need to take a break, I
24 just ask that you first answer the
25 question if there's one pending.

1 Is that fair?

2 A. Yes.

3 Q. We need to speak as clearly as
4 possible and avoid talking over each other
5 for the court reporter's sake.

6 Do you understand that?

7 A. Yes.

8 Q. Do you understand you need to
9 provide verbal responses since gestures
10 will not be recorded on the record? Do
11 you understand that?

12 A. Yes.

13 Q. Is there any reason, medical or
14 otherwise, that would prevent you from
15 giving complete and accurate testimony
16 here today?

17 A. I don't believe so.

18 Q. If that changes at any point,
19 will you please let me know?

20 A. Yes.

21 Q. Did you bring anything with you
22 to the deposition today?

23 A. No.

24 Q. No documents?

25 A. No.

1 MS. DEL DOTTO: So, I'd like to
2 mark this as the next exhibit in
3 IPR-1346, which is Exhibit 2003. And
4 this is the Notice of Deposition of
5 Dr. Robin Rogers for the
6 IPR2023-01346.

7 And, counsel, I have a copy.

8 (Rogers Exhibit 2003, Notice of
9 Deposition of Dr. Robin D. Rogers in
10 IPR2023-01346, was marked for
11 identification, as of this date.)

12 MS. DEL DOTTO: And I'd like to
13 mark as the next exhibit the notice of
14 Dr. Robin D. Rogers in IPR2023-01347.

15 (Rogers Exhibit 2004, Notice of
16 Deposition of Dr. Robin D. Rogers in
17 IPR2023-01347, was marked for
18 identification, as of this date.)

19 MS. DEL DOTTO: And, counsel,
20 again I have a copy.

21 BY MS. DEL DOTTO:

22 Q. Dr. Rogers, do you recognize
23 what has been marked as Exhibits 2003 and
24 2004?

25 A. I understand what they are.

1 Q. Do you understand that you are
2 here to testify on behalf of Novartis
3 Pharmaceuticals for two IPR proceedings
4 that are numbered IPR2023-01346 and
5 IPR2023-01347?

6 A. Yes.

7 Q. When were you first retained by
8 Novartis for this matter?

9 A. When you say "this matter,"
10 you're talking about this -- these IPR
11 proceedings?

12 Q. Yes.

13 A. I don't remember the exact date.
14 I believe it was last year.

15 Q. Do you remember the season?

16 A. No.

17 Q. Do you recall if you were first
18 retained for the IPR or the litigation?

19 A. My understanding is that I was
20 retained for the litigation, but I'd have
21 to go back and look.

22 Q. I'm just going to hand you
23 Novartis Exhibit 1001. This is United
24 States Patent 10,633,344.

25 Dr. Rogers, do you recognize

1 this document?

2 A. I do.

3 Q. Is this the patent that you
4 analyzed in forming your opinions in these
5 two IPR proceedings?

6 A. Yes, it is.

7 Q. If I refer to this patent as the
8 '344 patent, will you understand that I'm
9 referring to what's been marked as
10 Novartis Exhibit 1001?

11 A. Yes, I will.

12 Q. Did you read the '344 patent
13 prior to Novartis engaging you in the IPR?

14 A. Yes.

15 Q. Did you read the '344 patent
16 prior to Novartis engaging you in the
17 litigation to the extent that it occurred
18 before you were engaged in the IPR?

19 A. I had seen it.

20 Q. When had -- when did you first
21 see the '344 patent?

22 A. It probably was about the time
23 that it published.

24 Q. What were the circumstances
25 that -- under which you first saw the '344

1 patent?

2 A. At the time, I was the editor of
3 a journal called Crystal Growth and
4 Design, founding editor-in-chief, and this
5 was a -- a patent in the field of
6 co-crystals which I had been developing as
7 a community to publish in the journal.

8 Q. And are you familiar with the
9 inventors that are on the '344 patent?

10 A. I do know them, yes.

11 Q. And how do you know inventor
12 Michael Zaworotko?

13 A. Mike and I graduated with our
14 Ph.D.s in chemistry from the University of
15 Alabama at the same time. So I overlapped
16 with him in graduate school.

17 Q. And another listed inventor is
18 Nair Rodriguez-Hordedo.

19 How do you know Nair?

20 A. Professionally from her work
21 with solubility studies that I also
22 encouraged for publication in Crystal
23 Growth and Design.

24 Q. And Brian Moulton is the third
25 listed inventor.

1 How do you know Brian Moulton?

2 A. I believe I first met Brian when
3 he was a graduate student with Professor
4 Zaworotko, and I have met him several
5 times over the years as well.

6 Q. Have you spoken to Dr. Zaworotko
7 or any of the other inventors since you've
8 been engaged as an expert on either the
9 district court litigation or the IPR?

10 A. I want to make sure I under
11 your -- understand your question, so I'm
12 going to repeat it.

13 I have talked to them since
14 then, not about the litigation or the
15 IPRs.

16 Q. Okay. Thank you for that
17 clarification.

18 And were you communicate --
19 which of the inventors have you
20 communicated with since being engaged on
21 the district court litigation or IPRs?

22 A. I have talked with Dr. Moulton
23 and Dr. Zaworotko.

24 I don't remember if I have
25 talked to Nair recently.

1 Q. And what were the subject matter
2 of your conversation, at a high level
3 without revealing any confidential
4 information?

5 A. It was about an ACS award. It
6 was an award dinner, actually, for our
7 supervisor Dr. Jerry Atwood at an American
8 Chemical Society meeting.

9 Q. And when was that?

10 A. It was Indianapolis, so --
11 again, I wouldn't -- it's got to be either
12 the spring or the fall, but I don't
13 remember the year.

14 Q. You can put that aside for now.
15 If at any point during today's deposition,
16 you need to reference it, please just let
17 me know and we can take a look, okay.

18 I'm going to hand you what's
19 been marked as Novartis Exhibit 1002
20 labeled the "Declaration of Robin D.
21 Rogers, Ph.D. in Support of Petition For
22 Inter Partes Review" and this is in the
23 IPR2023-01346.

24 Dr. Rogers, do you recognize
25 this document?

1 A. I do.

2 Q. Is this the declaration that you
3 signed for IPR2023-01346?

4 A. Yes, that is my signature.

5 Q. And I think you were a step
6 ahead of me, but if you can turn to page
7 203.

8 A. I'm there.

9 Q. And is that the signature that
10 you were referencing?

11 A. Yes, it is.

12 Q. And you signed this declaration
13 on August 27th, 2023?

14 A. That's correct.

15 Q. How much time did you spend
16 preparing this declaration?

17 A. I would not be able to
18 quantitate that for you.

19 Q. Can you provide an estimate of
20 how much time you spent on this
21 declaration?

22 A. I have -- only have general
23 impressions it took a lot of time. But I
24 don't have -- I don't have the number of
25 hours.

1 Q. Do you know if this was more
2 than 25 hours?

3 A. Pretty sure it was more than 25,
4 but again, I just can't give you a -- a
5 quantitative answer.

6 Q. Okay.
7 Do you have an understanding
8 whether it was more than 50 hours?

9 A. Again the higher that you go,
10 the just less uncertain I'm going to be.

11 Q. Okay.
12 How is this declaration --

13 A. Sorry, more uncertain. Excuse
14 me.

15 Q. How was this declaration
16 prepared?

17 A. The declaration was prepared
18 starting with, if I can go through the
19 whole process.

20 MS. SCHWARZ: And, Dr. Rogers,
21 I'll just caution you not to disclose
22 the substance of any confidential
23 communications with attorneys as you
24 go through this process.

25 THE WITNESS: Okay.

1 A. First I was retained in this
2 matter, and then I was given a set of
3 legal instructions. I was given a -- a
4 task, and those are outlined I believe in
5 Appendix B of this IPR. Then I was
6 considering the task, and I reviewed the
7 '344 patent. I reviewed its prosecution
8 history.

9 I don't know how detailed you
10 want this process to be, but it was in the
11 preparation of understanding the case,
12 understanding the patent, developing an
13 understanding of a person of ordinary
14 skill in the art and all of the portions
15 that have gone into the -- the
16 declaration.

17 I provided some initial drafts
18 of sections to the attorneys and then just
19 continued to -- to work on this. I had
20 several discussions with the attorneys
21 about my report. I got some help when I
22 asked for, like, prosecution histories
23 that I thought they could get more easily
24 than me. And then the -- the report
25 evolved from that.

1 Q. You mentioned that you were
2 given a task in -- at the beginning of
3 your work on this IPR.

4 Do you recall what that task or
5 assignment was?

6 A. The -- those are in Appendix B
7 of -- of the report, what I call task.
8 Essentially it's what I was asked to opine
9 on.

10 Q. So Appendix B starts on page 210
11 of your declaration, Exhibit 1002. Is
12 that correct?

13 A. Yes, page 210.

14 Q. So when you say the tasks, are
15 you referring that you were provided legal
16 standards and asked to apply -- asked to
17 provide opinions on the legal standards
18 that are contained in Appendix B?

19 A. No, I was not asked to opine on
20 the legal standards.

21 Q. So what were you asked to do,
22 based on Appendix B?

23 A. I actually put the task at the
24 beginning of the -- the IPR -- I'm sorry,
25 of my declaration.

1 There were a few things in the
2 legal standards where I remembered being
3 asked to -- yeah, so for example, in page
4 215 at page -- paragraph 15 of Appendix B
5 where I indicated I here have been asked
6 to assess whether patent owners are
7 entitled to the benefit of the 2002-2003
8 filing dates of the priority application.
9 So that's an example of what I meant by
10 what I was asked to do.

11 And then in 14 on page 214 I was
12 asked to assess anticipation and
13 obviousness as of 2014.

14 Q. And are those the tasks that you
15 were referring to when you said that you
16 were given tasks at the beginning of your
17 work on this IPR?

18 A. Those and what's written in my
19 declaration at -- at the beginning. I
20 think I explained what I was asked to do.

21 Q. Who did you talk to, aside from
22 counsel, when you were working on this
23 declaration?

24 A. I don't remember talking to
25 anyone.

1 Q. Okay.

2 So you didn't speak to anyone at
3 Novartis?

4 A. No, I didn't speak to anyone at
5 Novartis.

6 Q. Did you speak to anyone else in
7 the relevant field?

8 A. No.

9 Q. Are you aware that Novartis
10 submitted a declaration from another
11 expert, Dr. Appel?

12 A. I am. And I note that in my
13 declarations.

14 Q. Did you speak with Dr. Appel in
15 forming your opinions for this
16 declaration?

17 A. I did not speak to Dr. Appel.

18 Q. Can you turn to paragraph 17 of
19 Exhibit 1002?

20 A. I'm there.

21 Q. And in this paragraph you list
22 certain materials that you considered in
23 rendering your opinions in this
24 declaration, correct?

25 A. Yes.

1 Q. You analyzed the '344 patent,
2 correct?

3 A. Yes.

4 Q. The file history of the '344
5 patent?

6 A. What I call the prosecution
7 history, yes.

8 Q. And you also analyzed the
9 prosecution history of the '344 patent's
10 parent application as well, correct?

11 A. Yes.

12 Q. And then you also considered the
13 materials that are listed in Appendix A,
14 Exhibits 1501 to 1586, correct?

15 A. I reviewed those, yes.

16 Q. Are there any other documents
17 that you considered in rendering your
18 opinions for this declaration that are not
19 listed in paragraph 17 or Appendix A?

20 A. If they're not in there, they
21 are in the declarations themselves and
22 didn't happen to make it into Appendix A,
23 I would have considered those as well.

24 Q. Anything outside of the
25 documents listed in paragraph 17, those

1 cited in your declaration, and those
2 included in Appendix A?

3 A. Not that I relied on for my
4 opinions.

5 Q. Have you analyzed the board's
6 institution decision that was filed on
7 March 13th, 2024?

8 A. I believe I -- I believe I was
9 given a copy of that. I really just don't
10 remember.

11 Q. Is it fair to say then since you
12 don't remember seeing the board's
13 institution decisions, that the opinions
14 in your declaration have not changed in
15 any way?

16 A. My --

17 MS. SCHWARZ: Objection to form.

18 A. My opinions have not changed.

19 Q. Do you have any corrections or
20 clarifications that you need to make to
21 your declaration today?

22 A. I didn't see anything
23 substantial.

24 Q. What did you do to prepare for
25 your deposition today?

1 A. I reviewed my declarations, the
2 documents that went with my declarations,
3 and I met with the attorneys from Venable.

4 Q. Approximately how long did you
5 meet with the attorneys from Venable?

6 A. For about seven hours over --
7 seven hours on two days.

8 Q. Was anyone other than counsel
9 present?

10 A. No.

11 Q. Did you speak with anyone other
12 than counsel to prepare for your
13 deposition today?

14 A. No.

15 Q. Okay. I'm going to hand you
16 what has been marked as Novartis Exhibit
17 1502, the Declaration of Robin D. Rogers,
18 Ph.D. in Support of Petition For Inter
19 Partes Review, and this is for the
20 IPR2023-01347.

21 Dr. Rogers, do you recognize
22 this document?

23 A. I do.

24 Q. Okay.

25 Is this the declaration that you

1 signed for the IPR2023-01347?

2 A. It is.

3 Q. And if you could turn to page
4 226.

5 A. I'm there.

6 Q. Is this your signature on page
7 226?

8 A. It is.

9 Q. And you signed this declaration
10 on August 27th, 2023?

11 A. I did.

12 Q. How much time did you spend
13 preparing this declaration?

14 A. I couldn't give you an estimate
15 of that. It was a lot.

16 Q. Is a lot more than 25 hours?

17 A. Pretty sure it was more than 25.

18 Q. Was it more than 50?

19 A. Again this -- my -- uncertain.
20 I can't quantify the number.

21 Q. Was the declaration for
22 IPR2023-01347 prepared in a similar way
23 that you prepared what's been marked as
24 Exhibit 1002?

25 A. Yes.

1 Q. Were there any differences in
2 how you prepared your opinions that are
3 included in Exhibit 1502 from how you
4 prepared your other declaration for the
5 IPR?

6 A. Obviously the opinions are not
7 the same. The analysis is not -- not the
8 same, but the process was essentially the
9 same.

10 Q. In preparing the opinions that
11 are included in Exhibit 1502, did you
12 speak with anyone at Novartis?

13 A. No.

14 Q. Did you speak with anyone else
15 in the field?

16 A. No.

17 Q. Did you speak with Dr. Appel in
18 forming your opinions that are included in
19 Exhibit 1502?

20 A. I read her reports.

21 I did not speak to her.

22 Q. Did you read Dr. Appel's reports
23 before signing your -- your declarations
24 which are marked as 1502 and 1002?

25 A. Yes.

1 Q. Did you speak to anyone else
2 other than the lawyers in preparing your
3 declaration which has been marked as
4 Novartis Exhibit 1502?

5 A. No.

6 Q. Can you turn to paragraph 17,
7 which I believe is on page 14?

8 A. I'm there.

9 Q. And in this paragraph you
10 identify certain materials that you
11 considered in rendering your opinions
12 for -- that are included in Exhibit 1502,
13 correct?

14 A. Yes.

15 Q. And some of the materials you
16 considered are the '344 patent, correct?

17 A. Yes.

18 Q. You also considered the
19 prosecution history of the '344 patent; is
20 that right?

21 A. Yes.

22 Q. And you considered the
23 prosecution history for the '344 patent's
24 parent application as well; is that
25 correct?

1 A. Yes.

2 Q. And then you also list Exhibits
3 1501 to 1586 in Appendix A as materials
4 that you considered in rendering the
5 opinions in this declaration, correct?

6 A. Can you repeat those numbers?

7 Q. 1501 to 1586.

8 A. Yes.

9 Q. Other than the documents you
10 identify in Appendix A, the documents you
11 identify in paragraph 17, and any
12 documents you cited throughout the
13 declaration that's been marked as Exhibit
14 1502, did you consider any other materials
15 in rendering your opinions for this
16 declaration?

17 A. I did not rely on any other
18 materials.

19 Q. You can put that to the side.
20 I'd like to focus on
21 Exhibit 1 -- Novartis Exhibit 1002, and if
22 you could turn to paragraph 19 of
23 Exhibit 1002.

24 A. I'm there.

25 Q. Paragraph 19 contains the

1 definition of a person of ordinary skill
2 in the art that you applied for purposes
3 of rendering your opinions in this
4 declaration, correct?

5 A. Yes.

6 Q. And your definition remains the
7 same whether you're looking at the
8 analysis from the time period 2002 to 2003
9 or 2014; is that correct?

10 A. The identity -- the definition
11 of the POSA, yes, it's the same.

12 Q. And does your definition of a
13 POSA for your declaration that's marked
14 Exhibit 1002 change at all when you're
15 analyzing claim 16 in your declaration
16 marked as Exhibit 1502?

17 A. I'm sorry, could you repeat
18 that, please?

19 Q. Sure.

20 Did you apply the same -- I'll
21 try to rephrase to make it more clear.

22 Did you apply the same
23 definition of a person of ordinary skill
24 in the art for both of your IPR
25 declarations?

1 A. Yes.

2 Q. Do you think your definition of
3 a person of ordinary skill in the art
4 requires a relatively high level of
5 education and training?

6 MS. SCHWARZ: Objection to form.

7 A. I believe I -- I do, and I note
8 that when I'm analyzing inability.

9 Q. You would agree that your
10 definition of a person of ordinary skill
11 in the art differs from a definition of a
12 person of ordinary skill in the art that
13 the patent owner proposed during claim
14 construction in the related litigation,
15 correct?

16 A. Yes. I believe Dr. Childs'
17 definition required a little bit less
18 relevant working experience, if I recall
19 correctly. But I do point that out in my
20 declaration.

21 Q. Your definition of a person of
22 ordinary skill in the art is a higher
23 level of training required than what Dr.
24 Childs proposed; is that correct?

25 MS. SCHWARZ: Objection to form.

1 A. I believe as I stated, more
2 working ex -- relevant working experience.

3 Q. Does your opinion -- do your
4 opinions change at all if you're applying
5 Dr. Childs' definition of a person of
6 ordinary skill in the art as compared to
7 your definition of a person of ordinary
8 skill in the art?

9 A. No. As I indicated in the
10 declaration, my opinions would not change
11 if adopting Dr. Childs' definition of a
12 POSA.

13 Q. Why do you think it's more
14 appropriate to include a higher level of
15 working experience in your definition of a
16 person of ordinary skill in the art?

17 MS. SCHWARZ: Objection to form.

18 A. Having been a professor for a
19 long time, I understand a lot about
20 education, and in reviewing the '344
21 patent and its prosecution history,
22 understanding the field of -- from my
23 personal involvement and experience, I
24 believe that it -- it would require a
25 higher level of working experience than

1 Dr. Childs indicated.

2 Q. I understand that you believe it
3 requires a higher level of working
4 experience than Dr. Childs indicated,
5 but -- but why?

6 A. I'm sorry, I just thought I just
7 explained that.

8 If you review the '344 patent
9 and the prosecution history and the -- the
10 field of -- of co-crystals and have an
11 understanding of that, it requires, I
12 believe, that the POSA needs a little bit
13 more working experience than Dr. Childs
14 had said.

15 Q. I'd like to switch gears a
16 little bit, and I'd like to talk about
17 hydrogen bonding.

18 So, this is a topic that you
19 covered in your declaration at a high
20 level, but at a high level, can you
21 explain what a hydrogen bond is?

22 A. Yes.

23 Can you take me to where I
24 discuss hydrogen bonding?

25 Q. Yes. So for example, in

1 paragraph 45 of Exhibit 1002, 1002, you
2 mention that: An example of a
3 supramolecular synthon formed via a
4 non-hydrogen bonding of a first chemical
5 functionality of an API and a second
6 functionality of a co-former is shown
7 below.

8 So you're talking about hydrogen
9 bonding in paragraphs 45 and 56.

10 So my question was at a high
11 level, what is a hydrogen bond?

12 MS. SCHWARZ: Objection to form.

13 A. In chemistry, a hydrogen bond is
14 an electrostatic interaction between a
15 hydrogen bonded to a very electronegative
16 element, which would be the -- considered
17 to be the -- the donor, and an element
18 such as nitrogen, oxygen or sulfur which
19 would have a partial negative charge and
20 would attract -- be attracted to that
21 hydrogen.

22 Q. You used the term hydrogen --
23 excuse me. You used the term "donor" in
24 your answer.

25 What is a hydrogen bond donor?

1 A. The donor is the atom to which
2 the hydrogen is covalently bonded.

3 Q. Is there also a hydrogen bond
4 acceptor in a hydrogen bond?

5 A. Yes.

6 Q. And what is a hydrogen bond
7 acceptor?

8 A. The hydrogen bond acceptor is
9 the one that the donor hydrogen is
10 interacting with in a hydrogen bond.

11 Q. Are there principles of hydrogen
12 bonding that you just explained, are
13 these -- would you consider these basic
14 principles that would be known to a person
15 of ordinary skill in the art?

16 MS. SCHWARZ: Objection to form.

17 A. I think they're very simple
18 concept at a high level that you asked me
19 to explain to you would be known by a
20 person of skill in the art.

21 Q. And will those principles be
22 understood to a person of ordinary skill
23 in the art as of 2002 or 2003?

24 A. Yes.

25 Q. Are you familiar with the work

1 of Margaret, or Peggy, Etter?

2 A. I am.

3 Q. And are you familiar with
4 Margaret Etter's work in hydrogen bonding?

5 A. I am.

6 Q. And when did Margaret Etter's
7 work in hydrogen bonding come to -- when
8 was it published or it became public?

9 MS. SCHWARZ: Objection to form.

10 A. There's a body of work, so I --
11 I don't know the exact date that it's --
12 that she started publishing. It was some
13 time ago.

14 Q. Do you know if it was before
15 2002 and 2003?

16 A. Yes, it was.

17 MS. DEL DOTTO: I'd like to mark
18 as Exhibit 2005 an article labeled
19 "Encoding and Decoding Hydrogen-Bond
20 Patterns of Organic Compounds" by
21 Margaret C. Etter.

22 (Rogers Exhibit 2005, Etter
23 article, 1990, was marked for
24 identification, as of this date.)

25 BY MS. DEL DOTTO:

1 Q. Dr. Rogers, do you recognize
2 this article?

3 A. I have seen it before. I
4 haven't looked at it in a long time.

5 Q. Do you recall generally when you
6 reviewed this article?

7 A. No. It would have been a long
8 time ago.

9 Q. And this article was published
10 in 1990; is that correct?

11 A. That is correct.

12 Q. By the American Chemical
13 Society?

14 A. It is an ACS journal, Accounts
15 of Chemical Research.

16 Q. And is Accounts of Chemical
17 Research a reputable journal, in your
18 opinion?

19 A. It is.

20 MS. SCHWARZ: Objection to form.

21 A. It is.

22 Q. Are you familiar with the
23 subject matter contained in Margaret
24 Etter's article that was marked as Exhibit
25 2005?

1 A. The general subject matter, yes.

2 Q. Can you please turn to page 124,
3 124? There's table 1.

4 Please let me know when you're
5 there.

6 A. I'm there.

7 Q. Under table 1 "Hydrogen Bond
8 Rules For Organic Compounds" do you see
9 that there are three general rules listed?

10 A. Yes.

11 Q. So, the first rule: All good
12 proton donors and acceptors are used in
13 hydrogen bonding.

14 Do you agree with that rule as a
15 general principle as of the time this
16 article was published?

17 MS. SCHWARZ: Objection to form;
18 outside the scope of the expert's
19 declarations.

20 A. I think if you look at table 1,
21 you -- you're looking at what are called
22 general rules, and it's not -- it's --
23 it's simply a POSA would not consider that
24 to be hard and fast.

25 I think you'd have to go back

1 and look at other aspects of this paper
2 where she talks about needing to know the
3 structure of the entire molecule.

4 Q. Do you agree that a person of
5 ordinary skill as of 2002-2003 would have
6 been aware of Margaret Etter's work in
7 hydrogen bonding?

8 MS. SCHWARZ: Objection to form.

9 A. I believe that they would, yes.

10 Q. Do you agree that a person of
11 ordinary skill in the art as of 2002-2003
12 would have been aware that Margaret
13 Etter's work could apply to co-crystals?

14 MS. SCHWARZ: Objection to form.

15 A. I think by 2002-2003 people were
16 looking at co-crystals and looking at Dr.
17 Etter's work, especially in the concept of
18 another concept called crystal
19 engineering.

20 Q. Okay. I think my question was a
21 little different.

22 So, do you agree that a person
23 of ordinary skill in the art as of
24 2002-2003 would have been aware that
25 Margaret Etter's work could apply to

1 co-crystals?

2 MS. SCHWARZ: Objection to form.

3 A. By 2002-2003 I would say yes,
4 because it was simply the concept of
5 hydrogen bonding.

6 Q. You can put that aside.

7 Can you turn to paragraph 7 of
8 your expert declaration marked as Novartis
9 Exhibit 1002?

10 A. I'm there.

11 I'm sorry, did you say page 7?

12 Q. I said paragraph 7.

13 A. Okay.

14 I'm there.

15 Q. Okay. In this paragraph you
16 refer to the phenomenon of polymorphism.

17 Do you see that?

18 A. I do.

19 Q. How are you -- what does
20 polymorphism mean?

21 A. Polymorphism in its scientific,
22 its strict scientific sense, is a given
23 compound that crystalizes into different
24 crystal structures.

25 Q. And how does polymorphism differ

1 from, or how do polymorphs differ from
2 co-crystals, if at all?

3 A. Well, co-crystals may be
4 polymorphic, but a co-crystal is not a
5 polymorph of a pure other -- of any of its
6 components.

7 Q. Are you aware of the term
8 "high-throughput screening"? Are you
9 familiar with that term?

10 A. I am.

11 Q. Okay.

12 And what does high-throughput
13 screening mean to you?

14 A. This is a -- a methodology to
15 try to run many experiments at one time, a
16 lot of time using robots and developed
17 algorithms.

18 Q. As of 2002-2003, was
19 high-throughput screening for polymorphism
20 available?

21 MS. SCHWARZ: Objection to form;
22 outside the scope of the expert's
23 declarations.

24 A. I'd have to go back and look.
25 Some time in the 2000s, as polymorphism

1 became more important to the
2 pharmaceutical industry, high-throughput
3 screening, at least in early stages, was
4 being developed, but I -- I have not
5 looked at the date compared to 2002-2003.

6 MS. DEL DOTTO: I'd like to mark
7 as Exhibit 2006 an article titled
8 "Iterative High-Throughput
9 Polymorphism Studies on Acetaminophen
10 and an Experimentally Derived
11 Structure for Form III," the first
12 author Peterson.

13 (Rogers Exhibit 2006, Peterson
14 article, 2002, was marked for
15 identification, as of this date.)

16 BY MS. DEL DOTTO:

17 Q. Dr. Rogers, I'll give you a
18 moment to review, and please let me know
19 when you're ready for a question.

20 A. (Witness reads document.)
21 I'm ready.

22 Q. My first question is do you
23 recognize this article?

24 A. I do. I have seen this article.
25 I don't recall the details.

1 Q. Do you recall when you first saw
2 this article?

3 A. Probably about the time when it
4 came out.

5 Q. And it was published in August
6 of 2002; is that correct?

7 A. That's when it was published on
8 the Web, August 24th, 2002.

9 Q. So is it your understanding that
10 you would have reviewed the article around
11 that time?

12 A. It probably would have been in
13 2002 at some point.

14 Q. And this article was published
15 in the Journal Of American Chemical
16 Society; is that correct?

17 A. That is correct.

18 Q. And is that a reputable journal,
19 in your opinion?

20 A. Yes, it is.

21 Q. Is it your understanding that
22 this article publishes the potential to
23 use high-throughput screening for
24 polymorphism?

25 MS. SCHWARZ: Objection to form;

1 outside the scope of the expert's
2 declarations.

3 A. I'd have to read this to get all
4 the -- the detail of the paper. It looks
5 like a research paper.

6 Q. What do you mean by "a research
7 paper"?

8 A. Some new development out of
9 someone's research lab that they're trying
10 to develop or they're trying to
11 understand.

12 Q. How generally -- so, is it -- am
13 I correct that high-throughput screening
14 for polymorphism came about in the 2000s,
15 you're just unsure of when exactly in the
16 2000s it came out?

17 A. Yes.

18 I actually discuss
19 high-throughput screening in my
20 declaration, just not when it started.

21 Q. And can you point me to where
22 you discuss high-throughput screening in
23 your declaration?

24 A. I can try.

25 I think it might be around page

1 93.

2 (Pause.)

3 Yes, I don't actually see it on
4 that page.

5 I'd have to do a word search to
6 find it. I simply don't remember.

7 Q. How does high-throughput
8 screening for polymorphism work,
9 generally?

10 MS. SCHWARZ: Objection to form;
11 outside the scope of the expert's
12 declarations.

13 A. It's actually a lot of work.
14 You have to essentially be able to set up
15 one or two types of experiments, and
16 essentially it's more like the
17 old-fashioned if you had a hundred
18 graduate students and you set them all to
19 work and gave them certain tasks. So
20 you're trying to run a series of many
21 experiments and they're -- they have to be
22 run according to an algorithm or the way
23 that you've set -- set them up. So you
24 have to have a way for polymorphism. You
25 have to have a way -- and a decision has

1 to be made what type of crystallization
2 method are you going to use, 'cause you
3 never can use them all. And then you have
4 to decide what type of reactions. Are you
5 going to use solvents; if so, which ones.

6 Again, a lot of different
7 choices in how that's set up. You simply
8 can't do it all.

9 I think one of the biggest
10 things is you have to have some way to
11 detect a result. That held back the field
12 for a long time because how do you know if
13 you have a new polymorph, or an old
14 polymorph for that matter. And so you
15 have to have some type of detection.

16 Q. And what are some of the types
17 of detection that you can use to determine
18 what polymorphic form you have?

19 MS. SCHWARZ: Objection to form;
20 outside the scope of the expert's
21 declarations.

22 A. I don't know if I remember all
23 of the different types of declarations.
24 One way would be to try to use powder
25 X-ray diffraction. Unfortunately, the

1 time that it takes to do that is really
2 not amenable to what anyone would call
3 high-throughput.

4 Another possible way might be to
5 try to use spectroscopy if it's possible
6 to distinguish between polymorph using
7 spectroscopy, because that's not always
8 possible.

9 Ultimately it would have to come
10 down to some sort of direct interrogation
11 of the result, and direct interrogation
12 would be by X-ray diffraction.

13 Q. Okay. You can put that to the
14 side, if you'd like.

15 And can you turn to paragraph 27
16 of exhibit Novartis Exhibit 1002?

17 A. I'm there.

18 Q. In paragraph 27 you copy the
19 language of claim 10, correct? Claim 10
20 of the '344 patent?

21 A. Yes, claim 10 is broken down
22 into different elements.

23 Q. You would agree that claim 10 of
24 the '344 patent is not a method claim,
25 correct?

1 A. Claim 10 is not a method claim,
2 as I understand that.

3 Q. And it's a claim directed to a
4 pharmaceutical composition, correct?

5 A. That is my understanding.

6 Q. Okay.

7 If you turn to paragraph 28,
8 here you copy the language of claim 11 of
9 the '344 patent, correct?

10 A. The limitations of claim 11,
11 yes.

12 Q. And you would agree that claim
13 11 of the '344 patent is not a method
14 claim, correct?

15 A. I do not believe claim 11 is a
16 method claim.

17 Q. Claim 11 is a claim directed to
18 a pharmaceutical composition, correct?

19 A. That is my understanding.

20 Q. Okay.

21 And if you turn to paragraph 29,
22 here you include the elements of claim 18,
23 correct?

24 A. Yes.

25 Q. And you agree that claim 18 of

1 the '344 patent is not a method claim,
2 correct?

3 A. Claim 18 does -- is not a method
4 claim.

5 Q. It's a claim directed to a
6 pharmaceutical composition?

7 A. Yes.

8 Q. And you can either turn to
9 Exhibit 1502 or the '344 patent to look at
10 claim 16.

11 A. I'm there.

12 Q. Would you agree that claim 16 of
13 the '344 patent is not a method claim?

14 A. Claim 16 is not a method -- is
15 not a method claim.

16 Q. It's a claim directed to a
17 pharmaceutical composition, correct?

18 A. Yes.

19 Q. You would agree that because
20 these claims are to pharmaceutical
21 compositions, a person of skill in the art
22 would not use a known carcinogen as a
23 co-former, correct?

24 MS. SCHWARZ: Objection to form.

25 A. I don't know if I can answer

1 that question generically. Maybe you can
2 give me some more context on that.

3 Q. What other context would you
4 need in order to answer the question?

5 A. You asked -- maybe just restate
6 it so I understood it.

7 Q. You would agree that because
8 these claims are to pharmaceutical
9 compositions, a person of ordinary skill
10 in the art would not use a known
11 carcinogen as a co-former?

12 MS. SCHWARZ: Objection to form.

13 A. No, I can't agree to that. In
14 the research and development of a -- of a
15 co-crystal, no, that was -- now I
16 understand -- remember what the context
17 question I had was about.

18 It's like for what purpose? Are
19 they studying how to make co-crystals?
20 What is the -- the reason for the
21 methodology?

22 A lot of work with
23 pharmaceuticals is done with very toxic
24 compounds.

25 Q. So it's your understanding that

1 to create a pharmaceutical composition, a
2 person of skill in the art could use a
3 known carcinogen in the composition?

4 MS. SCHWARZ: Objection to form.

5 A. It depends on how you're testing
6 it. If you're testing it to test its
7 toxicity, yes, you could.

8 Q. So is it your opinion that a
9 person of ordinary skill in the art would
10 use or could use a known toxic compound as
11 a co-former in a pharmaceutical
12 composition under these claims?

13 MS. SCHWARZ: Objection to form.

14 A. Yes. So there it's going to be
15 a matter of how toxic. Everything is
16 essentially toxic.

17 Q. Would you agree that a person of
18 ordinary skill in the art would generally
19 want to use a co-former in a
20 pharmaceutical composition that had
21 already been approved by the FDA?

22 MS. SCHWARZ: Objection to form.

23 A. No, I can't agree to that.

24 Q. And why not?

25 A. If you repeat the question so I

1 can break it down effectively?

2 Q. Sure.

3 Would you agree that a person of
4 ordinary skill in the art would generally
5 want to use a co-former in a
6 pharmaceutical composition that had
7 already been approved by the FDA?

8 MS. SCHWARZ: Objection to form.

9 A. No. They may, just as an
10 example, they may be looking for an
11 entirely new composition that they could
12 patent.

13 Q. Would you agree that because
14 these claims are directed to
15 pharmaceutical compositions, a person of
16 ordinary skill in the art would not use a
17 solvent that was a known carcinogen in the
18 composition?

19 MS. SCHWARZ: Objection to form.

20 A. Again it would depend upon the
21 exact chemical.

22 Q. Why would it depend on the exact
23 chemical?

24 A. Pharmaceuticals are toxic by
25 nature, and sometimes it's the only

1 possible way that you can get a compound
2 or a composition. I wouldn't rule it out.

3 Q. You wouldn't rule out known
4 carcinogens when creating a pharmaceutical
5 composition -- excuse me.

6 You wouldn't rule out known
7 carcinogens as a solvent when trying to
8 create a pharmaceutical composition?

9 MS. SCHWARZ: Objection to form.

10 A. Again I just want to make sure
11 it's clear, it depends upon the reason for
12 making the pharmaceutical composition.

13 Q. Would you agree that a person of
14 ordinary skill would not use a known toxic
15 solvent when creating a pharmaceutical
16 composition?

17 MS. SCHWARZ: Objection to form.

18 A. No, I wouldn't agree to that.

19 Q. Why not?

20 A. First, it depends on how toxic,
21 what is the compound, what is the
22 solvent's role, how's -- how's it being
23 used, what's the purpose of the
24 composition that's being made.

25 Q. Would you agree that a person of

1 ordinary skill in the art would generally
2 want to use a solvent that had already
3 been approved by the FDA in creating a
4 pharmaceutical composition?

5 MS. SCHWARZ: Objection to form.

6 A. My answer would be the same. It
7 depends on why they're making the
8 pharmaceutical composition.

9 Q. Can you turn to paragraph 78 of
10 Exhibit 1002?

11 A. I'm there.

12 Q. About halfway through paragraph
13 78 you state: A POSA would have
14 understood that the entire structure of
15 the API and co-former must be taken into
16 account in determining whether any
17 particular co-crystal will form. It is
18 not sufficient to just look at the
19 functional groups.

20 Do you see that?

21 A. I do.

22 Q. What did you mean when you said
23 that "a POSA would have to take" -- excuse
24 me, "...would have understood that the
25 entire structure of the API and co-former

1 must be taken into account in determining
2 whether any particular co-crystal will
3 form"? What did you mean by "particular
4 co-crystal"?

5 A. Essentially any co-crystal.

6 Q. So this statement, it's your
7 position that a person of ordinary skill
8 would have understood that the entire
9 structure of the API and co-former must be
10 taken into account in determining whether
11 any co-crystal will form?

12 A. Yes.

13 That's essentially what Dr.
14 Etter says as well.

15 Q. And in what publication are you
16 referring to by Dr. Etter?

17 A. The one you just showed me.

18 Q. What did you mean by a person of
19 ordinary skill would have understood that
20 the entire -- would have understood that
21 the entire structure of the API and
22 co-former must be taken into account?

23 A. A person of ordinary skill would
24 understand that in order for a crystal of
25 any type, much less a co-crystal, to form,

1 it's not just one functional group that
2 will be important. It's the entire
3 structure; how many other functional
4 groups; how many other atoms; what sizes;
5 what geometry; what molecular recognition.
6 And I could go on and on.

7 But the -- the point is that you
8 can't determine from one functional group
9 or one hydrogen bond anything at all about
10 what might result.

11 Q. In order to fall under the scope
12 of the claims that you are analyzing in
13 your declarations, would a person of
14 ordinary skill in the art need to know
15 sizes, geometry, molecular recognition?
16 Are those required elements of the claims?

17 MS. SCHWARZ: Objection to form.

18 A. I think that's -- you're getting
19 to the heart of the problem with the
20 claims. So you're -- you asked me
21 questions from one side of making things,
22 and then now you're asking me a question
23 about a legal analysis of does it fit
24 within the claims. And because the claims
25 are based upon some function, you can

1 analyze a co-crystal and determine whether
2 it falls within the scope of the claims
3 after the fact.

4 Q. But it's your opinion that you
5 need to know before forming the co-crystal
6 whether it would fall within the scope of
7 the claims?

8 A. No.

9 MS. SCHWARZ: Objection.

10 A. I think I was saying pretty --
11 it sounded like I was saying the opposite.
12 You're not looking at the claims. You're
13 trying to make a co-crystal. And that's
14 how I was answering your questions before.

15 The POSA's not a lawyer.

16 Q. Can you turn to paragraph 120 of
17 the same declaration?

18 A. I'm there.

19 Q. Here you quote from an article
20 Desiraju 2001, and towards the bottom of
21 that paragraph you include the quote:
22 Even after identifying an important
23 intermolecular interaction, failure to
24 predict a crystal structure can arise
25 because the same interaction can be used

1 to make many different synthons.

2 Do you see that?

3 A. I do.

4 Q. Are you suggesting that in order
5 for the asserted claims of the '344 patent
6 to be valid, a person of ordinary skill in
7 the art would have to be able to predict
8 the particular crystalline structure that
9 would form even if many different synthons
10 could form that meet the elements of the
11 claim?

12 A. I don't believe --

13 MS. SCHWARZ: Objection to form.

14 A. I don't believe I gave that
15 opinion.

16 Q. Okay.

17 Is that your opinion, or not?

18 A. My opinions are in my
19 declaration.

20 Q. So you cannot answer that
21 question?

22 MS. SCHWARZ: Objection;
23 mischaracterizes the witness's
24 testimony.

25 A. You could ask the question again

1 'cause it really was strange.

2 Q. Okay. Well, if you don't
3 understand the question, please let me
4 know. I'll ask the question.

5 Are you suggesting that in order
6 for the asserted claims of the '344 patent
7 to be valid, a person of ordinary skill in
8 the art would have to be able to predict
9 the particular crystalline structure that
10 would form even if many different synthons
11 could form?

12 A. No, I --

13 MS. SCHWARZ: Objection to form.

14 A. No, I didn't make that opinion.

15 MS. DEL DOTTO: We've been going
16 for about an hour. Could we take a
17 quick bio break?

18 THE VIDEOGRAPHER: The time
19 right now is 10:04 a.m.

20 We're off the record.

21 (Recess taken.)

22 THE VIDEOGRAPHER: The time
23 right now is 10:15 a.m.

24 We're back on the record.

25 BY MS. DEL DOTTO:

1 Q. Dr. Rogers, can you please pull
2 up the '344 patent? This is Exhibit 1 --
3 Novartis Exhibit 1001.

4 A. I have it.

5 Q. Okay. And can you please turn
6 to column 9 of the '344 patent?

7 A. I'm there.

8 Q. And can I ask you to read lines,
9 to yourself, lines 27 through 34, and let
10 me know when you're done, please?

11 A. (Witness reads document.)
12 37 kind of ends in the middle.
13 It was column 9, 27 through 37?

14 Q. 27 through 34.

15 A. 34, yes, I've read it.

16 Q. Okay.

17 Is it your understanding that
18 the '344 patent defines "active
19 pharmaceutical ingredient" interchangeably
20 with "pharmaceutical entity,"
21 "pharmaceutical moiety," "pharmaceutical
22 component," and "pharmaceutical molecule"?

23 MS. SCHWARZ: Objection to form.

24 A. I have given the construction of
25 "active pharmaceutical ingredient" in my

1 "Claim Construction" section of my
2 reports.

3 Q. Okay. We can turn to that, and
4 I refer you to paragraph 55 of
5 Exhibit 1002.

6 A. I'm there.

7 Q. Okay.

8 And is this the agreed upon
9 definition that you applied in rendering
10 for "active pharmaceutical ingredient,"
11 API, that you applied in rendering your
12 opinions in this case?

13 A. Yes, it is.

14 Q. And that definition is:
15 Biologically active moiety having a
16 therapeutic effect on a human or animal
17 suffering from a given pathological
18 condition when administered in a given
19 concentration.

20 Correct?

21 A. Yes. It's at the top of page
22 37: Biologically active moiety having a
23 therapeutic effect on a human or animal
24 suffering from a given pathological
25 condition when administered in a given

1 amount.

2 Q. In a given concentration,
3 specifically, correct?

4 A. I'm sorry, I misread that.
5 Thank you. In a given concentration.

6 Q. All of the claims that you
7 analyzed for purposes of your IPR
8 declarations require an API, correct?

9 MS. SCHWARZ: Objection to form.

10 A. That is correct.

11 Q. So is it your understanding that
12 a pharmaceutical composition -- excuse me.
13 That a person of ordinary skill in the art
14 creating a pharmaceutical composition
15 under the claims of the '344 patent would
16 still use a known carcinogen as a
17 co-former?

18 MS. SCHWARZ: Objection to form;
19 asked and answered.

20 A. Yeah, I think the analysis is --
21 is a little bit flipped in that question.
22 The POSA is not looking at the '344 to
23 make a pharmaceutical composition.

24 Q. The person of ordinary skill --
25 you would agree that a person of ordinary

1 skill in the art to create a
2 pharmaceutical composition would include
3 an API?

4 MS. SCHWARZ: Objection to form.

5 A. Yes. So, they would include a
6 pharmaceutical of some sort, yes, an API.

7 Q. And you agree --

8 A. At least one.

9 Q. And you agree that in order to
10 create a pharmaceutical composition
11 comprising a co-crystal of an API, they
12 would also under the claims of the '344
13 patent there would also need to be a
14 co-former?

15 A. I didn't quite understand your
16 question.

17 To make a co-crystal there would
18 be -- there would have to be a co-former
19 which could be another API.

20 Q. So in order to create a
21 pharmaceutical composition comprising a
22 co-crystal, including an API, it's your
23 understanding that a person of skill in
24 the art would potentially use a known
25 carcinogen?

1 MS. SCHWARZ: Objection to form.

2 A. Depending on the purpose for
3 what they're making the pharmaceutical
4 composition and what tests they're --
5 they're planning to run, yes, it is
6 possible.

7 Q. Okay. Well, we already
8 identified that the API is a biologically
9 active moiety having a therapeutic effect
10 on a human or animal suffering from a
11 given pathological condition.

12 Do you understand that this
13 definition of API means that the API in
14 the pharmaceutical composition of the
15 claims of the '344 patent is going to be
16 given to a human or animal suffering from
17 a given pathological condition?

18 MS. SCHWARZ: Objection to form.

19 A. I don't know that -- I'm -- you
20 spoke really fast and a lot of words, so
21 I'm not sure I got all that. So maybe you
22 could parse that down a little bit for me.

23 Q. Sure.

24 Do you understand the definition
25 of API means that the API in the

1 pharmaceutical composition of the claims
2 of the '344 patent is going to be given to
3 a human or animal suffering from a given
4 pathological condition?

5 MS. SCHWARZ: Objection to form;
6 lack of foundation.

7 A. I don't think the '344 requires
8 it -- the pharmaceutical composition to be
9 given to anything. I didn't see that in
10 the claims.

11 Q. Isn't that part of your
12 definition of active pharmaceutical
13 ingredient that you applied in rendering
14 your opinions in this case?

15 MS. SCHWARZ: Objection to form.

16 A. Yeah, I guess I'm
17 misunderstanding the -- the question.

18 The person of skill -- I mean,
19 the API to look at whether it infringes
20 the claims of the '344 meets a certain
21 definition, and that definition is what I
22 gave in paragraph 55 of this declaration.

23 Q. So under the definition of "API"
24 that you applied in rendering your
25 opinions in this case, isn't it the intent

1 of the API used in the claimed
2 pharmaceutical composition to be used on a
3 human or animal suffering from a given
4 pathological condition?

5 MS. SCHWARZ: Objection to form;
6 lack of foundation.

7 A. Yeah, I think that there's like
8 the cart before the horse a little bit.

9 So, the API may or may not have
10 been invented yet. We don't know. But I
11 don't know the intent of the POSA making a
12 pharmaceutical composition of an API.

13 Q. I want you to assume that the
14 pharmaceutical composition is given to a
15 human.

16 In that instance, do you agree
17 that a person of ordinary skill in the art
18 would not knowingly include a carcinogen
19 in the composition?

20 MS. SCHWARZ: Objection to form.

21 A. Not necessarily, based upon
22 what's known about certain drugs. Some
23 are sometimes considered to be
24 carcinogens, others aren't.

25 But I just can't answer that

1 generically.

2 Q. Why can't you answer that
3 generically?

4 A. There are some things like --
5 well, I can't -- I can't really think of
6 an example right now.

7 I'm thinking of DMSO. DMSO had
8 a bad reputation as being highly toxic at
9 one time. It's still used in
10 pharmaceutical compositions.

11 Q. Are you aware of known
12 carcinogens being used in pharmaceutical
13 compositions given to humans?

14 A. I actually don't --

15 MS. SCHWARZ: Objection to form.

16 A. I actually don't know all known
17 carcinogens off the top of my head.

18 Q. That wasn't my question.

19 My question was are you aware of
20 any known carcinogens being used in
21 pharmaceutical compositions being given to
22 humans?

23 A. And, I'm sorry, I was trying to
24 answer that question.

25 I'm not aware of all known

1 carcinogens, so I can't -- I -- I am not
2 aware of any that are being given right
3 now. I'd have to go back and look.

4 Q. So sitting here today, you're
5 not aware of a single carcinogen that's
6 included in a single pharmaceutical
7 composition that's given to a human,
8 correct?

9 MS. SCHWARZ: Objection to form.

10 A. Not knowing everything that's
11 currently labeled as a carcinogen, I'd
12 have to say no, I can't answer your
13 question.

14 Q. Your answer is a little
15 confusing.

16 You can't answer the question,
17 or the answer is no, you are not aware of
18 a single carcinogen that's included in a
19 single pharmaceutical composition that's
20 given to a human?

21 A. My difficulty in answering that
22 question is that I can't -- I don't want
23 to give you an untruthful answer, and I
24 just, I can't remember. So I can't recall
25 anything right now.

1 Q. Okay.

2 Okay. Let's switch topics a
3 little bit and talk about claim 16. And
4 we can turn to your other declaration,
5 Novartis Exhibit 1502. You can refer to
6 that as needed.

7 A. I have it.

8 Q. Okay.

9 Can you turn to paragraph 72?

10 A. I'm there.

11 Q. In this paragraph you state:
12 Since challenged claim 16, particularly
13 the co-crystal and supramolecular synthon
14 limitations are described in terms of
15 their function, not structure (other than
16 the first chemical functionality of the
17 API) there are no structural features
18 common to all embodiments of challenged
19 claim 16.

20 Do you see that?

21 A. I do.

22 Q. Okay.

23 So, you said that the
24 limitations of claim 16 are described in
25 terms of their function, not structure?

1 How so?

2 MS. SCHWARZ: Objection to form.

3 A. That I explain in detail in my
4 declaration. I don't remember whether
5 it's in declaration 1 or declaration 2.

6 Declaration 1, by the way,
7 covers claim 10 which is part of claim 16.

8 So, if we go to paragraph 68 on
9 page 42: Other than the structural
10 feature of the first chemical
11 functionality of the API that is a
12 carboxamide, carbonyl, or amine, the
13 limitations of claim 16 are described in
14 terms of function, not structure, i.e. the
15 co-crystal is formed from the API,
16 co-former, and solvent; the API and
17 co-former must form supramolecular
18 synthons.

19 And I could continue reading, if
20 you'd like.

21 Q. Okay. Let's take the first
22 example that you provided, that the
23 co-crystal is formed from the API,
24 co-former, and solvent.

25 Doesn't that imply a structure

1 of the co-crystal?

2 MS. SCHWARZ: Objection to form.

3 A. Now, if I understood your
4 question, you're saying does this require
5 a certain result in the co-crystal.

6 To that I would say yes, the
7 claims require a result.

8 Q. I think my question was a little
9 different.

10 So, when you -- in the first
11 example you provided you said the
12 co-crystal is formed from the API,
13 co-former and solvent. And my question is
14 where is the function in that? That seems
15 structural to me.

16 A. What I was trying to point out
17 is, and I think you actually asked the
18 question a little bit differently, that
19 you talked about the co-crystal after it
20 had formed when you can go in and look at
21 the structure. Before it's formed, then
22 the function of the chemical -- the --
23 there is a function of the first chemical
24 group that it can form a hydrogen bond or
25 the co-crystal is formed from. That's

1 a -- a function of having that chemical
2 functionality and only on one molecule.

3 Q. Okay. Let's take a look at the
4 next example that you supplied in
5 paragraph 68. You said: The API and
6 co-former must form supramolecular
7 synthons between the first chemical
8 functionality of the API (carboxamide,
9 carbonyl or amine) and the second
10 functionality of the co-former.

11 Why does that language suggest
12 function and not structure?

13 MS. SCHWARZ: Objection to form.

14 A. There is no structural
15 information that's being given, and so
16 this is again you're looking at a possible
17 result. So that's a function. The first
18 chemical functionality has a -- a
19 function.

20 The second chemical
21 functionality, which is undefined, also
22 has a function.

23 Q. What do you mean by the second
24 chemical functionality is undefined?

25 A. There's no information on what

1 the second chemical functionality is.

2 Q. Okay. And then your third
3 example in paragraph 68 is that the
4 supramolecular -- supramolecular synthons
5 must non-covalently bond to a solid
6 molecule.

7 Again, why is that function
8 rather than structure?

9 MS. SCHWARZ: Objection to form.

10 A. There simply is no structural
11 information.

12 Q. Why isn't the non-covalent bond
13 a structural -- why isn't that considered
14 structural information?

15 A. Again --

16 MS. SCHWARZ: Objection to form.

17 A. -- you're looking after the
18 fact. If you can go in and if you can
19 find and determine a crystal structure,
20 sure, you got structure all over the
21 place. But before it forms, you have no
22 way of knowing what's going to form. And
23 so all you're given in the claim is a
24 solvent that whose function is to
25 non-covalently bridge supramolecular

1 synthons.

2 Q. Sitting here today, do you stand
3 by the opinions in both of your
4 declarations?

5 A. I do.

6 Q. Do you have any changes or
7 alterations to the opinions that you
8 listed in either of your declarations?

9 A. I do not.

10 Q. Was it your goal to --

11 (Fire alarm sounds.)

12 MS. SCHWARZ: Off the record.

13 MS. DEL DOTTO: Could we go off
14 the record?

15 THE VIDEOGRAPHER: The time
16 right now is 10:33 a.m.

17 We're off the record.

18 (Recess taken.)

19 THE VIDEOGRAPHER: The time
20 right now is 10:35 a.m.

21 We're back on the record.

22 BY MS. DEL DOTTO:

23 Q. Before we were interrupted by
24 the fire alarm, I was going to ask you my
25 next question. So let me ask that now.

1 Was it your goal to provide
2 complete and accurate opinions in both of
3 your declarations?

4 A. Yes. That's always my goal.

5 Q. And do you believe that you did
6 that in both of your declarations?

7 A. I do.

8 MS. DEL DOTTO: Okay.

9 Those are my only questions for
10 you, Dr. Rogers.

11 THE WITNESS: Thank you.

12 MS. DEL DOTTO: Thank you for
13 your time.

14 MS. SCHWARZ: Can we go off the
15 record?

16 THE VIDEOGRAPHER: The time
17 right now is 10:36 a.m.

18 We're off the record.

19 (Recess taken.)

20 THE VIDEOGRAPHER: The time
21 right now is 10:58 a.m.

22 We're back on the record.

23 EXAMINATION BY

24 MS. SCHWARZ:

25 Q. Hello, Dr. Rogers.

1 Do you recall being asked
2 earlier this morning about high-throughput
3 screening?

4 A. Yes.

5 Q. If you had used high-throughput
6 screening to make co-crystals as of 2002
7 or 2003, what types of declarations would
8 you use to determine whether any
9 co-crystal that was formed has the
10 non-covalent bonding required by the
11 asserted claims of the '344 patent?

12 A. Determine whether you even had a
13 co-crystal would require single crystal
14 X-ray diffraction. So you'd have to grow
15 a single crystal, and then you would have
16 to analyze the crystal structure of that,
17 if you could.

18 Q. And would growing a single
19 crystal and analyzing its structure be
20 routine?

21 A. Growing any crystal structure
22 for the first -- crystal for the first
23 time is not routine. Often single
24 crystals are even difficult to obtain.

25 Q. And what about the analysis of

1 that single crystal structure?

2 MS. DEL DOTTO: Object to the
3 form.

4 A. Again, the analysis is not
5 routine. One would have to go in and try
6 to determine this. I could give you a
7 whole dissertation on single crystal X-ray
8 diffraction, but it's really not easy and
9 the subject of interpretation.

10 MS. SCHWARZ: Thank you, Dr.
11 Rogers. We have no further questions.

12 MS. DEL DOTTO: I have no
13 further questions.

14 THE VIDEOGRAPHER: The time
15 right now is 10:59 a.m.

16 We're off the record.

17 (Deposition adjourned at
18 approximately 10:59 a.m. EDT)

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INSTRUCTIONS TO WITNESS

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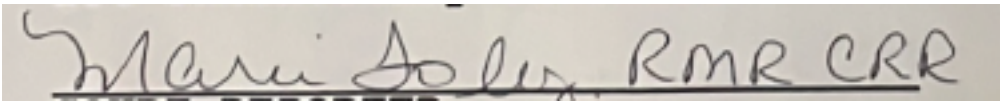
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4 Notary Public for the State of New York,
5 do hereby certify that prior to the
6 commencement of the examination, ROBIN D.
7 ROGERS, Ph.D., was duly sworn by me to
8 testify to the truth, the whole truth and
9 nothing but the truth.

10 I DO FURTHER CERTIFY that the foregoing
11 is a verbatim transcript of the testimony
12 as taken stenographically by me at the time,
13 place and on the date hereinbefore set forth,
14 to the best of my ability.

15 I DO FURTHER CERTIFY that I am neither
16 a relative nor employee nor attorney nor
counsel of any of the parties to this action,
17 and that I am neither a relative nor employee
of such attorney or counsel, and that I am
18 not financially interested in the action.

19 
20 Marie Foley, RMR CRR

21 COURT REPORTER
22 Registered Merit Reporter
23 Certified Realtime Reporter
24 Notary Public
25 Dated: May 25, 2024

1 Robin D. Rogers, Ph.D., c/o

2 VENABLE, LLP

3 151 West 42nd Street, 49th Floor

4 New York, New York 10036

5

6 Case: Novartis Pharmaceuticals Corporation v. Regents of the University of
Michigan et al.

7 Date of deposition: May 23, 2024

8 Deponent: Robin D. Rogers, Ph.D.

9

10 Please be advised that the transcript in the above
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9 Deposition Date: May 23, 2024

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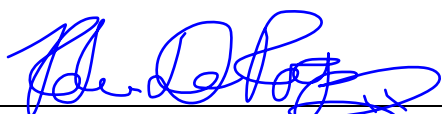
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*Novartis Pharmaceuticals Corporation v.
Regents of the University of Michigan and University of South Florida
IPR Nos. 2023-01346, 2023-01347*

Errata to the Transcript of the May 23, 2024 Deposition of Robin D. Rogers, Ph.D.

Page	Line	Change	To	Reason for Change
19	5	IPR.	IPR declaration.	Mistranscription/Misspoke
20	7	task.	the tasks.	Mistranscription
21	3	in	on	Mistranscription
21	5	I here	here I	Mistranscription
21	11	in 14	in paragraph 14	Mistranscription/Misspoke
23	22	Appendix A,	Appendix A.	Mistranscription
31	8	inability.	enablement.	Mistranscription
34	2	An example	“An example	Mistranscription
34	3-4	via a non-hydrogen	via non-covalent hydrogen	Mistranscription
34	7	below.	below.”	Mistranscription
35	18	concept	concepts	Mistranscription
35	19	you would	you that would	Mistranscription
39	17-18	the concept of another concept	another concept	Misspoke
41	5	other	component	Mistranscription/Misspoke
44	4	detail	details	Mistranscription
45	24	a way for	a way to detect for	Mistranscription/Misspoke
46	1	made what	made as to what	Mistranscription/Misspoke
46	2	are you	you are	Mistranscription/Misspoke
46	2	'cause	because	Mistranscription
46	23	declarations.	detection.	Mistranscription
47	6	polymorph	polymorphs	Mistranscription
59	1	'cause	because	Mistranscription
66	7	that there's like	that that's like putting	Mistranscription/Misspoke
71	5	co-crystal.	co-crystal?	Mistranscription
73	3	the	“the	Mistranscription
73	5-6	solid molecule.	solvent molecule.”	Mistranscription
73	24	that whose	whose	Mistranscription/Misspoke
76	7	declarations	detection	Mistranscription
76	12	Determine	Determining	Mistranscription
76	24	even	very	Mistranscription

Date: 5/30/2024

Signature: 
Robin D. Rogers, Ph.D.