

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

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NOVARTIS PHARMACEUTICALS CORPORATION,

Petitioner,

-against-

CERTIFIED COPY

REGENTS OF THE UNIVERSITY OF MICHIGAN

AND UNIVERSITY OF SOUTH FLORIDA,

Patent Owners.

-----X

Case IPR2023-01346
U.S. Patent No. 10,633,344
Ref & #: 51957.0001IP1

STENOGRAPHIC DEPOSITION OF:
ROBIN D. ROGERS, Ph.D.
Wednesday, October 2, 2024
9:01 a.m. - 11:23 a.m.
Reported Remotely through Videoconference

Reported stenographically by:
Richard Germosen, FAPR, CA CSR No. 14391
RDR, CRR, CCR, CRCR, CSR-CA, NYACR, NYRCR
NCRA/NJ/NY/CA Certified Realtime Reporter
NCRA Realtime Systems Administrator
Job No. 24-141768

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TELECONFERENCED STENOGRAPHIC DEPOSITION of
ROBIN D. ROGERS, Ph.D., taken in the above-entitled
matter before RICHARD GERMOSEN, Fellow of the Academy of
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2024, commencing at 9:01 a.m.

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I N D E X

WITNESS	EXAMINATION
ROBIN D. ROGERS, Ph.D.	
BY ATTORNEY KANE	5
BY ATTORNEY SCHWARZ	73
BY ATTORNEY KANE	76

E X H I B I T S

NONE

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ROBIN D. ROGERS, Ph.D. | 10.02.24

P R O C E E D I N G S

9:01 a.m.

CERTIFIED STENOGRAPHER: On the
stenographic record at 9:01 a.m.

Good morning. My name is Rich
Germosen. I am a certified stenographic
reporter. My license is available for
inspection.

- - -

(Whereupon, the Certified
Stenographic Reporter administered the oath to
the witness.)

- - -

R O B I N D. R O G E R S, Ph.D.,
having been first duly sworn or affirmed, was
examined and testified as follows:

EXAMINATION BY ATTORNEY KANE:

BY ATTORNEY KANE:

Q. Good morning, Dr. Rogers.
Can you please state your full name
for the record.

A. My name is Robin Don Rogers.

1 ROBIN D. ROGERS, Ph.D. | 10.02.24

2 Q. And I know you've been deposed
3 before and I appreciate that, so -- but you do
4 understand that you're under oath today and
5 testifying as you would in a courtroom before
6 a judge?

7 A. Yes.

8 Q. Okay. And you do understand that
9 your attorneys will likely make objections.
10 So you do understand, Dr. Rogers, that your
11 attorneys will likely make objections today,
12 but that unless you're instructed not to
13 answer, you're obligated to answer the
14 question to the best to the extent possible?

15 A. Yes.

16 Q. And I'll try to do my best to ask
17 clear questions today and -- but if I don't,
18 please ask me to clarify. If you don't ask me
19 to clarify, I'll take it that you understand
20 my question. Is that fair?

21 A. Yes.

22 Q. If you need to take a break, just
23 ask and we can take a break, okay?

24 A. Yes.

25 Q. As the court reporter indicated

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2 earlier, he's trying to take down our
3 conversation today. So I'll try not to speak
4 over you and I'd ask that you do the same as
5 not speak over me.
6 Do you understand that?
7 A. Yes.
8 Q. Also since he is trying to take
9 down a record of our conversation, we need to
10 answer verbally, not shakes of the heads or
11 uh-uhs or uh-huhs, those kinds of comments.
12 Do you understand that?
13 A. Yes.
14 Q. And any medical reason or otherwise
15 that would prevent you from giving complete
16 and accurate testimony today?
17 A. Not that I know of, no.
18 Q. Okay. Did you bring anything with
19 you to your deposition today?
20 A. I did not.
21 Q. Okay. Do you have the box of
22 exhibits that I understand were delivered to
23 counsel's office yesterday?
24 A. I have a package, a white package
25 that was delivered yesterday I understand.

1 ROBIN D. ROGERS, Ph.D. | 10.02.24

2 Q. Okay. Why don't you go ahead and
3 open that package up. So we'll be using some
4 of those during the questioning today.

5 A. These are what I have.

6 Q. Looks like about what I have as
7 well, so thank you.

8 So you'll see that in those
9 Redwelds, there are Manila folders and each
10 one has a tab that will say, you know, exhibit
11 number at the top.

12 Do you see those?

13 A. I do.

14 Q. Okay. And in addition -- well, so
15 the first one I'd ask you to find I think is
16 Exhibit 1072, which is your declaration in
17 support of the reply?

18 A. I have it.

19 Q. Okay. And can you tell me what
20 that document is, Exhibit 1072?

21 A. 1072 is my declaration in support
22 of petitioner's reply in the inter partes
23 review of U.S. Patent Number 10633344.

24 Q. Okay. If you'd turn to Page 97,
25 that's your signature?

1 ROBIN D. ROGERS, Ph.D. | 10.02.24

2 A. It is.

3 Q. Okay. And this is a declaration

4 that you prepared in connection with this

5 proceeding?

6 A. It is.

7 Q. Do you know approximately how much

8 time you spent preparing this declaration?

9 A. I don't have a good estimate of the

10 time.

11 Q. More than eight hours?

12 A. I would -- it was definitely more

13 than eight hours. I just don't -- I can't

14 quantify the time.

15 Q. Okay. And who did you work with to

16 prepare the declaration?

17 A. I worked with the attorneys for

18 Nova here at Venable.

19 Q. Did you talk to anyone at Nova?

20 A. No.

21 Q. Did you talk to anyone else other

22 than the attorneys at Venable?

23 A. No.

24 Q. Did you talk to Dr. Apple?

25 A. No. In preparing this report, no.

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2 Q. Okay. Have you ever talked to

3 Dr. Apple?

4 A. I don't remember. I do remember

5 her report, which I did study for my -- and

6 relied on for my first report.

7 Q. But you did not talk to Dr. --

8 well, did you talk to Dr. Apple in preparing

9 your first report?

10 A. I don't remember if I talked to her

11 specifically. I did read her report.

12 Q. Did you talk to anyone other than

13 the lawyers at Venable in preparing this

14 report?

15 A. In preparing my reply report, no.

16 Q. Okay. Did you talk to anyone other

17 than the lawyers at Venable preparing your

18 initial report?

19 A. I believe -- no, I don't -- I don't

20 remember. I think that if I talked to

21 somebody, it would have been in my report.

22 Q. All right.

23 And if you'd turn to Paragraph 10

24 on Page 9 of Exhibit 1072, please?

25 A. I'm at Page 10.

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2 Q. Actually, it was Paragraph 10. I'm
3 sorry if I said that. Paragraph 10, Page 9.

4 A. I'm at Paragraph 10.

5 Q. And this is a paragraph describing
6 the materials you considered in preparing this
7 report?

8 A. That's correct.

9 Q. Okay. And you state there that
10 you've prepared -- in considering this, you --
11 or, excuse me, in preparing the report, you
12 considered the materials set forth in the
13 patent owner's response and the Ward
14 declaration, Exhibit 2014, in the exhibits
15 referenced therein.

16 Do you see that?

17 A. Yes.

18 Q. Okay. Did you consider any other
19 materials?

20 A. As it indicates, the materials that
21 are set forth in the declaration.

22 Q. Okay. Did you review the
23 petitioner's reply brief submitted with this
24 declaration?

25 A. I believe that I did.

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2 Q. Do you recall when you reviewed
3 that?

4 A. I do not.

5 Q. Was it before or after you prepared
6 your declaration?

7 A. It would have -- let's see. I
8 think that would have had to have been after.

9 Q. What did you do to prepare for your
10 deposition today?

11 A. I studied the reports that I have
12 prepared in this case, my opening report, the
13 reply report, Dr. Ward's declaration, the
14 exhibits and references in both my reports and
15 Dr. Ward's. I had meetings with the attorneys
16 pretty much studying the documents.

17 Q. Did you review the deposition
18 transcripts in the case?

19 A. I did review my deposition
20 transcripts, yes.

21 Q. Okay. Did you review Dr. Ward's
22 deposition transcript?

23 A. I didn't know he had one.

24 Q. Okay. In your review, did you find
25 any errors or any clarifications you would

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2 like to make in the declaration?
3 A. No.
4 ATTORNEY SCHWARZ: Sorry to interrupt.
5 Rich, could we mute you by any chance?
6 - - -
7 (Whereupon, a discussion is held
8 off the record.)
9 - - -
10 BY ATTORNEY KANE:
11 Q. Dr. Rogers, I believe in your pile
12 of exhibits there you also have Exhibit 1002.
13 A. I do.
14 Q. And what is Exhibit 1002?
15 A. This appears to be my opening
16 declaration in this inter partes review.
17 Q. If you'd turn to Paragraph 19,
18 please.
19 A. I'm there.
20 Q. And you see there that that's a
21 description in your opinion of what a person
22 of skill in the art -- the qualifications of a
23 person of skill in the art as of 2002, slash,
24 2003 or 2014.
25 Do you see that?

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2 A. I do.

3 Q. And you state there that: Such a

4 person would have a Ph.D. in chemistry or a

5 related field with at least two years of

6 experience in solid state chemistry; correct?

7 A. Yes, it is stated there.

8 Q. Yeah. And you continue to say

9 that: Including experience preparing

10 multicomponent crystallin solids; correct?

11 A. Yes.

12 Q. And evaluating their single crystal

13 structures; correct?

14 A. Yes.

15 Q. And that's the definition that you

16 used in preparing both of your declarations in

17 this matter?

18 A. We didn't read the entire

19 definition, but it is explained in

20 Paragraph 19, yes, and I believe that Dr. Ward

21 agreed with that as well.

22 Q. Okay. So the entire definition --

23 I didn't mean to suggest otherwise, but the

24 entire definition as laid out in Paragraph 19

25 is what you used in formulating your opinions

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2 in both the opening declaration and in the
3 reply declaration?

4 A. That is correct.

5 Q. And you see there that it talks
6 about formulation of pharmaceutical
7 compositions compromising such multicomponent
8 crystalline solids.

9 Do you see that?

10 A. I do.

11 Q. Okay. What kind of experience are
12 you referring to in terms of in connection
13 with multiple component crystalline solids?

14 A. As it stated here, they'd have two
15 years of experience in formulation of
16 pharmaceutical compositions. Sorry, I lost my
17 place.

18 And they -- and a POSA would
19 consult with others having ordinary experience
20 in other disciplines, such as solid state
21 chemistry, including experience preparing
22 multiple component crystalline solids and
23 evaluating their crystal structures.

24 Q. Okay. So what does experience in
25 preparing multiple component crystalline

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2 solids entail?
3 A. Well, that's the same experience
4 for the POSA in the definition at the
5 beginning of Paragraph 19. That is experience
6 in actually preparing, synthesizing, and
7 crystallizing multicomponent crystalline
8 solids.
9 Q. And would that include single
10 crystal X-ray diffraction?
11 A. That's the other part of that
12 sentence, in evaluating their single crystal
13 structures, that would be done using single
14 crystal X-ray diffraction.
15 Q. So a person of ordinary skill would
16 have experience using -- evaluating single
17 crystal structures using single crystal X-ray
18 diffraction?
19 A. That's in the fourth line of
20 Paragraph 19, including experience preparing
21 multicomponent crystalline solids and
22 evaluating their single crystal structures,
23 and to do that you would use single crystal
24 X-ray diffraction.
25 Q. Could we turn to Paragraph 59.

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2 Going back to the, excuse me, Exhibit 1072.

3 Paragraph 59.

4 A. I'm there.

5 Q. And this is a portion of your
6 report where you're describing hydrogen
7 bonding crystal principles, including the
8 so-called Etter rules; correct?

9 A. This is a paragraph where I'm
10 discussing what Dr. Ward and the patent owners
11 provide as a discussion.

12 Q. Right. Discussion of hydrogen
13 bonding and including the Etter rules;
14 correct?

15 A. Yes, they specifically cite a 1990
16 paper by Dr. Etter.

17 Q. And you agree that a person of
18 ordinary skill in the 2002 or 2003 or the 2014
19 time period would be familiar with Dr. Etter's
20 paper and the so-called Etter rules?

21 ATTORNEY SCHWARZ: Objection to the
22 form.

23 A. I believe that a person of skill
24 would know that it's in the literature.

25 Q. Would a person of ordinary skill

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2 have applied that knowledge in turn in
3 connection with trying to create multiple
4 component crystals?

5 ATTORNEY SCHWARZ: Objection to form.

6 A. How are you using the word
7 "applied"?

8 Q. Would they take that information
9 into account in trying to form multiple
10 component crystals?

11 ATTORNEY SCHWARZ: Objection. Form.

12 A. Yeah, I don't see that. Maybe
13 there is a disconnect with me understanding
14 your question and what Etter's rules do in the
15 word that you used in terms of applied.
16 Etter's rules are about hydrogen bonding.

17 Q. Okay. How would a person of
18 ordinary skill take into account hydrogen
19 bonding when attempting to create multiple
20 component crystals?

21 ATTORNEY SCHWARZ: Objection to the
22 form.

23 A. I don't think it would be in terms
24 of Etter's rules. It would be in terms of
25 looking for hydrogen bonding. In fact, I

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2 think this is one of the criticisms I had of
3 Dr. Ward. He suggests Etter's rules would be
4 used by a POSA, but he never actually says how
5 they would be used.

6 Q. Have you ever used Etter's rules in
7 your work?

8 A. I'm aware of Etter's rules, but
9 again, there is a difficulty in you using the
10 word "used." Etter's rules are more of an
11 observation of known crystal structures, and
12 so a person of skill can certainly look at a
13 crystal structure after a structure has been
14 crystalized, made, and studied to get the
15 single crystal structure. They can certainly
16 look at the crystal structure and go back to
17 Etter's rules and say, Do they follow these or
18 not? Often they do not.

19 Q. So is it your testimony that the
20 hierarchical Etter's rules have no -- give a
21 person of skill no indication of how
22 structures may be formed prior to the
23 structure being formed?

24 ATTORNEY SCHWARZ: Objection to the
25 form.

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2 A. I think that's -- if I understood
3 your question, I believe that you're correct.
4 Etter's rules do not predict whether a crystal
5 structure will form or not, and a POSA cannot
6 use Etter's rules to predict whether a crystal
7 structure will form or not.

8 Q. Is it your view that Etter's rules
9 provide no guidance, as to a person of skill,
10 how different functional groups in a
11 co-crystal may interact?

12 ATTORNEY SCHWARZ: Objection to the
13 form.

14 A. The way you asked that -- sorry,
15 the way you asked that question, you know, I
16 can't necessarily agree to that. I think that
17 Etter's rules does -- Etter's papers rather do
18 discuss hydrogen bonding between different
19 functional groups. My comments to you are
20 there is a disconnect between that and a
21 crystal structure.

22 Q. Well, do you agree that Etter's
23 rule provide guidance on how different
24 functional groups in a co-crystal may
25 interact?

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2 ATTORNEY SCHWARZ: Objection to the
3 form.

4 A. So you're using an important word,
5 "may interact." I think they may interact as
6 Etter says and they may not.

7 Q. Do you think Etter's rules have no
8 value to a person of skill in the art?

9 ATTORNEY SCHWARZ: Objection to the
10 form.

11 A. I think Etter's rules were very
12 important in the beginning of the field of
13 crystal engineering, and there have been
14 subsequent papers, which I discuss in my
15 reports, which talk about the problems with
16 Etter's rules, including the fact that her
17 papers don't take into account a lot of other
18 factors that go into crystallizing a substance
19 and they're not a prediction of crystal
20 structure.

21 Q. When you say "prediction of crystal
22 structure," what do you mean?

23 A. There is nothing in Etter's rules
24 to help a POSA predict that a crystal will
25 form.

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2 Q. Any crystal?

3 A. Any crystal. There is no
4 predictive capability of crystallization, and
5 a lot of that is discussed in the papers that
6 I discuss, which go into the many factors
7 which Dr. Etter does not consider, which she
8 admits herself.

9 Q. Can you turn to Paragraph 63 of
10 your report or declaration. Excuse me. Here
11 you're referring to a paper by Dr. Braga
12 toward the bottom of Paragraph 63 on Page 51?

13 A. Paragraph 63. I'm there. Thank
14 you.

15 Q. And that's -- you'll see on the
16 next page that's Exhibit 1080. So why don't
17 you grab that out of your pile, please.

18 A. I have it.

19 Q. And you state there that: And
20 Dr. Braga explained in a 2002 paper that a
21 POSA would not have understood from Etter's
22 rules how to assess hydrogen bonding donor and
23 acceptor capabilities, particularly in view of
24 other factors, such as sterics and electronic
25 interactions, e.g., ionic bonding.

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2 Do you see that?
3 A. I do.
4 Q. Just because there are other
5 factors doesn't mean that Etter's rules have
6 no importance in the field; correct?
7 ATTORNEY SCHWARZ: Objection to the
8 form.
9 A. It depends what you mean by
10 "importance" and "in the field." I think that
11 they were important in the early generation of
12 the field called crystal engineering.
13 Q. And when you say "early," what time
14 frame are you talking about?
15 A. The papers were around the '90s,
16 and the field of crystal engineering came up
17 probably in the early '90s, and it came up in
18 the late '90s, early 2000s, and continues
19 today.
20 Q. Would you turn to Paragraph 67 of
21 your declaration, please, Dr. Rogers.
22 A. I'm there.
23 Q. And you see toward the -- Page 56,
24 about halfway down the page you have, I'll
25 probably butcher this, Vishweshwar paper,

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2 Exhibit 1082, V-I-S-H-W-E-S-H-W-A-R.

3 Do you see that?

4 A. I do.

5 Q. And that should also be in your
6 pile of exhibits. If you could grab that,
7 please.

8 A. I have it.

9 Q. And if we look at the first page of
10 that Exhibit 1082, the first sentence says:
11 Hydrogen bonding is the master key in crystal
12 engineering, supramolecular chemistry, and
13 biological recognition.

14 Do you see that?

15 A. I do.

16 Q. Do you agree with that statement?

17 ATTORNEY SCHWARZ: Objection to the
18 form.

19 A. No, not the way that it's written
20 right there. I think that Vishweshwar does a
21 good job of explaining this as well. They do
22 call it a master key and feel that it's
23 important in supramolecular chemistry and
24 biological recognition, but again, it's
25 nothing about predicting a crystal -- that a

1 ROBIN D. ROGERS, Ph.D. | 10.02.24
2 crystal will form.
3 Q. Well, so you disagree with the
4 statement though?
5 ATTORNEY SCHWARZ: Objection --
6 Q. Is the master key in crystal
7 engineering supramolecular chemistry and
8 biological recognition?
9 A. I personally would not --
10 ATTORNEY SCHWARZ: Objection.
11 (Unintelligible, simultaneous
12 testimony interrupted by the certified
13 stenographer.)
14 CERTIFIED STENOGRAPHER: I need one at
15 a time, please.
16 ATTORNEY KANE: Let me ask it again.
17 BY ATTORNEY KANE:
18 Q. So, Dr. Rogers, do you disagree
19 with the statement at the beginning of this
20 paper where the authors state that: Hydrogen
21 bonding is the master key in crystal
22 engineering, supramolecular chemistry, and
23 biological recognition?
24 ATTORNEY SCHWARZ: Objection to the
25 form.

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2 A. I disagree with the wording of
3 that. I understand the intent of the author
4 in stating it that way as a master key. I
5 simply wouldn't have used those terms. I do
6 think it's important.

7 Q. And how would you have stated the
8 concept?

9 A. First, I would have made it clear
10 that -- and I believe that the paper does,
11 that they're talking about hydrogen bonding,
12 but they're not talking about predicting
13 crystal structure. Sorry, they're not
14 predicting -- they're not talking about
15 predicting that a crystal will form based upon
16 a hydrogen bond.

17 Q. Is there anything in the sentence
18 about stating that a crystal will form based
19 on a hydrogen bond?

20 A. No, and that's -- that was my
21 problem with the statement -- the paper does
22 go on, I think, and does a better job of
23 explaining where Etter's rules fail and other
24 things.

25 Q. Well, do you think hydrogen bonding

1 ROBIN D. ROGERS, Ph.D. | 10.02.24
2 is important in crystal engineering?
3 A. I actually do think hydrogen bond
4 is one of many intermolecular interactions
5 that's important in crystal engineering.
6 Q. Do you think hydrogen bonding is
7 important in supramolecular chemistry?
8 A. I think hydrogen bonding, among the
9 many other intermolecular interactions, is
10 important in supramolecular chemistry.
11 Q. And do you think hydrogen bonding
12 is important in biological recognition?
13 A. I do believe that hydrogen bonding
14 is important in biological recognition, along
15 with the other intermolecular interactions.
16 Q. And if you'd turn to Page 2 of that
17 document.
18 A. Page 2 as the number at the bottom
19 or --
20 Q. Yes, Page 2 as the number at the
21 bottom, which I believe 784 at the top of the
22 page in the article.
23 A. I have it.
24 Q. Okay. And you see there in the
25 first full paragraph on the left-hand side

1 ROBIN D. ROGERS, Ph.D. | 10.02.24
2 there is a discussion of a proposal by, and
3 again, this is another name that I'm sure I'll
4 butcher, A-A-K-E-R-O-Y.
5 Do you see that?
6 A. Oh, down in the fifth line,
7 Aakeroy.
8 Q. Yeah, Aakeroy.
9 And you see there that it states
10 that it's a recently -- recently proposed by
11 Aakeroy based on hydrogen bonding hierarchy,
12 paren, ranking rules formulated by Etter, best
13 donor, paren, COH, paren, hydrogen bonds to
14 the best acceptor pyridine, P-Y-R-I-D-I-N-E,
15 space, capital N, end paren, and the second
16 best donor in acceptor groups, hydrogen bond
17 next, paren, amide dimer.
18 Do you see that?
19 A. I do.
20 Q. Okay. So that is a -- in that
21 sentence, it's describing that Aakeroy was
22 using the Etter rules to propose a bonding
23 approach; correct?
24 ATTORNEY SCHWARZ: Objection to form.
25 A. Again, I think you're getting to

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2 the heart of how Etter was used. Aakeroy was
3 proposing that specific hydrogen bonds may
4 form based upon Etter's rules. Aakeroy was
5 not predicting that crystals would form.

6 Q. What distinction are you making
7 between saying that bonds would form, but
8 crystal would not form?

9 A. In Dr. Etter's papers, she talks
10 about hydrogen bonding and she talks about
11 hydrogen bonding in solution, as well as
12 hydrogen bonding that she observed in known
13 crystal structures. She's talking about
14 hydrogen bonding, not crystallization.

15 Q. So is it your view that Etter's
16 rules -- again, your view is that Etter's
17 rules give no indication to a person of
18 ordinary skill what type of bonding and
19 crystals may form in a solid?

20 ATTORNEY SCHWARZ: Objection to form.

21 A. If I understood your question
22 correctly, I'll restate it a little bit, do
23 Etter's rules give any information about what
24 will crystalize? I would say no.

25 Q. Could you turn to Page 7 of the

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2 document, Page 789 of the paper.
3 A. I'm there.
4 Q. And beginning at the, again,
5 left-hand column, third line down, and again,
6 I will butcher all the chemical information.
7 I apologize in advance.
8 The sentence that begins: Five
9 co-crystals of diacid, dash, capital I,
10 capital N, with 12 stoichiometry are isolated
11 and characterized by XRD. Hydrogen bonding in
12 these five structures obeys hierarchy rules.
13 Do you see that?
14 A. I do.
15 Q. And so that indicates that in those
16 structures, the hydrogen bonding followed the
17 hierarchy rules that Aakeroy was proposing and
18 based on Etter?
19 ATTORNEY SCHWARZ: Objection to the
20 form.
21 A. I'd have to -- you'd have to take
22 me to where he's saying this about Aakeroy,
23 but I think that you've actually come right to
24 the problem that I'm trying to address with
25 you.

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2 A POSA has taken crystal structures
3 that they made and then they respectively,
4 after they have solved the crystal structure,
5 gone back and said, Do these follow Etter's
6 rules?

7 Q. If you'd turn back to Page 2 of the
8 document where we looked earlier at Aakeroy's
9 discussion or the discussion of Aakeroy?

10 A. I'm there.

11 Q. So at the beginning of that
12 sentence that we looked at earlier, starts off
13 with: A modular self-assembly approach to
14 carboxylic acid isonicotinamide. I'm not sure
15 how you say that, Dr. Rogers.

16 A. Isonicotinamide.

17 Q. Okay. Isonicotinamide, paren, NI
18 co-crystal stabilized by acid peridine
19 synthon, Roman VI, and amide dimer two was
20 proposed by Aakeroy; right?

21 A. Yes.

22 Q. So is that describing a prospective
23 modular self-assembly approach?

24 A. This is something I discuss I
25 believe in my opening report. Discussing a

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2 supramolecular synthon approach, and that's --
3 and I've indicated the problems with trying to
4 use that to predict a crystal structure, which
5 you can't do.

6 Q. And what are the problems with
7 doing that or why can't you predict the
8 crystal structure?

9 A. You cannot predict whether a
10 crystal will form. That's true today and it
11 was true at the priority date for this
12 application, and the reason -- part of the
13 reason for that is the other intermolecular
14 interactions and solvents, which can
15 interfere, and the fact that supramolecular
16 synthons may form in different ways, and this
17 goes beyond hydrogen bonding, by the way.

18 Q. So is it your testimony that you
19 can't predict that any crystal will be formed?

20 ATTORNEY SCHWARZ: Objection to form.

21 A. That is actually the correct --
22 that is actually my testimony. You cannot
23 predict whether an unknown crystal will form,
24 and you cannot predict whether an unknown
25 co-crystal will form just by looking at the

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2 components.

3 Q. Can you have a reasonable belief
4 that it will form?

5 ATTORNEY SCHWARZ: Objection to the
6 form.

7 A. The literature that I have read,
8 that I understand as an expert, and also
9 looking at this from a POSA at the priority
10 date, would indicate that it's not possible to
11 predict whether a crystal will form,
12 particularly a co-crystal which has two
13 component -- two or more components. You
14 cannot predict whether that will form a
15 co-crystal or not.

16 Q. So in any particular experiment
17 between components trying to form a
18 co-crystal, a POSA would have no belief that
19 the crystal could form or would form?

20 ATTORNEY SCHWARZ: Objection.

21 A. I can't talk for belief of
22 individual POSAs when they're trying to do
23 something. They're obviously trying to make
24 something, but they cannot predict in advance
25 whether a co-crystal will form and that's why

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2 they have to do the experiments.
3 Q. Right, but have you ever created a
4 co-crystal?
5 A. I have.
6 Q. Okay. And did you have a belief
7 before you did the experiment that you were
8 going to be able to create a co-crystal?
9 A. I had -- I didn't know. In fact, I
10 work in an area that's at the interface
11 between crystalline solids and liquids.
12 Sometimes I would get a liquid. Sometimes I
13 would get a crystalline solid.
14 Q. Okay. But did you have -- so
15 you're saying that in every experiment that
16 you do, you have no idea whether you're
17 getting a crystal or not?
18 ATTORNEY SCHWARZ: Objection to the
19 form.
20 A. I think in the field of
21 co-crystals, you actually do have that
22 problem, because you have two components and
23 they could crystalize separately. They could
24 interact and form a liquid. They may not
25 crystalize at all, and, of course, you have no

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2 way of knowing whether they would fit within
3 the specific limitations of the claims of the
4 '956 application.

5 Q. Right. I'm just talking about your
6 work in your lab now, Dr. Rogers, because
7 you've said you've created co-crystals;
8 correct?

9 A. Yes.

10 Q. And it's just pure happenstance
11 that they form?

12 A. I don't know -- I didn't get your
13 response there from my answer. We don't --

14 Q. You're telling me that for any
15 particular set of components, you have no idea
16 whether you're going to get a co-crystal?

17 A. Can I finish my answer?

18 Q. Please. I was trying to explain my
19 explanation.

20 A. Could you repeat the previous
21 question?

22 Q. Well, my question is: So when you
23 are forming co-crystals in your work for any
24 particular set of components, you have no idea
25 before you do the experiment whether you're

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2 going to get a crystal?
3 A. That's actually correct. That's
4 the problem, but that's the beauty of science.
5 Q. So why would you even believe that
6 you could form a co-crystal if you have no
7 idea that it will work?
8 A. You would want to try.
9 Q. How would you know which components
10 to try?
11 A. That depends what experiment that
12 you're doing and for what purpose.
13 Q. Okay. So give me an example of an
14 experiment that you would do and how you would
15 pick the components that you would hoped would
16 result in a crystal -- a co-crystal.
17 A. In my own work, I have used two
18 active pharmaceutical ingredients and tried to
19 react them to form new material. Those
20 materials are sometimes liquid, sometimes
21 they're crystalline, sometimes they're salt.
22 Q. Okay. And were you attempting to
23 try to form co-crystals?
24 A. I was attempting to form a
25 multicomponent solid.

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2 Q. Okay. Were you successful?

3 A. I have been successful in some
4 instances. Well, again, this depends on what
5 you consider to be success. In many cases, I
6 was trying to make sure I got a liquid. I
7 failed sometimes, my students, sometimes we
8 succeeded. Sometimes we were trying to make
9 crystalline solid. Sometimes we succeeded.
10 Sometimes we failed.

11 Q. Okay. How did you pick the
12 components that you interacted with the active
13 pharmaceutical ingredient?

14 A. Here, I looked at the potential to
15 form a salt or not or to interact. They could
16 interact with pi-pi stacking a lot of times in
17 the components.

18 - - -

19 (Clarification requested by the
20 stenographer.)

21 - - -

22 A. Pi-pi, P-I, P-I, stacking. It is
23 an -- it's also an inter -- could be
24 considered a supramolecular synthon.

25 So you're looking at essentially

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2 the shape, geometry, and all of the potential
3 intermolecular interactions of the components
4 to see if you can bring them together and
5 crystalize them.

6 Q. Okay. And a person of ordinary
7 skill knows how to look at those different
8 aspects of the components to see if they could
9 bring them together; correct?

10 ATTORNEY SCHWARZ: Objection to form.

11 A. I think a person of ordinary skill
12 would look at the entire structure of the
13 components that they want to try to crystalize
14 together, and they would make some
15 determinations about whether they should try
16 the experiment or not, but this goes well
17 beyond just hydrogen bonding and it involves
18 the entire structure.

19 Q. Okay. But that is how a person of
20 ordinary skill would approach that problem?

21 A. There is no one approach that every
22 person of ordinary skill will take.

23 Q. I understand, but you are offering
24 your opinions as a person of ordinary skill;
25 correct?

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2 A. I am, and you asked me for what I

3 did.

4 Q. Correct.

5 And so as a person of ordinary

6 skill, that's the approach that you took?

7 A. Can you repeat your question?

8 Q. Sure.

9 We may have talked over each other.

10 I'm sorry on that.

11 ATTORNEY KANE: Well, can you read back

12 my question, Rich? I'm not sure if I --

13 CERTIFIED STENOGRAPHER: (Complies.)

14 (Whereupon, the requested portion

15 is read back by the certified stenographer as

16 follows:

17 "QUESTION: Correct. And so as a

18 person of ordinary skill, that's the approach

19 that you took?")

20 A. My approach is typically as an

21 expert. If you'd like me to tell you what a

22 person of ordinary skill would do, I think

23 that I did -- I think that I did answer your

24 question previously.

25 Q. Yeah. Thank you.

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2 And turning back to Page 7 then of
3 Exhibit 1082, Dr. Rogers?

4 A. I'm there.

5 Q. And just to be clear then, you
6 agree that the authors describe the five
7 co-crystals in the structures that were formed
8 obeyed the hierarchy rules?

9 A. What's stated on Page 789 of the
10 article is that the five co-crystals of diacid
11 isonicotinamide, that's IN, with one to two
12 stoichiometry are isolated and characterized
13 by XRD. Hydrogen bonding of these five
14 structures obeys hierarchy rules. That's what
15 it says.

16 Q. Okay. If you'd turn to
17 Exhibit 1081, please.

18 A. I have it.

19 Q. And if we'd turn to Page 3, which
20 is -- of the exhibit, which is Page 2211 of
21 the article.

22 A. I'm there.

23 Q. And you see in the upper -- on the
24 right-hand column, first paragraph at the top
25 the sentence states: Inspection of the

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2 carboxy dimer motif in these 10 structures
3 shows that while the complexes 2 and 10
4 contain the expected heterodimer, the crystal
5 structure of one contains dinitrobenzoic and
6 dimethylaminobenzoic homodimers, Figure 2.
7 Do you see that?
8 A. I see that sentence.
9 Q. Okay.
10 Here the authors are stating that
11 complexes 2 to 10 contain the expected
12 heterodimer; correct?
13 A. That's what they say.
14 Q. And the expected heterodimer is
15 following the hierarchy hydrogen bonding
16 rules?
17 A. I don't see that in that sentence.
18 Q. Well, what do you understand it to
19 mean when they say "the expected heterodimer"?
20 A. I'd have to go through and look at
21 this. I think it's important to note the
22 title of this paper: Molecular Recognition
23 Involving an Interplay of OH $\cdots$ O, CH $\cdots$ O, and π - π
24 Interactions.
25 This is an example of somebody

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2 looking, as I had indicated to you before, of
3 more than hydrogen bonding in terms of how
4 they're trying to understand their crystal
5 structures.
6 Q. I understand, but so you don't have
7 any understanding today what expected
8 heterodimer means?
9 ATTORNEY SCHWARZ: Objection to form.
10 A. I would have to study the paper,
11 maybe you've already studied it to find where
12 they are explaining what they mean by expected
13 heterodimer.
14 The heterodimer that they're
15 showing is an example of a geometric effect,
16 by the way, which Etter doesn't describe.
17 Q. Do you see where it says that: The
18 crystal structure of one contains these
19 homodimers; correct?
20 A. The crystal structure of one
21 contains dinitrobenzylic and dimethylamino
22 benzoic homodimers.
23 Q. Right. Then the next sentence
24 says: This is an unusual result.
25 Do you see that?

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2 A. I do.

3 Q. Okay. Do you understand why it's
4 an -- can you explain why it was an unusual
5 result?

6 A. The authors are saying this is an
7 unusual result, and the absence of such
8 homodimers and other systems was verified by
9 the Cambridge structural database. They're
10 saying it's unusual because they -- and I have
11 to interpret what they say, that there are not
12 many other examples in the CSD.

13 Q. So do you have any -- so as you sit
14 here today, do you have any explanation -- do
15 you have any understanding as to why the
16 structures in 2 to 10 are expected and the
17 structure in one is unusual?

18 ATTORNEY SCHWARZ: Objection to the
19 form.

20 A. I'd have to read the entire paper
21 to go through that, but my impression, which I
22 would have to go back and look in more detail,
23 is that they're discussing a geometric effect
24 that Etter did not discuss.

25 Q. So your testimony today is this has

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2 the -- whether expected or unusual, it has
3 nothing to do with the Etter hierarchy rules?
4 ATTORNEY SCHWARZ: Objection to the
5 form. Mischaracterizes testimony.
6 A. I don't believe that's what I said.
7 Q. Well, what -- you mentioned Etter
8 specifically in here. So I'm curious why
9 you're mentioning Etter.
10 A. Because I thought -- and I
11 apologize if this isn't the case -- that I
12 thought you asked me a question about
13 hierarchy rules in Etter, and I was responding
14 to you're asking me that question in
15 relationship to this paper.
16 Q. Okay. So in connection with the
17 sentences that we've looked at, what are the
18 expected structures and the unusual structure,
19 does that have any connection to the hierarchy
20 rules or the Etter rules?
21 ATTORNEY SCHWARZ: Objection to the
22 form.
23 A. That's actually what I was
24 answering. No. Because these -- they're
25 looking at geometric effects.

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2 Q. When you say "geometric effects,"
3 what do you mean?

4 A. The hydrogen bond donors and
5 acceptors have geometry besides the
6 electronics and besides their donor
7 acceptability. They have structure
8 themselves. In this case you have a
9 carboxylic acid, which has a donor and
10 acceptor that are arranged in a particular
11 way, and that's what I mean by geometric
12 effect.

13 Q. If you look at Paragraph 67 of your
14 declaration, Doctor.

15 A. I'm there.

16 Q. You cite these papers in connection
17 with the statements, the -- quoted here it
18 says: Contradicts Etter's general principle
19 in hydrogen bonded networks the strongest
20 proton donor hydrogen bonds to the strongest
21 proton acceptor due to the important pi-pi
22 stacking interactions; correct?

23 A. I'm sorry, I lost where you are in
24 67.

25 Q. It's on Page 56.

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2 A. 56.

3 Q. About the middle of the paragraph
4 there. It's the left-hand side that starts
5 off with "contradicts."

6 A. I see that.

7 Q. Yeah.

8 So you say, as I read: Contradicts
9 Etter's general principle that in hydrogen
10 bonded networks, the strongest proton donor
11 hydrogen bonds to the strongest proton
12 acceptor due to important pi-pi stacking
13 interactions; correct?

14 A. Yes.

15 Q. And then you cite Sharma and
16 Vishweshwar in support of that statement;
17 correct?

18 A. It looks like I'm citing Sharma in
19 support of that statement, Exhibit 1081.

20 Q. And then further down you cite
21 Exhibit 1082; correct?

22 A. This is a new sentence in
23 Vishweshwar, June 2003, Exhibit 1082,
24 disclosed to one-to-one co-crystals, and I go
25 on in that sentence.

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2 Q. Right, and you say: That do not
3 follow Etter's best donor acceptor order;
4 correct?

5 A. Yes.

6 Q. Okay. So you've cited Vishweshwar
7 that we looked at, 1082, saying that it did
8 not follow Etter's rules; correct?

9 A. That the disclosed co-crystals and
10 this is what Vishweshwar reports.

11 Q. And where does Vishweshwar report
12 that it did not follow Etter's best donor
13 acceptor order?

14 A. That's the sentence that's in
15 quotes. I would have to go find it in the
16 paper.

17 Q. It's on Page 789, your cite there.
18 Page 7 of 8 of Exhibit 1082.

19 A. I have it, and I'm on Page 7 of 8.

20 Q. Yeah.

21 So again, left-hand column, we
22 looked at this earlier, I think you're citing
23 there, the sentence says: Furthermore, the
24 two co-crystals with the one-to-one
25 composition are characterized in which the

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2 hydrogen bonding does not follow the best
3 donor acceptor order; correct?
4 A. Yes.
5 Q. And you're referring to that as the
6 Etter rules?
7 A. I'm referring that to Etter's.
8 That's one of the first concepts in her
9 papers.
10 Q. Right. But the previous sentence
11 that we've previously looked at says that:
12 The five other structures did follow the
13 hierarchy rules; correct?
14 A. Yes. That's basically the problem
15 with Etter's rules, that once you have a
16 crystal structure, you can look to see do they
17 follow it or do they not?
18 ATTORNEY KANE: Counsel, I have to do
19 the call, so why don't we plan on a 30-minute
20 break. Again, I apologize, and then we can
21 resume, but we will not be taking a long time
22 today so.
23 ATTORNEY SCHWARZ: Okay. Sounds good.
24 Thank you.
25 ATTORNEY KANE: Thank you.

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2 CERTIFIED STENOGRAPHER: Off the
3 stenographic record at 10:01 a.m.
4 - - -
5 (Whereupon, a short recess was
6 taken.)
7 - - -
8 CERTIFIED STENOGRAPHER: On the
9 stenographic record at 10:35 a.m. eastern.
10 BY ATTORNEY KANE:
11 Q. Hello, Dr. Rogers.
12 A. Hello.
13 Q. So we were talking before we had to
14 take our break about Paragraph 67 of your
15 Exhibit 1072 of the reply declaration.
16 A. I'm there.
17 Q. And there is a statement, again, on
18 Page 56, that refers in the middle of the page
19 there that we started, quote: Contradicts
20 Etter's general principle that in hydrogen
21 bonded networks, the strongest proton donor
22 hydrogen bonds to the strongest proton
23 acceptor, end quote, due to important pi-pi
24 stacking interactions.
25 Do you see that?

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2 A. I do.

3 Q. And you then cite the Sharma paper,

4 which is Exhibit 1081?

5 A. Correct.

6 Q. And can you pull Exhibit 1081 for

7 me?

8 A. I have it.

9 Q. And you see there in Paragraph 67

10 it says: Sharma 1993 at 2209; correct?

11 A. That's what it says.

12 Q. Right. And if we look at 1081,

13 2209 is the first page of the exhibit?

14 A. Yes.

15 Q. And I note up in the -- sort of the

16 abstract, the second sentence states: The

17 formation of these homodimers contradicts the

18 general principle that in hydrogen bonded

19 networks, the strongest protein donor hydrogen

20 bonds to the strongest protein acceptor.

21 Do you see that?

22 A. Yes, the word is "proton."

23 Q. Oh, excuse me. Yeah. I'm sorry.

24 I was thinking about some other -- I have

25 cases that involve proteins and I slipped up

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2 there, so thanks for correcting me. Proton
3 donors, yes.
4 And then it continues to say: The
5 unusual homodimer is obtained because of the
6 difficulties in the CH, dot, dot, dot, O
7 hydrogen bond formation, and the consequence
8 importance of the pi-pi stacking interactions.
9 Do you see that?
10 A. I do.
11 Q. So that's the portion -- it appears
12 that that's the portion of the Sharma paper
13 that you are quoting; is that correct?
14 A. Yes, I'm talking about what they
15 have reported here.
16 Q. Yeah.
17 And so they're reporting here that
18 the homodimer obtained in the structure,
19 crystal structure one, contradicts the general
20 principle of the Etter rules; correct;
21 correct?
22 A. I'd have to go back to look at
23 compound one, but it does say the formation of
24 these homodimers contradicts the general
25 principle.

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2 Q. Right. So if you go back to -- we
3 talked about earlier Page 2211, upper
4 right-hand portion of the page.

5 A. Yep.

6 Q. It starts off: The inspection of
7 the carboxy dimer motif in these 10 structures
8 shows that while the complexes 2 to 10 contain
9 the, quote, expected heterodimer, the crystal
10 structure of one contains homodimers; correct?

11 A. Yes.

12 Q. And so is that the -- do you
13 understand that to be the unusual homodimer
14 referred to in the abstract?

15 ATTORNEY SCHWARZ: Objection to the
16 form.

17 A. I'll need to check that. It says:
18 The crystal structure of the complex of
19 3,5-dinitrobenzylic acid and 4 NN
20 dimethylamino benzoic acid.

21 Oh, there it is. Yes, that the
22 structure of one.

23 Q. So could you explain what you were
24 referring to?

25 A. The abstract for the -- leading

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2 into the sentence that you just had me read.
3 Q. Right.
4 A. It's talking about the crystal
5 structure of the one-to-one donor acceptor
6 complex of 3,5-dinitrobenzylic acid and 4 NN
7 dimethylamino benzoic acid, and I was trying
8 to confirm that that was what they were using
9 later, the nomenclature Number 1, and I looked
10 at Figure 2 where they have a portion of the
11 crystal structure of that, and I can see that
12 that is the complex that they're referring to
13 as one.
14 Q. Okay. And that that structure they
15 characterized as different than the expected
16 structure?
17 A. I will point out, so it's not
18 confusing to the board, that they're not using
19 homodimer and heterodimer in the same sense
20 that they're used in the '956 application.
21 Q. My question was though that they're
22 referring to the crystal structure of one as
23 being unusual -- the unusual result; correct?
24 ATTORNEY SCHWARZ: Objection to the
25 form.

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2 A. On Page 2211 --

3 Q. Yes.

4 A. -- they indicate a crystal

5 structure of one is an unusual result.

6 Q. Thank you.

7 If we turn to Paragraph 46 of your

8 declaration, Dr. Rogers.

9 A. I'm there.

10 Q. This is a section of your

11 declaration that relates to high throughput

12 screening; correct?

13 A. Yes, it is.

14 Q. And you state that -- the bottom of

15 Paragraph 46 that: In connection with high

16 throughput screening, it does not enable the

17 POSA to predict the results before running the

18 test and evaluating the results.

19 Do you see that?

20 A. I do.

21 Q. Okay. Do you think that in order

22 to enable a claim that a POSA would need to be

23 able to predict the results before running and

24 evaluating the test?

25 ATTORNEY SCHWARZ: Objection to the

form.

A. Again, in looking at that section, this is about high throughput screening would not have allowed a POSA to visualize or recognize the full scope of the claimed co-crystals, and I don't believe that high throughput screening could be used in that manner. They can't predict the result before running and evaluating the tests as they can't visualize or recognize the full scope of the claims.

Q. Okay, and because they can't predict the result before they do the test?

A. In this particular section, I'm just pointing out that high throughput screening is not predictive and it would not allow a POSA to predict any crystallization results.

Q. And you think that would be necessary in order to enable the full scope of the claim?

ATTORNEY SCHWARZ: Objection to the form.

A. I go through a lot on enablement

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2 and it's not just high throughput screening.

3 Q. No, but my question was whether or
4 not you believed that a POSA would need to be
5 able to predict the result in order to enable
6 the claim?

7 ATTORNEY SCHWARZ: Objection to the
8 form.

9 A. In this particular paragraph, I'm
10 saying that if a POSA can't predict the
11 results before running the tests, then high
12 throughput screening is not going to help to
13 visualize or recognize the full scope of the
14 claims.

15 Q. Well, I'm not asking -- the
16 statement here is that it does not enable the
17 POSA to predict the results before running the
18 results; correct?

19 ATTORNEY SCHWARZ: Objection to the
20 form.

21 A. That's the word, yes, yeah, that
22 sentence.

23 Q. And so my question is: You're
24 saying that since it does not enable -- since
25 it does not -- let me start over. Sorry.

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2 It does not allow the POSA to
3 predict the results before running the tests
4 and evaluating the results, it does not enable
5 the claims?

6 ATTORNEY SCHWARZ: Objection to the
7 form. Mischaracterizes the document.

8 A. I'm not using enable as a legal
9 term in that sentence. This section is about
10 written description. Visualize or recognize.

11 Q. Okay. Do you think high throughput
12 screening enables the scope of the claims, a
13 person of ordinary skill to practice the
14 claims?

15 A. No, I have a whole separate section
16 on high throughput screening with regard to
17 the legal concept of enablement.

18 Q. Yeah.
19 Are you familiar with the concept
20 of using high throughput screening in
21 connection with polymorphs?

22 A. I am.

23 Q. Have you ever used high throughput
24 screening in connection with studying
25 polymorphs?

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2 A. I haven't done it myself. I have

3 worked with companies that do do it and I have

4 certainly reviewed the results of polymorph

5 screens.

6 Q. So the concept of high throughput

7 screening for polymorphs was known to persons

8 of ordinary skill in the art in 2002 and 2003?

9 ATTORNEY SCHWARZ: Objection to the

10 form.

11 A. I think a person of skill in the

12 art of 2003 would understand that high

13 throughput screening for polymorph and form

14 searches was out there.

15 Q. Turn to Paragraph 56 for me,

16 Dr. Rogers.

17 A. I'm there.

18 Q. You state there at the beginning:

19 Dr. Ward does not consider or account for all

20 the steps involved in performing single

21 crystal X-ray diffraction analysis for even a

22 single product resulting from a screening

23 experiment.

24 Do you see that?

25 A. I do.

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2 Q. Okay. And you state in the next
3 sentence that: It's unlikely that a high
4 throughput screening would provide a suitable
5 sample; correct?

6 A. Yes, that is part of the sentence.

7 Q. Okay. And you don't have any --
8 you don't cite to any reference in support of
9 that statement; do you?

10 A. I do not have a reference in that
11 for that sentence.

12 Q. And a couple of sentences down,
13 about two-thirds of the way down that
14 paragraph it says: And in situations where a
15 single crystal resulted, but was not suitable
16 for single crystal X-ray diffraction analysis,
17 the more likely scenario for most
18 co-crystallization experiments forming a solid
19 product, a POSA would have needed to undergo
20 an additional step of growing a suitable
21 multiple crystal -- a suitable single crystal
22 before performing a single crystal X-ray
23 diffraction analysis. And confirming it was
24 the same co-crystal as produced in the high
25 throughput experiment, which could take weeks,

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2 months, in some cases even years to prepare
3 for one API and one co-former having a
4 specific stoichiometric ratio.
5 Do you see that?
6 A. I do.
7 Q. And, again, you don't have any --
8 cite any references in support of that;
9 correct?
10 A. This is based on my experience both
11 in research and 20 years as the editor and
12 chief of Crystal Growth & Design, in the
13 American Chemical Society Journal. This is
14 common knowledge to a POSA.
15 Q. Okay. Are you aware of any
16 commercial products involving co-crystals?
17 ATTORNEY SCHWARZ: Objection to form.
18 A. I'm not sure I understand your
19 question.
20 Q. Are you aware of anybody that's
21 ever commercialized a pharmaceutical product
22 involving utilizing a co-crystal technology?
23 ATTORNEY SCHWARZ: Objection to form.
24 A. I guess that depends. Nothing is
25 really coming to mind, and part of my problem

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2 is understanding how the word "co-crystal" is
3 being used. You understand that there are
4 different uses for that term, and the
5 patent -- the '956 application uses it in one
6 way and typically you have to define how
7 you're using that term.
8 Q. Okay. You can turn back to your
9 original declaration, the 1002.
10 A. I have it.
11 Q. Okay. And if we turn to
12 Paragraph 259 I guess, Page 153.
13 A. I'm there.
14 Q. Okay. And here you're offering an
15 analysis of some prior art references with
16 respect to using a co-crystal pharmaceutically
17 effective acceptable carrier --
18 - - -
19 (Clarification requested by the
20 stenographer.)
21 - - -
22 Q. In Paragraph 259 you're starting an
23 analysis of some prior art references, the
24 Hickey 2007, Almarsson with Hickey 2007, and
25 Martindale 2011 to prepare a pharmaceutical

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2 composition comprising a pharmaceutically
3 acceptable carrier and therapeutically
4 effective amount of co-crystal meeting all of
5 the elements of Claim 10 of the '344 patent.

6 Do you see that?

7 Oh, you're on mute, Dr. Rogers,
8 somehow.

9 A. I'm sorry, I think my documents hit
10 the wrong button.

11 I do.

12 Q. Okay. And then in Paragraph 260,
13 they're talking -- it's Almarsson and Hickey
14 2007 both relate to pharmaceutical
15 compositions comprising a one-to-one
16 co-crystal of an API carbamazepine and a
17 co-former saccharin with a pharmaceutically
18 acceptable carrier and disclose carbam --
19 however we're saying that, carbamazepine is
20 indicated to treat epilepsy.

21 Do you see that?

22 A. I do.

23 Q. Okay. And so in this case, a
24 person of ordinary skill were able to form a
25 co-crystal between that API and that co-former

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2 and successfully to create a product to treat
3 epilepsy; correct?
4 ATTORNEY SCHWARZ: Objection to form.
5 A. So if I could break that down a
6 little bit. So a one-to-one co-crystal of
7 carbamazepine and saccharin was made, and what
8 was the rest of your question?
9 Q. Well, it was successfully made;
10 right?
11 A. I believe that's in the '956
12 application as well.
13 Q. Right. So a person of ordinary
14 skill can achieve this result then, correct,
15 if they form a co-former of a
16 pharmaceutically -- an API to create a
17 pharmaceutically acceptable composition;
18 correct?
19 ATTORNEY SCHWARZ: Objection to form.
20 A. I'm confused by you're stringing a
21 few things together. If you're talking about
22 could a person of ordinary skill make
23 carbamazepine and saccharin, that compound was
24 made, and I believe it's an example in the
25 '956 application, if I remember correctly.

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2 Q. Okay. Do you know if the creators
3 of that compound did single crystal X-ray
4 diffraction analysis on it?

5 A. That's my understanding, yes. I
6 believe that's in the '956 application.

7 Q. And do you know how long it took
8 for the single crystal to be grown?

9 A. I do not. I don't remember that
10 information. I'd have to go back and look and
11 see if it's specified.

12 Q. Okay. Do you have any reason to
13 believe it took years?

14 A. I don't know the answer.

15 Q. Have you ever taken years to grow a
16 single crystal --

17 A. Yes.

18 Q. -- analysis?

19 A. I'm sorry, could you repeat your
20 question? I spoke over you.

21 Q. Have you ever taken years to grow a
22 single crystal for analysis?

23 A. Yes.

24 Q. In what contexts?

25 A. Crystallization is -- often takes a

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2 long time. There is a kinetic aspect related
3 to nucleation, and often in a crystallographic
4 lab, you will make a compound and you may let
5 it sit for years, a year or more. Sometimes
6 you get a result and sometimes nothing ever
7 crystalizes, but I have had that experience,
8 yes.

9 Q. And why would you wait that long to
10 see what the result would be?

11 A. If you've already expended the time
12 and the effort in the experiment and you know
13 that nucleation could take a long, long time,
14 then you wait.

15 Q. Okay. In any of the -- have you
16 done work with commercial entities trying to
17 develop co-crystals?

18 A. I would have to go back and look.
19 I remember one paper with a pharmaceutical
20 firm, it either was a co-crystal or very
21 similar. I'm sorry, I just don't remember.

22 Q. Did they wait a year or more to see
23 if they could create a single crystal?

24 A. That I don't know. I don't believe
25 so, no.

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2 Q. If you'd turn to Paragraph 20 of
3 your declaration, Exhibit 1072, Doctor.

4 A. I'm sorry, did you say 20?

5 Q. 20. 20.

6 A. I'm there.

7 Q. So in Paragraph 20, you state
8 that -- referring to Figure 24 of the patent:
9 That it lacks at least the following
10 information that a POSA would have needed in
11 March of 2003 to make and use the full scope
12 of the claimed co-crystals, and neither
13 Dr. Ward nor the patent owner explained how a
14 POSA would have determined this information at
15 all, let alone without expending an
16 unreasonable amount of time and effort;
17 correct?

18 A. It's not the exact wording, but
19 yes, that's essentially what it says.

20 Q. Okay. And then you list several
21 paragraphs, paragraph small Roman i, ii, iii,
22 iv, ivA, B, Roman v, Roman vi, etc.; correct?

23 A. Yes.

24 Q. Okay. And is it your testimony
25 that persons of ordinary skill would not have

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2 knowledge and experience about how to perform
3 those steps?

4 ATTORNEY SCHWARZ: Objection to form.

5 A. Given the limitless structural
6 variation within the claims of the '956
7 application, they would not.

8 Q. And when you say the limitless
9 application, what do you mean?

10 A. I believe I said limitless
11 structural variation. The person of skill in
12 trying to enable the full scope of this is
13 faced with claims which are primarily
14 functional. There is one structural element,
15 a first functional group carbonyl or amine.
16 Other than that, there is no information about
17 the structure of the API or of the co-formers,
18 nor of multiple APIs or multiple co-formers.

19 Q. And so your evaluation assumes that
20 the patent would have had to have described
21 every potential API and every potential
22 co-former?

23 ATTORNEY SCHWARZ: Objection to the
24 form.

25 A. I don't believe I said that, no.

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2 Q. So then what do you mean when you
3 describe all these structural differences
4 between all the potential APIs and co-formers?

5 A. I was stating a fact. Limitless
6 structural variations.

7 Q. Okay. But one particular API
8 doesn't have limitless structural variation;
9 correct?

10 A. Your analysis of looking at a
11 single API that the structure is known, a
12 person of skill can look at that structure,
13 but they're not going to get that from the
14 '956 application.

15 Q. Okay. But a person of ordinary
16 skill given an API knows how to analyze and
17 evaluate the structure of that particular API;
18 correct?

19 A. How do you mean "analyze"? I think
20 that's the problem with Figure 24. What do
21 you mean by "analyze" and what do the
22 inventors of the '956 mean?

23 Q. Well, I think you described earlier
24 your process for evaluating the structure of a
25 potential co-crystal.

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2 Do you remember that?

3 A. No, I don't remember the exact

4 words that I used.

5 Q. Okay. So if I gave you an API and

6 asked you to analyze the structure, would you

7 know how to do it?

8 ATTORNEY SCHWARZ: Objection to form.

9 A. It would depend on your purpose.

10 You'd have to tell me what you want analyzed.

11 Q. Form a co-crystal?

12 A. To analyze it to form a co-crystal

13 kind of makes no sense.

14 Q. Okay. If you can look at the

15 patent for me, Dr. Rogers.

16 A. You have a specific exhibit number

17 you want me to look at?

18 Q. Yeah, 1001.

19 A. I have a copy of the '344 patent in

20 front of me.

21 Q. Okay. So look at Figure 24,

22 please, Page 37?

23 A. I'm there.

24 Q. So if you look at step two in

25 Figure 24, it says: Identify if there are

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2 chemical functionalities in the API suitable,
3 paren, i.e., complementary from the
4 perspectives of geometry shape and molecular
5 recognition for formation of a supramolecular
6 synthons via a self-assembly, comma, i.e.,
7 will it form supramolecular synthons with
8 itself.
9 Do you see that?
10 A. I do.
11 Q. Would a person of ordinary skill be
12 able to perform that evaluation?
13 A. Not in all cases. I think the
14 problem here is going to be when you start
15 getting structures that have many functional
16 groups.
17 Q. Would you have any -- would a
18 person of ordinary skill have some ability to
19 understand the likelihood of forming the
20 supramolecular synthons described in step two?
21 ATTORNEY SCHWARZ: Objection to form.
22 A. If you're talking about will it
23 form supramolecular synthons in a crystalline
24 solid state, no, that would be very difficult
25 to predict or determine.

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2 I think at best you could look and
3 see does it hydrogen bond? Does it high stack
4 and look for a lot of different interactions,
5 but the problem in assessing it, it's going to
6 come when you have a lot of different groups
7 that you have -- that you may have.

8 Q. And I think we stated earlier in
9 the definition of person of ordinary skill in
10 the art, that that person would have knowledge
11 of evaluating single crystal structures?

12 A. Yes.

13 Q. And if we look at Column 12 of the
14 patent down at Line 65, there is a paragraph
15 that begins: X-ray powder diffraction.

16 Do you see that?

17 A. I do.

18 Q. And it continues on to Paragraph --
19 Line -- or, excuse me, Column 13?

20 A. Yes.

21 Q. Okay. And an X-ray powder
22 diffraction is a method used for evaluating
23 single crystal structures?

24 A. No, it is not.

25 Q. It's not?

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2 A. No.

3 Q. What is it used for?

4 A. It's for diffracting X-rays off of

5 powdered crystalline samples and typically

6 obtaining a diffractogram.

7 Q. Okay. But it does provide

8 information about the crystal structure in the

9 sample?

10 A. Not in the way that you seem to be

11 thinking it does. It provides information

12 about the unit cell, and the unit cell can be

13 derived from a powder X-ray diffractogram.

14 Q. And when you say "unit cell," what

15 do you mean?

16 A. A crystalline material is a

17 three-dimensional array of repeating units,

18 and the smallest repeating unit is a

19 mathematical concept called a unit cell. That

20 unit cell is repeated in all three dimensions

21 and makes up what is the concept of a

22 crystalline lattice.

23 Q. Thank you for that clarification.

24 ATTORNEY KANE: I have no further

25 questions at this time for the witness.

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2 ATTORNEY SCHWARZ: Can you give us five
3 minutes to see if we have any redirect?
4 ATTORNEY KANE: Sure.
5 CERTIFIED STENOGRAPHER: Off the
6 stenographic record at 11:09 a.m.
7 - - -
8 (Whereupon, a short recess was
9 taken.)
10 - - -
11 CERTIFIED STENOGRAPHER: Back on the
12 stenographic record at 11:19 a.m.
13 ATTORNEY SCHWARZ: All right.
14
15 EXAMINATION BY ATTORNEY SCHWARZ:
16 BY ATTORNEY SCHWARZ:
17 Q. Dr. Rogers, earlier this morning
18 you were asked about whether a POSA could make
19 a carbamazepine saccharin co-crystal. Just to
20 make sure that the transcript on this issue is
21 clear, I want to understand your answer for
22 that.
23 What is your basis for saying a
24 POSA could have made -- to the extent you said
25 that, what is the basis for saying the POSA

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2 could have made a carbamazepine saccharin
3 co-crystal?

4 A. Let me be clear, because I don't
5 remember actually -- I haven't got my
6 transcript memorized obviously.

7 But a POSA as of 2003, March 2003,
8 when the '956 application came out, at that
9 time -- before that time, I don't know if they
10 could have made it or not. That would be
11 unpredictable.

12 What I was trying to point out is
13 that it is an example in the '956 application
14 and, therefore, by following that recipe, a
15 POSA today could make it or a POSA after that
16 came out could have made it because the recipe
17 was given, but before that, the POSA would not
18 know that it could form.

19 Q. Dr. Rogers, you've been also asked
20 questions about X-ray powder diffraction.
21 Does X-ray powder diffraction allow a POSA to
22 determine if a co-crystal falls within the
23 scope of the '344 patent claims?

24 A. No. In order to determine if a
25 co-crystal falls within the scope of the

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2 claims, you'd have to have the crystal
3 structure, which is not just the unit cell.
4 It's the position of all the atoms within the
5 cell that allows the person of skill to
6 analyze the different interactions. So the
7 crystal structure is obtained from a technique
8 called single crystal X-ray diffraction.

9 Q. Dr. Rogers, you were asked about
10 Exhibit 1082. Do you have that handy?

11 A. I do.

12 Q. Does this paper teach that there
13 are formal rules for predicting crystal
14 structure?

15 A. No, it does not and, in fact, it
16 says the opposite.

17 Q. Where does it say that?

18 A. If you look at Page 789 of
19 Vishweshwar, which is Exhibit 1082, Page 7 of
20 8 of the PDF, on the left-hand column, about
21 two-thirds of the way down, the first partial
22 paragraph it says that: There are no formal
23 rules for predicting crystal structures with
24 competing supramolecular organization was
25 noted very recently in the same journal.

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2 Q. Thank you, Dr. Rogers.

3 ATTORNEY SCHWARZ: We have no further
4 questions.

5 ATTORNEY KANE: I couldn't hear you
6 there, Ms. Schwarz.

7 ATTORNEY SCHWARZ: Sorry. Just saying
8 nothing further from us.

9

10 EXAMINATION BY ATTORNEY KANE:

11 BY ATTORNEY KANE:

12 Q. Just staying with that, Dr. Rogers,
13 in 1082 where it says: There are no formal
14 rules for predicting crystal structures with
15 competing supramolecular organization.

16 Do you see that?

17 A. Yes.

18 Q. Okay. And what does it mean to say
19 "with competing supramolecular organization"?

20 A. The '956 application claims contain
21 no structural limitations other than one
22 functional group. Most APIs, many APIs have
23 more than one that can compete, not just
24 hydrogen bonding, but pi stacking and other
25 types of interactions, which I have noted in

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my reports.

Q. Okay.

ATTORNEY KANE: No further questions at
this point.

Thank you.

ATTORNEY SCHWARZ: Nothing further from
us.

Thank you.

CERTIFIED STENOGRAPHER: Off the
stenographic record 11:23 a.m.

- - -

(Time noted: 11:23 a.m.)

- - -

ROBIN D. ROGERS, Ph.D.

Subscribed and sworn to before me
this _____ day of _____ 2024.

Notary Public
My Commission Expires:

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C E R T I F I C A T E

I, RICHARD GERMOSEN, Fellow of the Academy of Professional Reporters, stenographic New Jersey Certified Court Reporter, New Jersey Certified Realtime Court Reporter, California Certified Shorthand Reporter, California Certified Realtime Reporter, NCRA Registered Diplomate Reporter, and NCRA Certified Realtime Reporter, do hereby certify:

That ROBIN D. ROGERS, Ph.D., the witness whose deposition is hereinbefore set forth, having been duly sworn, and that such deposition is a true record of the testimony of said witness.

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

IN WITNESS WHEREOF, I have hereunto set my hand this 4th day of October 2024.



RICHARD GERMOSEN,
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*Novartis Pharmaceuticals Corporation v.
Regents of the University of Michigan and University of South Florida
IPR No. 2023-01346*

Errata to the Transcript of the October 2, 2024 Deposition of Robin D. Rogers, Ph.D.

Page	Line	Change	To	Reason for Change
8	23	10633344	10,633,344	Mistranscription
9	18	Nova	Novartis	Mistranscription
9	19	Nova	Novartis	Mistranscription
9	24	Apple	Appel	Mistranscription
10	3	Apple	Appel	Mistranscription
10	8	Apple	Appel	Mistranscription
27	3	hydrogen bond	hydrogen bonding	Mistranscription
31	3	respectively	retrospectively	Mistranscription
36	19	form new	form a new	Mistranscription
36	21	they're salt.	they're a salt.	Mistranscription
42	21	dinitrobenzylic	dinitrobenzoic	Mistranscription
42	22	benzoic homodimers	benzoic acid homodimers	Mistranscription
44	14	you're	your	Mistranscription
45	7	acceptability	acceptor ability	Mistranscription
45	19	networks these	networks that the	Mistranscription
46	24	to	two	Mistranscription
47	9-10	co-crystals and this	co-crystals did not and this	Mistranscription
48	7	referring that to Etter's.	referring there to Etter's work.	Mistranscription
52	19-20	3,5-dinitrobenzylic acid and 4 NN dimethylamino benzoic	3,5-dinitrobenzoic acid and 4-(N,N-dimethylamino)benzoic	Mistranscription

52	21	that the	that is the	Mistranscription
53	6	3,5-dinitrobenzylic acid and 4 NN dimethylamino benzoic	3,5-dinitrobenzoic acid and 4-(N,N- dimethylamino)benzoic	Mistranscription
58	13	polymorph and	polymorphic	Mistranscription
59	25	take weeks,	take days, weeks	Mistranscription
60	11-12	editor and chief	editor-in-chief	Mistranscription
63	20	you're	your	Mistranscription
67	15	group carbonyl	group, carboxamide, carbonyl,	Misspoke/mistranscription
68	22	'956 mean	'956 application mean	Misspoke
71	3	high	pi	Mistranscription
71	5	it it's going	it is going	Mistranscription
75	22	that: There	that there	Mistranscription

Date: 10/5/2024

Signature: 
Robin D. Rogers, Ph.D.