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H. DERENDORF
UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEPTUNE GENERICS, LLC
Petitioner
v.
CORCEPT THERAPEUTICS, INC.
Patent Owner

IPR No. 2018-01494
Patent No. 8,921,348

DEPOSITION OF DR. HARTMUT DERENDORF
Washington, D.C.
August 2, 2019

Reported by: Mary Ann Payonk
Job No. 163994

H. DERENDORF

August 2, 2019
9:00 a.m.

Deposition of DR. HARTMUT DERENDORF, held at the offices of Latham & Watkins LLP, 555 11th St. N.W., Washington, D.C., pursuant to Notice before Mary Ann Payonk, Nationally Certified Realtime Reporter and Notary Public of the District of Columbia, Commonwealth of Virginia, and State of New York.

H. DERENDORF

APPEARANCES:

ON BEHALF OF PETITIONER:

CHRISTOPHER MAY, ESQUIRE
KENNETH GOLDMAN, ESQUIRE
MASSEY & GAIL
1000 Maine Avenue, SW
Washington, DC 20024

ON BEHALF OF PATENT OWNER and THE WITNESS:

MICHELLE ERNST, ESQUIRE
LATHAM & WATKINS
885 Third Avenue
New York, NY 10022

ALSO PRESENT:

Adolph "Ace" Green, Legal Video Specialist
Joshua Harris, Neptune Generics
Daniel Wiesner, Quinn Emanuel

H. DERENDORF

THE VIDEOGRAPHER: This is the start of tape labeled number 1 in the videotaped deposition of Dr. Hartmut Derendorf in the matter of Neptune Generics LLC v. Corcept Therapeutics, Inc. in the United States Patent and Trademark Office, Case Number IPR2018-01494.

This deposition is being held at 555 11th Street Northwest, Washington, D.C. on August 2, 2019 at approximately 8:51.

My name is Adolph Green from TSG Reporting, Inc., and I'm the legal video specialist.

The court reporter today is Mary Ann Payonk in association with TSG Reporting.

Will counsel please introduce yourselves?

(Whereupon, counsel placed their appearances on the video record.)

THE REPORTER: I'll swear the witness.

H. DERENDORF

DR. HARTMUT DERENDORF, called as a witness, having been duly sworn, was examined and testified as follows:

EXAMINATION

BY MR. MAY:

Q. Good morning, Dr. Derendorf.

A. Good morning.

Q. Have you had your deposition taken before?

A. I have.

Q. Okay. About how many times?

A. Probably 10, 12 times, something like that.

Q. Okay. Are any of those for patent cases?

A. Yes.

Q. Okay. How many?

A. Most of them.

Q. Okay. So you're an old hand at this.

A. I wouldn't -- I've done it before.

Q. Okay. Well, let me just quickly go over the ground rules again. I'm sure

Ms. Ernst went over them with you when she

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1 H. DERENDORF

2 talked with you. 08:53

3 I'm going to be asking you a series 08:53

4 of questions today, and I'd like you to answer 08:53

5 those questions as fully and completely as 08:53

6 possible. 08:53

7 The court reporter here is going to 08:53

8 be taking down my questions and your answers. 08:53

9 If there's something about my 08:53

10 question that you don't understand, please let 08:53

11 me know. I can try to rephrase it. But if you 08:53

12 don't tell me there's something that you don't 08:53

13 understand, I have to assume that you 08:54

14 understand the question. 08:54

15 Are you with me so far? 08:54

16 A. I understand. 08:54

17 Q. Okay. I may ask questions that are 08:54

18 yes/no. Try to answer them yes/no, because 08:54

19 uh-huh's and nods don't show up very well on 08:54

20 the transcript. 08:54

21 A. I'll try to -- 08:54

22 MS. ERNST: I'm just going to 08:54

23 object to form. The witness can answer 08:54

24 the questions how he chooses to answer 08:54

25 the questions. 08:54

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1 H. DERENDORF

2 A. No. 08:55

3 Q. Okay. Has a court ever not believed 08:55

4 or otherwise found your opinion to be not 08:55

5 reliable? 08:55

6 A. No. 08:55

7 MS. ERNST: Objection, foundation. 08:55

8 A. Not that I know of, no. 08:55

9 THE REPORTER: And if you could 08:55

10 just pause momentarily before you answer 08:55

11 so I can get the objection down. 08:55

12 BY MR. MAY: 08:55

13 Q. When did you agree to serve as an 08:55

14 expert in this case? 08:55

15 A. Approximately, my guess is a year 08:55

16 ago. 08:55

17 (Exhibit No. 2014, previously marked, was 08:55

18 referenced and indexed.) 08:55

19 BY MR. MAY: 08:55

20 Q. Okay. About how long did you spend 08:55

21 preparing the declaration that you have in 08:55

22 front of you, which is Exhibit 2014? 08:55

23 A. I don't know exactly. It was over a 08:56

24 long period of time, maybe three to four days. 08:56

25 Q. Okay. So 25 hours or so? 08:56

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1 H. DERENDORF

2 Q. Okay, which brings me to my next 08:54

3 point. Periodically, Ms. Ernst may object to 08:54

4 some of my questions. Unless she tells you 08:54

5 particularly not to answer the question, I 08:54

6 would ask that you go ahead and answer the 08:54

7 question. 08:54

8 This isn't a memory test. This isn't 08:54

9 a torture test of any kind. If you need a 08:54

10 break, please let me know. The only thing I 08:54

11 would ask is if you have a question pending 08:54

12 that you answer the question, and then you're 08:54

13 free to take a break. 08:54

14 I'll probably be stopping every 60 to 08:54

15 90 minutes. I understand that we need to get 08:54

16 done a little bit early so I will try to keep 08:54

17 breaks brief. 08:54

18 A. Appreciate it. 08:54

19 Q. All right. Have you ever been 08:54

20 convicted of a crime other than a traffic 08:55

21 offense? 08:55

22 A. No. 08:55

23 Q. Okay. Have you brought any documents 08:55

24 with you today other than I understand that you 08:55

25 have your declaration? 08:55

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1 H. DERENDORF

2 A. Something like that. 08:56

3 Q. Okay. And you're being paid \$600 an 08:56

4 hour for your time during this project? 08:56

5 A. Yes. 08:56

6 Q. Okay. So about \$15,000, roughly? 08:56

7 A. Approximately. 08:56

8 Q. Okay. Have you worked with 08:56

9 mifepristone in the past? 08:56

10 A. I have not worked with mifepristone 08:56

11 but I have worked extensively with 08:56

12 glucocorticoids. 08:56

13 Q. Can you give me some examples of the 08:56

14 glucocorticoids you've worked with? 08:56

15 A. Yes. I've -- my area of expertise is 08:56

16 pharmacokinetics and pharmacodynamics, and I've 08:56

17 studied the pharmacokinetics and 08:56

18 pharmacodynamics of glucocorticoids in 08:56

19 different kinds of products, injection, oral, 08:56

20 inhalation, and yes. 08:57

21 Q. Okay, let me reask the question. 08:57

22 Can you give me some examples of 08:57

23 specific glucocorticoid drugs that you have 08:57

24 worked with in the past? 08:57

25 A. Sure. For example, fluticasone 08:57

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1 H. DERENDORF

2 propionate, which is sold as Advair, I was 08:57

3 involved in the development in collaboration 08:57

4 with GSK, Glaxo at the time. And we have done 08:57

5 studies for the drug and dose optimization 08:57

6 studies, finding out what is the best dose to 08:57

7 use. 08:57

8 Q. Have you ever taken blood samples as 08:57

9 part of your work? 08:57

10 MS. ERNST: Objection to form. 08:57

11 A. I have analyzed thousands of blood 08:57

12 samples. I have never taken blood from an 08:57

13 individual subject because that's not my role, 08:57

14 but I've worked a lot with blood levels and 08:57

15 blood concentrations. 08:58

16 Q. And you've also administered 08:58

17 metabolite levels in blood samples? 08:58

18 A. I have. 08:58

19 Q. Can you explain in more detail -- and 08:58

20 I understand that in paragraph 5 and 6 you 08:58

21 talked a little bit about the sorts of research 08:58

22 that you do. I'd like you to explain that to 08:58

23 me in a little bit more detail, please. 08:58

24 A. Yes. My goal in my research is to 08:58

25 find ways to identify the optimum dose of a 08:58

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2 So you measure the concentrations and 09:00

3 you model the profiles that you then get and 09:00

4 with a final goal to identify the best dose. 09:00

5 Q. Okay. Does the pharmacokinetics of a 09:00

6 drug depend on the reason that the drug's being 09:00

7 taken? 09:00

8 MS. ERNST: Objection to form. 09:00

9 A. No. 09:00

10 Q. I think you also mentioned that you 09:00

11 study pharmacodynamics. 09:00

12 A. Yes. And that is what the drug does 09:00

13 to the body. So it's the desired therapeutic 09:00

14 activity that you want to achieve but also the 09:00

15 undesired side-effects, so the good and the 09:00

16 bad. 09:00

17 Q. Have you prepared expert reports or 09:00

18 declarations in the past? 09:00

19 A. I have. 09:00

20 Q. About how many? 09:00

21 A. Same number, 10 to 12. 09:01

22 Q. Have you testified in court before? 09:01

23 A. Yes. 09:01

24 Q. How many times? 09:01

25 A. I think three times. 09:01

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2 drug for an individual patient that will give 08:58

3 you the best risk/benefit ratio so it has the 08:58

4 highest probability to work with the least 08:58

5 chance of doing harm. 08:58

6 Q. So you would consider yourself an 08:58

7 expert in the optimization of the use of drugs 08:59

8 in the body? 08:59

9 A. Yes. 08:59

10 MS. ERNST: Objection to form. 08:59

11 A. With the focus on pharmacokinetics 08:59

12 and pharmacodynamics to identify the best dose 08:59

13 that should be used. 08:59

14 Q. Okay. Can you explain to me the term 08:59

15 "pharmacokinetics"? 08:59

16 A. Oh, sure. Pharmacokinetics is what 08:59

17 the body does to the drug. So if you take a 08:59

18 drug, it is absorbed in your bloodstream. It 08:59

19 is then metabolized, chemically changed. It is 08:59

20 distributed into the tissues, and it's finally 08:59

21 eliminated either through the urine or the 08:59

22 bile. And all of these steps can be 08:59

23 investigated, and pharmacokinetics is the field 08:59

24 that deals with that and does it in 08:59

25 quantitative way. 09:00

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1 H. DERENDORF

2 Q. And those were all for patent cases 09:01

3 as well? 09:01

4 A. Yes. 09:01

5 Q. We have talked about this a little 09:01

6 bit. Exhibit 2014, which you have in front of 09:01

7 you, this is the declaration that you submitted 09:01

8 in this matter; correct? 09:01

9 A. Yes. 09:01

10 Q. Okay. And did you prepare the entire 09:01

11 declaration yourself? 09:01

12 A. In collaboration with my counsel, 09:01

13 yes. 09:01

14 Q. Okay. You agree with everything 09:01

15 that's written in here when it was written? 09:01

16 A. I do. 09:01

17 Q. Okay. Do you still agree with 09:01

18 everything that's written there? 09:01

19 A. I do. 09:01

20 Q. Okay. Are there any changes or 09:01

21 corrections you want to make to the declaration 09:01

22 before we start discussing it? 09:01

23 A. No. 09:01

24 Q. Okay. So if you could turn to the 09:01

25 last page starting with the materials reviewed. 09:01

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1 H. DERENDORF

2 A. Yes. 09:01

3 Q. And is this a complete list of the 09:01

4 materials that you reviewed in preparing this 09:01

5 declaration? 09:01

6 A. These are the materials that are 09:02

7 specific to this case. Obviously, I also rely 09:02

8 on everything that I learned through my 40 09:02

9 years of experience. That is also part of my 09:02

10 opinion. 09:02

11 Q. Okay. So your collective knowledge 09:02

12 from working in the field for 40 years. 09:02

13 A. Yes. 09:02

14 Q. Okay. There aren't any other 09:02

15 documents that you relied on for the formation 09:02

16 of your opinion. 09:02

17 A. No. Again, these are the specific 09:02

18 documents for this case that I reviewed. 09:02

19 Q. Okay. Have you seen the patent 09:02

20 owner's response in this case? 09:02

21 A. I don't recall. 09:02

22 Q. Okay. 09:02

23 (Derendorf Exhibit No. 1 was marked for 09:03

24 identification.) 09:03

25 BY MR. MAY: 09:03

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2 A. Well, he's the clinical expert on the 09:04

3 use of this drug, so -- and he deals with 09:04

4 patients and expressed that drug level 09:04

5 monitoring in this field is not a common 09:04

6 practice. 09:05

7 Q. Do you deal with patients as part of 09:05

8 your research? 09:05

9 A. In research, yes, but I don't treat 09:05

10 patients. I'm not a medical doctor. 09:05

11 Q. Understood. 09:05

12 So do you work with medical doctors 09:05

13 to treat patients as part of your research? 09:05

14 A. Mostly I worked with medical doctors 09:05

15 in research studies, so to identify the dose or 09:05

16 not so much in treating patients. 09:05

17 Q. Okay. Did you have any discussions 09:05

18 with Dr. Kalin about his report? 09:05

19 A. No. 09:05

20 Q. Okay. About your report? 09:05

21 A. No. 09:05

22 Q. Okay. About anything else having to 09:05

23 do with this particular case? 09:05

24 A. With Dr. Kalin? 09:05

25 Q. Yes. 09:06

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1 H. DERENDORF

2 Q. And this is the patent owner's 09:03

3 response which was filed in this inter partes 09:03

4 review on May 20, 2019, and so I'll just ask 09:03

5 you to take a quick look at that and see if 09:03

6 that refreshes your recollection as to whether 09:03

7 or not you've seen this document before. 09:03

8 A. I don't think so. 09:03

9 Q. So you didn't consider any of the 09:03

10 arguments in that document as part of your 09:03

11 analysis in this declaration? 09:04

12 MS. ERNST: Objection to form. 09:04

13 A. Yeah, I -- I don't think I've seen it 09:04

14 so I couldn't have responded to it. 09:04

15 Q. Okay. So you reviewed Dr. Kalin's 09:04

16 declaration in this case? 09:04

17 A. I have looked at it, yes. 09:04

18 Q. Okay. And when did you review that 09:04

19 declaration? 09:04

20 A. I don't remember exactly when. 09:04

21 Q. Okay. And you relied on that to 09:04

22 formulate your opinion here? 09:04

23 A. Yes. 09:04

24 Q. Okay. In what way did you rely on 09:04

25 it? 09:04

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1 H. DERENDORF

2 A. No, I have not talked to him. 09:06

3 Q. Do you disagree with any of the 09:06

4 conclusions in Dr. Kalin's declaration? 09:06

5 A. Not that I can remember. 09:06

6 Q. Have you worked with psychiatrists in 09:06

7 the past as part of your research? 09:06

8 A. Yes. 09:06

9 Q. When? 09:06

10 A. Well, I do a lot of collaboration, 09:06

11 because we work with many different kinds of 09:06

12 drugs. One area is drugs of abuse, and I had 09:06

13 collaboration with the chair of psychiatry or 09:06

14 previous chair of psychiatry at the University 09:06

15 of Florida, Dr. Gold. 09:06

16 Q. So when you say "drugs of abuse," can 09:06

17 you tell me what that means? 09:06

18 A. Well, these are drugs that are taken 09:07

19 not for the intended medical purpose but for 09:07

20 other intentions. And usually they are 09:07

21 addicting, addicting drugs that -- opiates, for 09:07

22 example. 09:07

23 Q. Things like heroin -- 09:07

24 A. Yeah. 09:07

25 Q. -- oxycodone? 09:07

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