

1 IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

2 BEFORE THE PATENT TRIAL AND APPEAL BOARD

3 \*\*\*\*\*

4 MYLAN PHARMACEUTICALS INCORPORATED,

5 Petitioner

6 vs.

7 JANSSEN ONCOLOGY, INC.,

8 Patent Owner

9 \*\*\*\*\*

10 CASE IPR2016-01332

11 U.S. Patent No. 8,822,438

12 \*\*\*\*\*

13

14 VIDEOTAPED DEPOSITION of MARC B. GARNICK, M.D.

15 Thursday, February 16, 2017

16

17

18 .

19

20 9:02 a.m.

21 Held at: Eliot Hotel

22 360 Commonwealth Avenue

23 Boston, Massachusetts

24 Megan M. Castro, RPR, Court Reporter

Page 2

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 9  
 10 ALSO PRESENT:  
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 12  
 13  
 14  
 15  
 16  
 17  
 18  
 19  
 20  
 21  
 22  
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Page 4

1 INDEX  
 2 Witness Page  
 3 MARC B. GARNICK, M.D.  
 4 Direct Examination by Mr. Krause 5  
 5  
 6 EXHIBITS  
 7 Number Description Page  
 8 Exhibit JSN2009 Article entitled 104  
 9 "Eligibility and  
 10 Response Guidelines for  
 11 Phase II Clinical  
 12 Trials in  
 13 Androgen-Independent  
 14 Prostate Cancer:  
 15 Recommendations From  
 16 the Prostrate-Specific  
 17 Antigen Working Group"  
 18 by Glenn J. Bublely, et  
 19 al.  
 20 Exhibit JSN2010 Declaration of Scott R. 109  
 21 Serels, M.D.  
 22  
 23 Exhibit JSN2011 Two-page document from 184  
 24 The Journal of Urology  
 dated December 1991

Page 5

1 PROCEEDINGS  
 2 ---  
 3 THE VIDEOGRAPHER: We are now on the  
 4 record. My name is Marissa DeMonte, and I am a  
 5 videographer for Golkow Technologies.  
 6 Today's date is February 16, 2017, and  
 7 the time is 9:02 a.m. This video deposition is  
 8 being held in Boston, Massachusetts, in the  
 9 matter of Mylan Pharmaceuticals Incorporated  
 10 versus Janssen Oncology, Inc., for the United  
 11 States Patent and Trademark Office, before the  
 12 Patent Trial and Appeal Board.  
 13 The deponent is Marc B. Garnick, M.D.  
 14 Counsel will be noted on the stenographic record.  
 15 The court reporter is Megan Castro. She will now  
 16 swear in the witness and we can proceed.  
 17 ---  
 18 MARC B. GARNICK, M.D., first having been  
 19 satisfactorily identified by the production of  
 20 his driver's license and duly sworn by the Notary  
 21 Public, testified under oath as follows in answer  
 22 to direct examination by MR. KRAUSE:  
 23 ---

Page 6

1 your name and home address for the record?  
 2 A. Marc Bennett Garnick, G-A-R-N-I-C-K,  
 3 289 Marlborough Street, Boston, Massachusetts  
 4 02116.  
 5 Q. There are a few points I would like to  
 6 review before we get started. If I ask a  
 7 question that is not clear or you didn't hear me,  
 8 please let me know so I can ask the question  
 9 again. If you answer, I will assume you  
 10 understood and heard my question. Okay?  
 11 A. Yes.  
 12 Q. And we have a court reporter taking down  
 13 your answers to my questions, so please try to  
 14 give verbal answers to my questions. Okay?  
 15 A. Yes.  
 16 Q. We will try to take breaks about every  
 17 hour or so, but please let me know if you need a  
 18 break, and I will finish whatever question I am  
 19 on and we can take a break.  
 20 Is there any reason you cannot give  
 21 complete and accurate testimony here today?  
 22 A. No.  
 23 (Handing document to the witness.)  
 24 Q. I have handed you a document that has

Page 7

1 been marked as Mylan Exhibit 1002. Is this your  
 2 declaration?  
 3 (Witness viewing document.)  
 4 A. Yes, it is.  
 5 Q. Is that your signature on the last page  
 6 of the declaration?  
 7 A. Yes, it is, page 57.  
 8 Q. Yes, sir. Thank you.  
 9 Is the declaration marked as Mylan 1002  
 10 an accurate statement of the opinions that you  
 11 have reached in this case?  
 12 A. Yes, it is.  
 13 Q. We will be talking about a person of  
 14 ordinary skill in the art a lot today. When I  
 15 refer to a person of ordinary skill in the art,  
 16 will you understand that I am referring to a  
 17 person's knowledge as of -- that person's  
 18 knowledge as of August 25, 2006?  
 19 A. Yes.  
 20 MR. BEEL: Objection to form.  
 21 BY MR. KRAUSE:  
 22 Q. Please turn to the diagram following  
 23 paragraph 37 in your declaration. What does this

Page 8

1 A. This basically represents the steroid  
 2 pathway from cholesterol to various other  
 3 steroids, such as cortisol, aldosterone, and the  
 4 sex steroids.  
 5 Q. And the biosynthesis of all steroids  
 6 begins with the cleavage of the side chain of  
 7 cholesterol to form pregnenolone; is that  
 8 correct?  
 9 MR. BEEL: Objection to form.  
 10 A. Yes.  
 11 BY MR. KRAUSE:  
 12 Q. So if the conversion of cholesterol to  
 13 pregnenolone is blocked, so is the biosynthesis  
 14 of all the steroids; is that correct?  
 15 A. It would have to be a complete block, I  
 16 would assume.  
 17 Q. But if one had a complete block, that  
 18 would block the production of all of the steroids  
 19 in the pathways; correct?  
 20 MR. BEEL: Objection. Foundation.  
 21 A. I would assume so.  
 22 BY MR. KRAUSE:  
 23 Q. Some arrows in the diagram have the word  
 24 "CYP17" over them. What is CYP17?

Page 9

1 A. It is -- my understanding is that is an  
 2 enzyme complex that includes 17 alpha-hydroxylase  
 3 and 17,20-lyase, part of the cytochrome P450  
 4 system.  
 5 Q. Is it fair to say that these two  
 6 activities are represented in the diagram but not  
 7 specifically labeled?  
 8 A. I would assume so, yes.  
 9 Q. And paragraph 38 of your declaration  
 10 notes the 17 alpha-hydroxylase activities as a  
 11 hydroxyl group, OH, to pregnenolone and  
 12 progesterone at carbon 17 of the steroid D ring,  
 13 converting both to their 17-hydroxy forms. This  
 14 is represented in the horizontal arrows between  
 15 the first and second columns of the diagram; is  
 16 that correct?  
 17 A. Yes.  
 18 Q. Can you please circle those arrows for me  
 19 in your declaration and label them  
 20 "17 alpha-hydroxylase"?  
 21 (Witness marking document.)  
 22 A. They are not on the diagram.  
 23 Q. There are horizontal arrows between

Page 10

1 as progesterone and 17-hydroxy progesterone?  
 2 A. Correct.  
 3 Q. And don't those -- I believe you just  
 4 testified that those horizontal arrows represent  
 5 the 17 alpha-hydroxylase activity; is that  
 6 correct?  
 7 A. My understanding is that it is  
 8 incorporated into the CYP17 nomenclature,  
 9 C-Y-P 17.  
 10 Q. So the activity that is being represented  
 11 by those arrows is the 17 alpha-hydroxylase  
 12 activity of CYP17; is that correct?  
 13 A. Yes.  
 14 Q. Could you circle those arrows and label  
 15 them "17 alpha-hydroxylase" for me?  
 16 MR. BEEL: Objection to form and  
 17 foundation.  
 18 A. I am not sure I understand what you want  
 19 me to do.  
 20 BY MR. KRAUSE:  
 21 Q. I am trying to identify the activity in  
 22 this diagram that is associated with the  
 23 17-hydroxylase activity.  
 24 A. It is incorporated into the CYP17.

Page 11

1 Q. Correct.  
 2 A. Okay.  
 3 Q. And that is represented by these  
 4 horizontal arrows between the first and second  
 5 columns in the diagram; is that correct?  
 6 A. Yes, correct.  
 7 Q. So I am simply trying to ask you --  
 8 A. Want me to put 17 alpha-hydroxylase  
 9 there?  
 10 Q. Yes, sir. And just circle the arrows  
 11 that are correlated with that.  
 12 MR. BEEL: Objection to form and  
 13 foundation.  
 14 (Witness marking document.)  
 15 BY MR. KRAUSE:  
 16 Q. And I believe in your declaration,  
 17 paragraph 38, you note that 17,20-lyase activity  
 18 splits the side chain off of 17-hydroxy  
 19 progesterone and 17-hydroxy pregnenolone?  
 20 A. Yes.  
 21 Q. This is represented by the horizontal  
 22 arrows between the second and third columns of  
 23 the diagram; is that correct?

Page 12

1 MR. BEEL: Objection to form and  
 2 foundation.  
 3 THE WITNESS: Should I hear your  
 4 objection before I answer?  
 5 MR. BEEL: If you can pause for a second.  
 6 THE WITNESS: Okay.  
 7 BY MR. KRAUSE:  
 8 Q. And can you please label those arrows  
 9 "17,20-lyase"?  
 10 MR. BEEL: Objection to form and  
 11 foundation.  
 12 (Witness marking document.)  
 13 BY MR. KRAUSE:  
 14 Q. Let's talk first about the 17-hydroxylase  
 15 activity of CYP17. What does that do?  
 16 A. My understanding is it adds a hydroxy  
 17 group to pregnenolone.  
 18 Q. So if you completely block the  
 19 17-hydroxylase, you do not get any production of  
 20 cortisol or testosterone; is that correct?  
 21 MR. BEEL: Objection to form.  
 22 A. I would assume that you have to have  
 23 complete blockage to have that.  
 24 BY MR. KRAUSE:

Page 13

1 Q. So if one has complete blockage, is it  
 2 true that you would not get any production of  
 3 cortisol and testosterone?  
 4 A. That is a question for basically an  
 5 endocrine biochemist or enzymologist. That is  
 6 not an expertise that I have, whether it is  
 7 completely blocked or incompletely blocked, to  
 8 answer your question accurately.  
 9 Q. But my question was with reference to a  
 10 complete blockage. If one completely blocks that  
 11 activity, that is, the 17-hydroxylase activity,  
 12 one does not get any production of cortisol or  
 13 testosterone; is that correct?  
 14 MR. BEEL: Objection to form and  
 15 foundation.  
 16 A. I don't really know what you mean by  
 17 "completely blocked."  
 18 BY MR. KRAUSE:  
 19 Q. If there is a total absence of  
 20 17-hydroxylase activity, cortisol and  
 21 testosterone are not produced; is that correct?  
 22 MR. BEEL: Same objection.  
 23 A. Of 17-hydroxylase?

Page 14

1 Q. Yes, sir.  
 2 A. I am not sure that is correct.  
 3 Q. And if you get some but not complete  
 4 blocking of 17-hydroxylase, one could get some  
 5 cortisol and testosterone, but it would be less  
 6 than if it were completely blocked; is that  
 7 correct?  
 8 A. You are asking questions that are really  
 9 better addressed to a steroid biochemist or a  
 10 steroid enzymologist, in terms of the degree of  
 11 blockage, complete blockage versus incomplete  
 12 blockage. I am not really equipped to answer  
 13 those questions because I really don't know what  
 14 complete "blockage means" and what "incomplete  
 15 blockage" means.  
 16 Q. Okay. Now let's talk about 17,20-lyase  
 17 activity. What does 17,20-lyase do?  
 18 MR. BEEL: Objection. Foundation.  
 19 A. My understanding is that it basically is  
 20 involved in the pathway going to the sex  
 21 steroids.  
 22 BY MR. KRAUSE:  
 23 Q. And if one completely blocks the  
 24 17,20-lyase activity, no testosterone is

Page 15

1 produced, but cortisol could be produced; is that  
 2 correct?  
 3 MR. BEEL: Objection to form and  
 4 foundation.  
 5 A. That would be incorrect because  
 6 testosterone is produced other places as well.  
 7 BY MR. KRAUSE:  
 8 Q. Well, with respect to the pathway that we  
 9 have in front of us, isn't it true that if  
 10 one blocks the 17,20-lyase activity, the  
 11 production of testosterone would be blocked?  
 12 A. I guess my best answer to that question  
 13 is you are asking terms that I am really not  
 14 terribly familiar with. When you say "complete  
 15 block," "incomplete block," those questions are  
 16 really better addressed to an enzymologist.  
 17 Q. So is it fair to say you don't know the  
 18 answer to those questions?  
 19 A. I don't know what the term "blockage"  
 20 means. In strict enzymology, I don't understand  
 21 what that term means, complete versus incomplete  
 22 blockage.  
 23 Q. Okay. The diagram also has the word

Page 16

1 MR. BEEL: Objection to form.  
 2 A. That is another enzyme involved in  
 3 steroid synthesis.  
 4 BY MR. KRAUSE:  
 5 Q. What does that do?  
 6 MR. BEEL: Objection. Foundation.  
 7 A. It takes it from DOC to corticosterone,  
 8 from deoxy-corticosterone to corticosterone.  
 9 BY MR. KRAUSE:  
 10 Q. So is it true that if there is no  
 11 11-beta-hydroxylase activity, cortisol would not  
 12 be produced?  
 13 MR. BEEL: Objection to form and  
 14 foundation.  
 15 A. My answer is the same answer that I have  
 16 given you previously to the other quantitative  
 17 analyses of blockage or inhibition.  
 18 BY MR. KRAUSE:  
 19 Q. So is it your testimony that you have no  
 20 opinion with respect to a relative degree of  
 21 blockage of any of the enzymatic activities  
 22 represented on this diagram?  
 23 MR. BEEL: Objection to form.  
 24 A. I definitely have opinions on that.

Page 17

1 BY MR. KRAUSE:  
 2 Q. Well, what are your views with respect to  
 3 the relative degrees of blockage and the  
 4 potential production of steroids in light of  
 5 those relative degrees?  
 6 A. So I have been asked to be an expert  
 7 on -- and provide expert testimony on this  
 8 related to the clinical understanding of the way  
 9 in which pharmaceuticals are utilized in the  
 10 management of patients with prostate cancer that  
 11 affects steroid synthesis and sex steroid  
 12 synthesis.  
 13 So my opinions on agents that block  
 14 either 17-hydroxylase activity or 17,20-lyase  
 15 activity are agents which are commonly used --  
 16 which I commonly use in my day-to-day practice of  
 17 medicine, and the sequelae of those activities of  
 18 these particular enzymes relate -- result in  
 19 clinical activities and clinical sequelae that I  
 20 understand and treat.  
 21 So that is my understanding of the  
 22 opinions. I am not an expert in providing for  
 23 you specific enzymatic characteristics,

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