IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN PHARMACEUTICALS INCORPORATED,

Petitioner

vs.

JANSSEN ONCOLOGY, INC.,

Patent Owner

****

CASE IPR2016-01332

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

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

Thursday, February 16, 2017

9:02 a.m.

Held at: Eliot Hotel

360 Commonwealth Avenue

Boston, Massachusetts

Megan M. Castro, RPR, Court Reporter

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ALSO PRESENT:
Marissa DeMonte, videographer

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PROCEEDINGS

THE VIDEOGRAPHER: We are now on the record. My name is Marissa DeMonte, and I am a videographer for Golkow Technologies.

Today's date is February 16, 2017, and the time is 9:02 a.m. This video deposition is being held in Boston, Massachusetts, in the matter of Mylan Pharmaceuticals Incorporated versus Janssen Oncology, Inc., for the United States Patent and Trademark Office, before the Patent Trial and Appeal Board.

The deponent is Marc B. Garnick, M.D. Counsel will be noted on the stenographic record. The court reporter is Megan Castro. She will now swear in the witness and we can proceed.

MARC B. GARNICK, M.D., first having been satisfactorily identified by the production of his driver's license and duly sworn by the Notary Public, testified under oath as follows in answer to direct examination by MR. KRAUSE:

Q. Good morning, sir. Can you please state

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

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been marked as Mylan Exhibit 1002. Is this your declaration?
(Witness viewing document.)
A. Yes, it is.
Q. Is that your signature on the last page of the declaration?
A. Yes, it is, page 57.
Q. Yes, sir. Thank you.
Is the declaration marked as Mylan 1002 an accurate statement of the opinions that you have reached in this case?
A. Yes, it is.
Q. We will be talking about a person of ordinary skill in the art a lot today. When I refer to a person of ordinary skill in the art, will you understand that I am referring to a person's knowledge as of -- that person's knowledge as of August 25, 2006?
A. Yes.
MR. BEEL: Objection to form.
BY MR. KRAUSE:
Q. Please turn to the diagram following paragraph 37 in your declaration. What does this represent?

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A. This basically represents the steroid pathway from cholesterol to various other steroids, such as cortisol, aldosterone, and the sex steroids.
Q. And the biosynthesis of all steroids begins with the cleavage of the side chain of cholesterol to form pregnenolone; is that correct?
MR. BEEL: Objection to form.
A. Yes.
BY MR. KRAUSE:
Q. So if the conversion of cholesterol to pregnenolone is blocked, so is the biosynthesis of all the steroids; is that correct?
A. It would have to be a complete block, I would assume.
Q. But if one had a complete block, that would block the production of all of the steroids in the pathways; correct?
MR. BEEL: Objection. Foundation.
A. I would assume so.
BY MR. KRAUSE:
Q. Some arrows in the diagram have the word "CYP17" over them. What is CYP17?

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

as progesterone and 17-hydroxy progesterone?
A. Correct.
Q. And don't those -- I believe you just testified that those horizontal arrows represent the 17 alpha-hydroxylase activity; is that correct?
A. My understanding is that it is incorporated into the CYP17 nomenclature, C-Y-P 17.
Q. So the activity that is being represented by those arrows is the 17 alpha-hydroxylase activity of CYP17; is that correct?
A. Yes.
Q. Could you circle those arrows and label them "17 alpha-hydroxylase" for me?
MR. BEEL: Objection to form and foundation.
A. I am not sure I understand what you want me to do.
BY MR. KRAUSE:
Q. I am trying to identify the activity in this diagram that is associated with the 17-hydroxylase activity.
A. It is incorporated into the CYP17.

Q. Correct.
A. Okay.
Q. And that is represented by these horizontal arrows between the first and second columns in the diagram; is that correct?
A. Yes, correct.
Q. So I am simply trying to ask you --
A. Want me to put 17 alpha-hydroxylase there?
Q. Yes, sir. And just circle the arrows that are correlated with that.
MR. BEEL: Objection to form and foundation.
(Witness marking document.)
BY MR. KRAUSE:
Q. And I believe in your declaration, paragraph 38, you note that 17,20-lyase activity splits the side chain off of 17-hydroxy progesterone and 17-hydroxy pregnenolone?
A. Yes.
Q. This is represented by the horizontal arrows between the second and third columns of the diagram; is that correct?
A. Yes.

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

Q. So if one has complete blockage, is it true that you would not get any production of cortisol and testosterone?
A. That is a question for basically an endocrine biochemist or enzymologist. That is not an expertise that I have, whether it is completely blocked or incompletely blocked, to answer your question accurately.
Q. But my question was with reference to a complete blockage. If one completely blocks that activity, that is, the 17-hydroxylase activity, one does not get any production of cortisol or testosterone; is that correct?
MR. BEEL: Objection to form and foundation.
A. I don't really know what you mean by "completely blocked."
BY MR. KRAUSE:
Q. If there is a total absence of 17-hydroxylase activity, cortisol and testosterone are not produced; is that correct?
MR. BEEL: Same objection.
A. Of 17-hydroxylase?
BY MR. KRAUSE:

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

produced, but cortisol could be produced; is that correct?
MR. BEEL: Objection to form and foundation.
A. That would be incorrect because testosterone is produced other places as well.
BY MR. KRAUSE:
Q. Well, with respect to the pathway that we have in front of us, isn't it true that if one blocks the 17,20-lyase activity, the production of testosterone would be blocked?
A. I guess my best answer to that question is you are asking terms that I am really not terribly familiar with. When you say "complete block," "incomplete block," those questions are really better addressed to an enzymologist.
Q. So is it fair to say you don't know the answer to those questions?
A. I don't know what the term "blockage" means. In strict enzymology, I don't understand what that term means, complete versus incomplete blockage.
Q. Okay. The diagram also has the word "CYP11B1" near a couple of arrows. What is that?

MR. BEEL: Objection to form.
A. That is another enzyme involved in steroid synthesis.
BY MR. KRAUSE:
Q. What does that do?
MR. BEEL: Objection. Foundation.
A. It takes it from DOC to corticosterone, from deoxy-corticosterone to corticosterone.
BY MR. KRAUSE:
Q. So is it true that if there is no 11-beta-hydroxylase activity, cortisol would not be produced?
MR. BEEL: Objection to form and foundation.
A. My answer is the same answer that I have given you previously to the other quantitative analyses of blockage or inhibition.
BY MR. KRAUSE:
Q. So is it your testimony that you have no opinion with respect to a relative degree of blockage of any of the enzymatic activities represented on this diagram?
MR. BEEL: Objection to form.
A. I definitely have opinions on that.

BY MR. KRAUSE:
Q. Well, what are your views with respect to the relative degrees of blockage and the potential production of steroids in light of those relative degrees?
A. So I have been asked to be an expert on -- and provide expert testimony on this related to the clinical understanding of the way in which pharmaceuticals are utilized in the management of patients with prostate cancer that affects steroid synthesis and sex steroid synthesis.
So my opinions on agents that block either 17-hydroxylase activity or 17,20-lyase activity are agents which are commonly used -- which I commonly use in my day-to-day practice of medicine, and the sequelae of those activities of these particular enzymes relate -- result in clinical activities and clinical sequelae that I understand and treat.
So that is my understanding of the opinions. I am not an expert in providing for you specific enzymatic characteristics, equilibrium characteristics. That would be

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