

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

WOCKHARDT BIO AG,

CASE IPR2016-01582

PATENT 8,822,438

PETITIONER,

vs.

JANSSEN ONCOLOGY, INC.,

PATENT OWNER.

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MYLAN PHARMACEUTICALS INC.,

PETITIONERS,

CASE IPR2016-01332

PATENT 8,822,438 B2

vs.

JANSSEN ONCOLOGY, INC.,

PATENT OWNER

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FRIDAY, APRIL 28, 2017

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VIDEOTAPED DEPOSITION of IAN McKEAGUE, Ph.D.,  
taken at the offices of Perkins Coie, 700 13th Street  
NW, Suite 600, Washington, D.C., beginning at  
9:02 a.m., before Nancy J. Martin, a Registered Merit  
Reporter, Notary in and for the District of Columbia.

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Sun Pharmaceuticals Industries, Inc.,  
Teva Pharmaceuticals USA, Inc.,  
West-Ward Pharmaceutical Corp.,  
and Hikma Pharmaceuticals, LLC.

ALSO PRESENT:  
MICHAEL GAY, LEGAL VIDEOGRAPHER

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EXHIBITS PREVIOUSLY MARKED

NUMBER	Description	Page
Exhibit 2015	Selective Inhibition of CYP17 with Abiraterone Acetate is Highly Active in the Treatment of Castration-Resistant Prostate Cancer, 9 pages	123
Exhibit 2017	Phase II Study of Abiraterone Acetate in Chemotherapy-Naive Metastatic Castration-Resistant Prostate Cancer Displaying Bone Flare Discordant with Serologic Response, 9 pages	124
Exhibit 2038	Declaration of Matthew B. Rettig, M.D., in Support of Janssen Oncology, Inc.'s, Patent Owner Response,	92 108 pages

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BY MR. KRAUSE	6
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EXHIBITS

NUMBER	DESCRIPTION	PAGE
Exhibit 1146	Reply Declaration of Ian McKeague, Ph.D., in Support of Petition for Inter Partes Review of U.S. Patent No. 8,822,438, 55 pages	162
Exhibit 2016	Journal of Clinical Oncology, March 20, 2010, 8 pages	140
Exhibit 2183	The (mis)use of Overlap of Confidence Intervals to Assess Effect Modification, 2 pages	54
Exhibit 2184	A Brief Note on Overlapping Confidence Intervals, 1 page	54

EXHIBITS PREVIOUSLY MARKED

NUMBER	Description	Page
Exhibit 1091	Reply Declaration of Ian McKeague, Ph.D., in Support of Petition for Inter Partes Review of U.S. Patent No. 8, 822,438, 55 pages	7
Exhibit 1096	Significant and Sustained Antitumor Activity in Post-Docetaxel, Castration-Resistant Prostate Cancer with the CYP17 Inhibitor Abiraterone Acetate, 7 pages	105
Exhibit 1106	Reply Declaration of Ian McKeague, Ph.D., 55 pages	7

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WASHINGTON, D.C., FRIDAY, APRIL 28, 2017; 9:02 A.M.

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THE VIDEOGRAPHER: We are on the record. The time now is 9:02 a.m. This marks the beginning of Disk No. 1 for the videotaped deposition testimony of Ian McKeague in the matter of Mylan Pharmaceuticals, Inc. et al. v. Janssen Oncology, Inc. This case is pending in the United States Patent and Trademark Office, Case No. IPR:2016-01332. Today's date is April 28, 2017. This deposition is being conducted at 700 13th Street, Northwest, Washington, D.C.

Will all attorneys present, please identify themselves and who they represent.

MR. KRAUSE: This is Todd Krause of Sidley Austin, and I represent Janssen Oncology, Inc. And I'll just note for the record that this deposition, as well as being held in the Mylan action today, is also being held with respect to the Wockhardt action, which is Wockhardt Bio AGV, Janssen Oncology, Inc. Case IPR No. 2016-01582.

MR. SWANSON: Robert Swanson for Perkins Coie on behalf of Mylan.

MS. STUBBINGS: Maria Stubbings also from Perkins Coie on behalf of Mylan.

MS. LIN: Sharon Lin from Winston & Strawn on

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1 behalf of Actavis, Ameal, DRL, Sun, Teva, and  
2 Westward.  
3 THE VIDEOGRAPHER: My name is Michael Gay.  
4 I'm with Galkow Technologies. Our court reporter  
5 today is Nancy Martin with Veritext and will now swear  
6 in our witness.

7  
8 IAN RAY MCKEAGUE, PH.D.,  
9 having been first duly sworn/affirmed,  
10 was examined and testified as follows:

11  
12 THE VIDEOGRAPHER: You may proceed.

13  
14 EXAMINATION  
15 BY MR. KRAUSE:

16 Q. Good morning, Dr. McKeague. Can you please  
17 state your name and home address for the record.

18 A. Ian Ray McKeague. My home address is  
19 455 Central Park West, Apartment 8-D, New York,  
20 New York, 10025.

21 Q. There are a few points that I'd like to  
22 review before we get started.

23 If I ask a question and it's not clear or you  
24 don't hear me, please ask me. Please let me know so I  
25 can ask the question again. If you answer, I'll

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1 understand you heard and -- understood and heard my  
2 question. Is that fair?

3 A. Yes.

4 Q. And we have a court reporter taking down your  
5 answers to my questions. So please try to give verbal  
6 answers to my questions. Is that also understood?

7 A. Yes.

8 Q. We'll try to take breaks about every hour or  
9 so, but please let me know if you need a break. I'll  
10 finish whatever question I'm on, and we'll take a  
11 break. Okay?

12 A. Okay.

13 Q. Is there any reason you cannot give complete  
14 and accurate testimony here today?

15 A. No.

16 (Previously marked Exhibit 1091 was handed  
17 to the witness.)

18 MR. KRAUSE: I've handed you two documents.  
19 One is marked Mylan Exhibit 1091, and the other is  
20 marked Wockhardt Exhibit 1106 respectively.

21 (Previously marked Exhibit 1106 was handed  
22 to the witness.)

23 THE WITNESS: Yes.

24 BY MR. KRAUSE:

25 Q. Do you have those?

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1 A. I have those.  
2 Q. And Mylan Exhibit 1091 was submitted in IPR  
3 No. 2016-01332; is that correct?

4 A. That's correct.

5 Q. And Wockhardt Exhibit 1106 was submitted in  
6 IPR No. 2016-01582. Is that also correct?

7 A. That's correct.

8 Q. Do you recognize this document -- these --

9 A. Yes.

10 Q. -- documents?

11 A. Yes.

12 Q. And what are they?

13 A. These are my reply declarations in each of  
14 these cases.

15 Q. And is that your signature on the last page  
16 of both declarations?

17 A. Very last page. Do you mean right before my  
18 CV?

19 Q. Yes.

20 A. That's correct, yes.

21 Q. Okay. And that's true with respect to the  
22 declaration?

23 A. And -- yes. Yes.

24 Q. Do the declarations accurately reflect the  
25 opinions that you've reached in the Mylan and

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1 Wockhardt cases?

2 A. They do.

3 Q. And are there any errors in the declarations  
4 that you're aware of?

5 A. No, not that I'm aware of. There may be some  
6 minor verbal issues but no errors.

7 Q. Is it fair to say that the declarations are  
8 substantively identical but for the definitions of a  
9 person of ordinary skill in the art that you provided  
10 in each case?

11 A. Could you restate that question.

12 Q. Sure.

13 Is it fair to say that the declarations are  
14 substantively identical but for the definitions of a  
15 person of ordinary skill in the art that you've  
16 provided in each case?

17 A. That's correct.

18 Q. But your opinions are the same in the Mylan  
19 and Wockhardt matters regardless of any differences  
20 that may exist in the definitions of a person of  
21 ordinary skill in the art in those two cases; is that  
22 correct?

23 A. That's correct.

24 Q. So for purposes of today's deposition, we'll  
25 treat Mylan's and Wockhardt's person of ordinary skill

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1 in the art as the same. Is that all right with you?  
 2 MR. SWANSON: Object to form.  
 3 You can answer.  
 4 THE WITNESS: Yeah. Well, that's fine.  
 5 That's fine with me.  
 6 BY MR. KRAUSE:  
 7 Q. And when I refer to "a person of ordinary  
 8 skill in the art," or a POSA, P-O-S-A, I'm referring  
 9 to a person within the definitions that you've  
 10 provided in both your Mylan and Wockhardt  
 11 declarations. Is that understood?  
 12 A. That's understood.  
 13 Q. Moreover, when we talk about that person's  
 14 knowledge, it's referring to that person's knowledge  
 15 as of August 2006. Is that also understood?  
 16 A. Can we refer to the definitions?  
 17 Q. Certainly. Feel free to look at whatever  
 18 you'd like to look at.  
 19 A. So here we're talking about the Mylan one.  
 20 So this is -- as you see, the is the definition of  
 21 person of ordinary art in the skill is offered by  
 22 Dr. Garnick.  
 23 Q. Yes. Yes.  
 24 A. That's the source. You asked me about the  
 25 source.

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1 Q. No. I'm sorry. Maybe I didn't ask my  
 2 question very well.  
 3 I just wanted to make clear what date we're  
 4 talking about with respect to the person of ordinary  
 5 skill's knowledge.  
 6 A. When Dr. Garnick gave that definition?  
 7 Q. No. The date as of which one refers to prior  
 8 art, information that was known to a person of skill  
 9 in the area.  
 10 A. When one does? You mean in terms of a legal  
 11 question?  
 12 Q. The -- in this case there are certain dates  
 13 that are relevant.  
 14 A. Right.  
 15 Q. We're talking about the person of ordinary  
 16 skill in the art.  
 17 A. Yes.  
 18 Q. We've talked about that.  
 19 A. You mean the priority date?  
 20 Q. Yes, Doctor.  
 21 A. The 2006 priority date.  
 22 Q. Yes.  
 23 A. That's what you mean?  
 24 Q. Yes.  
 25 A. Yes.

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1 Q. So when we're talking --  
 2 A. So -- so this refers to -- as I understand  
 3 the definition as of the priority date, I expect.  
 4 Q. Right. So when I refer to a person of  
 5 ordinary skill's knowledge, I'm talking about that  
 6 person's knowledge as of August 2006. Do you  
 7 understand that?  
 8 A. Okay.  
 9 Q. Okay. Your declarations in the Mylan and  
 10 Wockhardt IPRs refer to many of the same documents; is  
 11 that correct?  
 12 A. Yes.  
 13 Q. But some of the documents bear different  
 14 Exhibit numbers in the two cases; is that correct?  
 15 A. Should we compare the --  
 16 Q. Feel free to, sure.  
 17 A. So the documents consulted in the last  
 18 pages --  
 19 Q. Yes, Doctor.  
 20 A. -- and you want to know whether the Exhibit  
 21 numbers are different? Indeed, they are.  
 22 Q. Right. My question was for some exhibits the  
 23 Exhibit numbers differ, but they're the same document;  
 24 is that correct?  
 25 A. Yes, I believe so. I believe that's the same

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1 set of documents in each one. Yeah. As you say, even  
 2 though the Exhibit numbers are slightly different.  
 3 Q. Yes.  
 4 Okay. By agreement of the parties during  
 5 today's deposition, I'll be using the declaration and  
 6 exhibits from the Mylan IPR in an effort to reduce  
 7 confusion. Is that all right?  
 8 A. Yes. That's a good idea.  
 9 Q. Okay. So, for example, when I refer to a  
 10 paragraph number, I'm referring to the paragraph  
 11 number in your Mylan declaration.  
 12 A. Yes.  
 13 Q. Now, Doctor, your understanding of prostate  
 14 cancer and its treatment comes entirely from the  
 15 references that are cited in your declarations; is  
 16 that correct?  
 17 MR. SWANSON: Object to form.  
 18 THE WITNESS: I knew about prostate cancer  
 19 long before my work on this case. No, it's not true  
 20 to say my knowledge comes entirely from that.  
 21 BY MR. KRAUSE:  
 22 Q. Okay. So what other knowledge did you have  
 23 with respect to prostate cancer before you started  
 24 working on this case?  
 25 A. Well, I mean I've had PSA tests myself. Of

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1 course, I'm an informed reader of the literature. I  
 2 think it's a vague question. But -- yeah.  
 3 **Q.** Okay. Well, if you could turn to Page 9 of  
 4 your Mylan declaration.  
 5 A. Uh-huh.  
 6 **Q.** In Footnote 2 you state, "My understanding of  
 7 prostate cancer and its treatment comes from the  
 8 references cited herein."  
 9 A. Yes.  
 10 **Q.** What area --  
 11 A. What are you talking about? Which paragraph?  
 12 **Q.** Footnote No. 2 on Page 9.  
 13 A. Uh-huh. Uh-huh.  
 14 **Q.** Do you see?  
 15 A. Uh-huh.  
 16 **Q.** It's the second sentence in Footnote No. 2.  
 17 A. Yes. Uh-huh. What about it?  
 18 **Q.** So what are you referring to there?  
 19 A. So it's good to have some background, and  
 20 citations are common and useful to a reader of this  
 21 document.  
 22 **Q.** So but for the references that you cited in  
 23 your declaration --  
 24 A. Uh-huh.  
 25 **Q.** -- what is your understanding of the state of

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1 the art with respect to the treatment of metastatic  
 2 castration-resistant prostate cancer as of August  
 3 2006?  
 4 **MR. SWANSON:** Object to form.  
 5 **THE WITNESS:** I think that's well outside  
 6 my -- my expertise is not as an expert in prostate  
 7 cancer if that's what you're asking.  
 8 **BY MR. KRAUSE:**  
 9 **Q.** So would it be fair to say that your  
 10 knowledge, with respect to the treatment of metastatic  
 11 castration-resistant prostate cancer as of August  
 12 2006, comes from the documents cited in your  
 13 declaration?  
 14 **MR. SWANSON:** Object to form.  
 15 **THE WITNESS:** I have a broad understanding of  
 16 what prostate cancer involves and the treatment of  
 17 prostate cancer, but I don't consider myself an  
 18 expert, no, in prostate cancer. My role in this is to  
 19 analyze the nature of Dr. Rettig's declaration in this  
 20 case, a reply to Dr. Rettig, not concerning --  
 21 concerning biostatistical issues.  
 22 **BY MR. KRAUSE:**  
 23 **Q.** So what is your understanding of the state of  
 24 the art with respect to the treatment of metastatic  
 25 castration-resistant prostate cancer as of August

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1 2006?  
 2 **MR. SWANSON:** Object to form. Calls for a  
 3 legal conclusion.  
 4 **THE WITNESS:** Yes. I'm not going to answer  
 5 that because I don't have an understanding of the  
 6 field as an expert in that field. I have an  
 7 understanding as a layman essentially.  
 8 **BY MR. KRAUSE:**  
 9 **Q.** And what is your understanding as a layman?  
 10 **MR. SWANSON:** Object to form. Vague.  
 11 **THE WITNESS:** That's a very broad and vague  
 12 question, and I don't think it's proper for me to  
 13 speculate on the state of the art in a field in which  
 14 I'm not an expert.  
 15 **MR. KRAUSE:** Okay. Counsel, during the  
 16 depositions of Dr. Bantle on Monday, a number of  
 17 inappropriate objections were made. It seems like,  
 18 despite my admonition during that deposition, you're  
 19 continuing to make inappropriate objections. I refer  
 20 you to the guidelines, particularly in the right  
 21 column of the federal register that I've just handed  
 22 you.  
 23 **MR. SWANSON:** What in particular do you find  
 24 objectionable?  
 25 **MR. KRAUSE:** You made an objection, vague.

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1 It states in the guidelines, "Examples of objections  
 2 that would not be proper are, among others, objection,  
 3 vague."  
 4 **MR. SWANSON:** Okay. So as long as I don't  
 5 make an objection, vague, I'm allowed to make other  
 6 objections in addition to just saying the word "form"  
 7 if there are objections based on your understanding?  
 8 **MR. KRAUSE:** Counsel, you can read the  
 9 guidelines if you're not familiar with them. I will  
 10 raise issues as they come up.  
 11 **MR. SWANSON:** I'm familiar with the  
 12 guidelines, and if you have an objection to the way  
 13 I'm objecting, I would appreciate it if you let me  
 14 know.  
 15 **MR. KRAUSE:** I just stated you made  
 16 objection, vague, and clearly, that's outside the  
 17 scope that's appropriate.  
 18 **MR. SWANSON:** Okay. We'll move on.  
 19 **BY MR. KRAUSE:**  
 20 **Q.** So in this Footnote 2 you refer to  
 21 Example 1092 as a reference that informed your  
 22 knowledge with respect to treatment of prostate cancer  
 23 and prostate cancer; is that correct?  
 24 A. Yes.  
 25 **Q.** Is that the primary reference that you relied

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