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

MYLAN PHARMACEUTICALS INC,

Petitioner,

v.

JANSSEN ONCOLOGY, INC.,

Patent Owner.

Case No. IPR2016-01332

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

WOCKHARDT BIO AG,

Petitioner,

v.

JANSSEN ONCOLOGY, INC.,

Patent Owner.

Case IPR2016-01582

U.S. Patent No. 8.822,438 B2

787 Seventh Avenue
New York, New York
9:08 a.m.

HIGHLY CONFIDENTIAL
VIDEOTAPED DEPOSITION OF
RICHARD J. AUCHUS, M.D., Ph.D.
APRIL 10, 2017

Page 2

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4 **HIGHLY CONFIDENTIAL VIDEOTAPED**
5 **OF RICHARD J. AUCHUS, M.D.. Ph.D., a Witness**
6 herein, taken by Petitioners, at the
7 offices of Sidley Austin LLP, 787 Seventh
8 Avenue, New York, New York, on Monday
9 April 10, 2017, before Debra Stevens, a
10 Certified Realtime and Registered
11 Professional Reporter and Notary Public of
12 the State of New York
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Page 4

1
2 **EXAMINATIONS**
3 Witness Page
4 Richard Auchus, M.D., Ph.D.
5 By Mr. Beel 7
6
7 **EXHIBITS**
8 Mylan
9 Exhibit Description Page
10 Exh 1090 Janssen's Patent Owner 34
11 Response
12
13 **PRIOR MARKED EXHIBITS**
14 Exhibit Description Page
15 Mylan 1001 U.S. Patent No. 26
16 8,822,438
17 Janssen Auchus declaration 30
18 2040
19 Mylan 1026 Auchus 2001 paper 37
20 Mylan 1025 Excerpt from 54
21 Harrison's "Principles
22 of Internal Medicine
23 Mylan 1003 O'Donnell paper 63
24 Mylan 1023 Attard 2005 84
25 Mylan 1005 U.S. Patent Number 86
 5,604,213
23 Mylan 1002 Declaration of Marc B. 87
 Garnick M.D.
24 Exh 2131 Van den Akker paper 101
25

Page 3

1
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Page 5

1
2 **VIDEOGRAPHER:** We are on the
3 record. Please note that the
4 microphones are sensitive and may pick
5 up whispering and private
6 conversations.
7 My name is Deverell Write,
8 representing Veritext Legal Solutions.
9 Today's date is April 10, 2017. The
10 time on the video monitor is
11 approximately 9:11 a.m. This
12 deposition is being held at the
13 offices of Sidley Austin, located at
14 787 Seventh Avenue, New York, New
15 York.
16 The caption of this case, Mylan
17 Pharmaceuticals Incorporated vs.
18 Janssen Oncology Incorporated, Case
19 Number IPR2016-01332; also, Wockhardt
20 Bio AG vs. Janssen Oncology
21 Incorporated, Case Number
22 IPR2016-01582. These cases are filed
23 in the U.S. Patent and Trademark
24 Office before the Patent Trial and

Page 6

1
 2 is Dr. Richard J. Auchus.
 3 At this time will counsel please
 4 state appearances?
 5 MR. BEEL: Bryan Beel for Mylan
 6 Pharmaceuticals. With me is my
 7 colleague Brandon White.
 8 MR. GALLO: Christopher Gallo,
 9 Sterne, Kessler Goldstein & Fox,
 10 representing Petitioner Wockhardt.
 11 MS. DONOVAN: Bindu Donovan from
 12 Sidley Austin LLP, representing
 13 Janssen Oncology Inc. With me is my
 14 colleague Alyssa Monsen.
 15 Whereupon,
 16 RICHARD J. AUCHUS,
 17 having been first duly sworn/affirmed,
 18 was examined and testified as follows:
 19 MR. BEEL: Ms. Donovan, I was
 20 going to begin by showing Dr. Auchus
 21 his Deposition Notice. Can we just
 22 stipulate that he is here pursuant to
 23 the Notice?
 24 MS. DONOVAN: Yes.
 25 MR. BEEL: Thank you very much.

Page 7

1 HIGHLY CONFIDENTIAL - R. AUCHUS, M.D.
 2 EXAMINATION BY
 3 MR. BEEL:
 4 Q. Good morning, Dr. Auchus.
 5 A. Good morning.
 6 Q. Let me begin with just a few
 7 comments. We are here today to discuss
 8 your declaration that you drafted and
 9 submitted in our inter partes review
 10 proceedings. I want to talk to you about
 11 certain topics in the declaration, but can
 12 we please be sure not to speak over each
 13 other? I will ask questions and if you
 14 can respond after I finish?
 15 A. Okay.
 16 Q. And I would ask that you please
 17 answer the question unless Ms. Donovan
 18 requests that you not answer.
 19 A. Okay.
 20 Q. If at any time you need a break,
 21 can you please let me know, but not when a
 22 question is pending? Please finish your
 23 answer?
 24 A. Right

Page 8

1 HIGHLY CONFIDENTIAL - R. AUCHUS, M.D.
 2 hour or so.
 3 A. Okay.
 4 Q. Is there any reason that you
 5 cannot give complete and truthful
 6 testimony today?
 7 A. No, there is not.
 8 Q. Okay. Thanks.
 9 Do you have an understanding of
 10 what this proceeding is related to?
 11 A. Yes, I do.
 12 Q. Can you tell me what that
 13 understanding is?
 14 A. So, Janssen holds a patent for
 15 the use of one of their medications in a
 16 specific way, and this is a challenge to
 17 that patent.
 18 Q. Do you understand that it is a
 19 proceeding under the U.S. Patent and
 20 Trademark Office as opposed to District
 21 Court?
 22 A. Yes, I do.
 23 Q. Have you been deposed before?
 24 A. A few months ago was the first
 25 time.

Page 9

1 HIGHLY CONFIDENTIAL - R. AUCHUS, M.D.
 2 Q. What case was that?
 3 A. That was the case of the same
 4 patent with a different company
 5 challenging it.
 6 Q. Do you recall the company?
 7 A. I believe it was Amerigen.
 8 Q. Thank you.
 9 That was your only prior
 10 deposition you said?
 11 A. That was my only prior
 12 deposition.
 13 Q. Have you ever testified at
 14 trial?
 15 A. I was -- I testified at a
 16 court-martial when I was in the Air Force.
 17 Q. Never in District Court
 18 proceedings?
 19 A. No. And I have also been
 20 involved with Court of Arbitrations board.
 21 Q. That sounds potentially more
 22 interesting --
 23 A. You might imagine what that was
 24 about

| | |
|---|---|
| <p style="text-align: right;">Page 10</p> <p>1 HIGHLY CONFIDENTIAL - R. AUCHUS, M.D. 2 a little about your professional 3 background. 4 Do you treat patients regularly? 5 A. Yes, I do. 6 Q. Do you have a hospital 7 appointment? 8 A. I work at the University of 9 Michigan. Our healthcare system recently 10 changed its name to Michigan Medicine. 11 And that's the only clinical practice that 12 I do is within that umbrella. 13 Q. How many patients do you have 14 regularly? 15 A. That's a hard question to 16 answer, but I will give you some ways of 17 calculating that. I have one or two 18 half-day clinics a week and I probably 19 have about 100 or 200 patients that I 20 manage, but I only see them usually once 21 every six months or so. 22 I also do in-hospital 23 consultation services for two weeks or so 24 every year, and I also staff our 25 Endocrinology Fellows Continuity of Care</p> | <p style="text-align: right;">Page 12</p> <p>1 HIGHLY CONFIDENTIAL - R. AUCHUS, M.D. 2 Q. What kind of basic research do 3 you do? 4 A. I do basic research on steroid 5 biosynthesis and metabolism. 6 Q. Is that like laboratory-based 7 research? 8 A. Yes. 9 Q. Do you know how many people are 10 in your laboratory? 11 A. Currently, one, two, three, 12 four, five -- if you count undergraduates, 13 that's six. 14 Q. Have you ever participated as an 15 investigator in clinical trials? 16 A. Yes -- 17 MS. DONOVAN: Objection to the 18 form of the question. 19 A. Yes, I have. 20 Q. And can you describe those 21 trials? 22 A. So, we have done Phase I trials 23 of either abiraterone acetate or a drug 24 called NBI-77860, for treating 25 21-hydroxylase deficiency. Actually, we</p> |
| <p style="text-align: right;">Page 11</p> <p>1 HIGHLY CONFIDENTIAL - R. AUCHUS, M.D. 2 Clinic, and those patients I share 3 responsibility with the Fellow and with 4 other attending physicians. 5 Q. What appointment do you have 6 that fills the rest of your time? Do you 7 have a university appointment? 8 A. Right. So, I am a professor of 9 internal medicine, endocrinology and 10 metabolism and professor of pharmacology 11 at the University of Michigan. So my 12 activities include the patient care, 13 running the fellowship program, 14 research -- both clinical and basic -- and 15 other academic activities. 16 Q. What kind of clinical research 17 do you do? 18 A. Well, it's clinical research on, 19 generally, endocrine diseases. The focus 20 would be on disorders of the adrenal 21 cortex, congenital adrenal hyperplasia, 22 Cushing's syndrome, primary aldosteronism 23 are the main diseases we study. We also 24 do some other things mainly in</p> | <p style="text-align: right;">Page 13</p> <p>1 HIGHLY CONFIDENTIAL - R. AUCHUS, M.D. 2 also have a trial of a drug called ATR-101 3 for 21-hydroxylase deficiency. 4 We are studying drugs for the 5 treatment of Cushing's syndrome. We also 6 do a lot of studies that aren't 7 interventional studies but are biomarker 8 studies in these diseases, where we 9 collect samples and measure steroid 10 hormones that are the sort of traditional 11 ones but also non-traditional ones, to 12 look for better disease markers. 13 That's not all, but that is kind 14 of the main things we have been doing. 15 Q. You mentioned a Phase I trial 16 with abiraterone acetate. When did that 17 occur? 18 A. That paper -- so that started 19 right after I moved to Michigan in 2011, 20 and that probably ran until 2013. I 21 believe the results were published in 22 2014. 23 Q. Can you describe the subject 24 matter of that clinical trial?</p> |

| | |
|---|--|
| <p style="text-align: right;">Page 14</p> <p>1 HIGHLY CONFIDENTIAL - R. AUCHUS, M.D. 2 deficiency have cortisol deficiency and 3 they make too much testosterone. And so 4 the traditional treatment has been to 5 suppress -- both replace the cortisol 6 deficiency and suppress the testosterone 7 with glucocorticoids, and that requires 8 doses that are above physiologic and lead 9 to complications. 10 So, we reduce the dose of 11 glucocorticoids to a physiologic level, 12 allow the testosterone to rise, and then 13 try to block the testosterone synthesis 14 with abiraterone. And it was a small 15 study of six participants, two different 16 dose levels, six days each. 17 Q. What was the purpose of the 18 study if it only lasted six days? 19 A. It was a proof-of-concept study 20 with the intention of then doing a larger 21 study in children, which is going -- which 22 is now funded by the NIH. So, that's on 23 the books for later this year. 24 Q. What do you mean by "proof of 25 concept"?</p> | <p style="text-align: right;">Page 16</p> <p>1 HIGHLY CONFIDENTIAL - R. AUCHUS, M.D. 2 primary hyperaldosteronism? 3 A. So, there is a long and involved 4 evaluation to determine what the source of 5 aldosterone is. And then if it's only one 6 side, only one adrenal gland that's the 7 source, we tend to treat that with 8 surgery. 9 I don't do the surgery. I refer 10 them to our surgeons. And that usually 11 cures the problem and then we don't have a 12 long-term relationship. 13 If it's both adrenal glands that 14 are making aldosterone in excess, we don't 15 do a bilateral surgery because that would 16 render the patient adrenal insufficient. 17 So, we treat that medically with drugs 18 like spironalactone, eplerenone, sometimes 19 amiloride, and in combination with other 20 blood pressure medicines. 21 Q. Has any of your research 22 involved prostate cancer patients? 23 MS. DONOVAN: Object to the form 24 of the question. You may answer. 25 Q. Clinical research. Sorry.</p> |
| <p style="text-align: right;">Page 15</p> <p>1 HIGHLY CONFIDENTIAL - R. AUCHUS, M.D. 2 MS. DONOVAN: Object to form. 3 You may answer. 4 A. A study that is large enough to 5 show that the idea has validity and that 6 would allow you to then -- would then 7 encourage one to do a larger study that 8 would be more definitive. 9 Q. You said those results were 10 published in 2014? 11 A. I believe that is the year, yes. 12 Q. Roughly. Okay. 13 Have you treated prostate cancer 14 patients in a clinical setting? 15 MS. DONOVAN: I object to the 16 form of the question. You may answer. 17 A. I don't treat patients for 18 prostate cancer. I do treat patients who 19 happen to have prostate cancer, for other 20 endocrine diseases. For example, I have 21 one patient with prostate cancer and 22 primary aldosteronism. I manage the 23 primary aldosteronism. I don't treat the 24 primary cancer. Somebody else does that</p> | <p style="text-align: right;">Page 17</p> <p>1 HIGHLY CONFIDENTIAL - R. AUCHUS, M.D. 2 A. So, my clinical research, no. I 3 have collaborators that do prostate cancer 4 research that do use patient-derived 5 samples or do have ongoing patient 6 management. 7 But we do basic research that 8 dovetails with that on steroid metabolism. 9 So, I have a number of papers with 10 prostate cancer collaborators, 11 particularly Dr. Sharifi at the Cleveland 12 clinic, where we do a combination of 13 human, mouse, tissue culture, in vivo 14 biochemistry. And we work more on the 15 chemical synthesis and in vitro 16 biochemistry, and he does more of the 17 animal and human experiments. 18 Q. You are familiar with the drug 19 abiraterone acetate? 20 A. Yes, I am. 21 MS. DONOVAN: Objection to the 22 form of the question. 23 Just allow him to finish his 24 question, allow me to object, and then</p> |

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