

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

WOCKHARDT BIO AG,

Petitioner,

v.

Case IPR2016-01582

JANSSEN ONCOLOGY, INC.,

Patent 8,822,438 B2

Patent Owner.

VIDEOTAPED DEPOSITION OF

PAUL A. GODLEY, M.D., Ph.D., MPP

Chapel Hill, North Carolina

Wednesday, April 26th, 2017

Reported in Stenotype by

Amy A. Brauser, RPR, RMR, CRR

Transcript produced by computer-aided transcription

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1 INDEX OF EXAMINATIONS
 2 By Ms. Donovan Page 9, 192
 3 By Mr. Powers Page 186

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 5 INDEX OF EXHIBITS
 6 Janssen Exhibit 2175 Notice of Deposition 11
 7 Janssen Exhibit 2176 ClinicalTrials.gov 77
 8 study synopsis
 9 Janssen Exhibit 2177 Reply Declaration of 138
 10 Marc B. Garnick, M.D. in support of
 11 Petition for Inter Partes Review of U.S.
 12 Patent No. 8,822,428

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1 VIDEOTAPED DEPOSITION OF PAUL A. GODLEY,
 2 M.D., Ph.D., MPP, a witness called on behalf of Patent
 3 Owner, before Amy A. Brauser, Notary Public, in and
 4 for the State of North Carolina, at the Rizzo Center,
 5 150 Dubose Home Lane, Chapel Hill, North Carolina, on
 6 Wednesday, the 26th day of April, 2017, commencing at
 7 9:36 a.m.
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1 PREVIOUSLY MARKED EXHIBITS
 2 Wockhardt Exhibit 1002 Declaration of 21
 3 Paul A. Godley, M.D., Ph.D., MPP
 4 Wockhardt Exhibit 1004 Prostate Specific 119
 5 Antigen for Assessing Response to
 6 Ketoconazole and Prednisone in Patients
 7 with Hormone Refractory Metastatic
 8 Prostate Cancer
 9 Wockhardt Exhibit 1005 Hormonal impact of 127
 10 the 17-a-hydroxylase/C17,20-lyase
 11 inhibitor abiraterone acetate (CB7630)
 12 in patients with prostate cancer
 13 Wockhardt Exhibit 1013 High-Dose 57
 14 Ketoconazole in Advanced
 15 Hormone-Refractory Prostate Cancer:
 16 Endocrinologic and Clinical Effects
 17 Wockhardt Exhibit 1022 Selective Inhibition 52
 18 of CYP17 with Abiraterone Acetate is Highly
 19 Active in the Treatment of
 20 Castration-Resistant Prostate Cancer
 21 Wockhardt Exhibit 1026 Serum Prostate-Specific 127
 22 Antigen Decline as a Marker of Clinical
 Outcome in Hormone-Refractory Prostate
 Cancer Patients: Association with
 Progression-Free Survival, Pain End
 Points, and Survival

Page 5

1 PREVIOUSLY MARKED EXHIBITS (con't)

2 Wockhardt Exhibit 1030 United States Patent 175

3 5,604,213

4 Wockhardt Exhibit 1040 New England Journal 44

5 of Medicine article The Use of

6 Ketoconazole as an Inhibitor of Steroid

7 Production

8 Wockhardt Exhibit 1083 Low Doses of Oral 48

9 Dexamethasone for Hormone-Refractory

10 Prostate Carcinoma

11 Wockhardt Exhibit 1096 Significant and 72

12 Sustained Antitumor Activity in

13 Post-Docetaxel, Castration-Resistant

14 Prostate Cancer with the CYP17 Inhibitor

15 Abiraterone Acetate

16 Wockhardt Exhibit 1104 Declaration of 16

17 Paul A. Godley, M.D., Ph.D., MPP

18 Janssen Exhibit 2015 Declaration of 179

19 Marc B. Garnick, M.D.

20 Janssen Exhibit 2016 Deposition transcript 182

21 of Marc B. Garnick, M.D. of

22 February 16, 2017

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1 PREVIOUSLY MARKED EXHIBITS (con't)

2 Janssen Exhibit 2057 Eligibility and 116

3 Response Guidelines for Phase II

4 Clinical Trials in Androgen-Independent

5 Prostate Cancer: Recommendations from

6 the Prostate-Specific Antigen Working Group

7 Janssen Exhibit 2063 Antiandrogen 158

8 Withdrawal Alone or in Combination with

9 Ketoconazole in Androgen-Independent

10 Prostate Cancer Patients: A Phase III

11 Trial (CALGB 9583)

12 Janssen Exhibit 2064 Randomized Phase-2 167

13 trial of ketoconazole and

14 ketoconazole/doxorubicin in androgen

15 independent prostate cancer

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1 PROCEEDINGS

2 THE VIDEOGRAPHER: We're now on record.

3 My name is Brad Smith, a videographer for Golkow

4 Technologies. Today's date is April the 26th of

5 2017 and the time on the video monitor is

6 9:36 a.m. This video deposition is being held

7 in Chapel Hill, North Carolina. It's being

8 taken in the matter of Wockhardt Bio Ag,

9 Petitioner, versus Janssen Oncology, Inc.,

10 Patent Owner. It's for the United States Patent

11 and Trademark Office before the Patent Trial and

12 Appeal Board. The deponent today is Dr. Paul A.

13 Godley.

14 Now will counsel, please, now introduce

15 themselves for the record and then our court

16 reporter will swear in the witness.

17 MR. POWERS: Sure. This is Rob Powers

18 III from Sterne Kessler Goldstein & Fox on

19 behalf of Wockhardt Bio AG.

20 MS. DONOVAN: Okay. And Bindu Donovan

21 from Sidley Austin, LLP on behalf of Janssen

22 Oncology, Inc.

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1 PAUL A. GODLEY, M.D., Ph.D., MPP,

2 having been first duly sworn to tell the truth, was

3 examined and testified as follows:

4 EXAMINATION

5 BY MS. DONOVAN:

6 Q. Good morning, Doctor.

7 A. Good morning.

8 Q. Could you, please, state your full name

9 and home address for the record?

10 A. Paul Alfonso Godley. My home address is

11 101 Songbird Lane in Chapel Hill, North Carolina.

12 Q. And you've been deposed previously,

13 correct?

14 A. I have.

15 Q. Okay. And, in fact, you were deposed in

16 this matter in March of this year; is that correct,

17 sir?

18 A. I believe it was March.

19 Q. So you're generally familiar with the

20 procedure?

21 A. I'm generally familiar with the procedure,

22 yes.

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1 Q. I'm going to just quickly review some
 2 background items. Most importantly, I'll be asking
 3 you questions. If there's a question that you don't
 4 understand, please, let me know and I will clarify it
 5 for you or rephrase it. I will assume that if you
 6 answer a question you -- that you have heard and
 7 understood my question. Is that okay?
 8 A. That is okay.
 9 Q. And the court reporter, as you know, is
 10 transcribing your answers and, therefore, I request
 11 that you answer the questions verbally. Okay?
 12 A. Yes.
 13 Q. And we will try to take a break every
 14 hour. If you need a break, then, please, let me know
 15 and we will definitely -- if you request a break, I'll
 16 be happy to break the proceeding but will request that
 17 you answer any question that's pending before we take
 18 a break. Okay?
 19 A. That is okay.
 20 Q. All right. Sir, is there any reason why
 21 you cannot give complete and accurate testimony today?
 22 A. Not that I know of.

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1 (JANSSEN EXHIBIT NUMBER 2175 WAS MARKED FOR
 2 IDENTIFICATION)
 3 BY MS. DONOVAN:
 4 Q. I've placed in front of you a document
 5 that's been marked Janssen Exhibit 2175. Have you
 6 seen this document before today, sir?
 7 MR. POWERS: May I have a copy of it,
 8 please?
 9 MS. DONOVAN: And I'll just state for
 10 the record this document is entitled Patent
 11 Owner's Notice of Deposition of Paul A. Godley,
 12 M.D., Ph.D., M.P.P.
 13 THE WITNESS: This is the first time
 14 I've seen this document as far as I know.
 15 BY MS. DONOVAN:
 16 Q. Okay. Do you understand that you are
 17 testifying here in this proceeding subject to a Notice
 18 of Deposition?
 19 A. I do understand that.
 20 Q. Okay. Very good.
 21 What did you do to prepare for your
 22 deposition today, sir?

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1 A. I reviewed my declaration, I reviewed the
 2 exhibits that I cited in the deposition, I worked with
 3 my attorneys to prepare.
 4 Q. Okay. And you said you "reviewed my
 5 declaration," are you referring to your reply
 6 declaration --
 7 A. I'm refer --
 8 Q. -- in this proceeding?
 9 A. I am referring to my reply declaration,
 10 yes.
 11 Q. Did you also review your original
 12 declaration in preparation for your deposition today?
 13 A. I did not rereview my original
 14 declaration.
 15 Q. Okay. And you, just to clarify the
 16 record, said "I reviewed the exhibits that I cited in
 17 the deposition," did you mean to say you reviewed the
 18 exhibits cited in your reply declaration?
 19 A. That is correct. I reviewed the exhibits
 20 I cited in my reply declaration.
 21 Q. Did you also review, in preparation for
 22 today, exhibits that were cited in your original

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1 declaration?
 2 A. I did not review those exhibits.
 3 Q. Okay. And you also stated that you met
 4 with your counsel, I believe. You worked with your
 5 attorneys to prepare for your deposition today? Did
 6 you meet with counsel in preparation for your
 7 deposition today?
 8 A. I did.
 9 Q. Okay. Who did you meet with?
 10 A. I met with my counsel, Trey.
 11 Q. Was that one meeting or more than one in
 12 preparation for your deposition today?
 13 A. It was at least one.
 14 Q. Could you -- all right, go ahead.
 15 A. At least one meeting in person and one
 16 meeting over the phone.
 17 Q. And when did you meet with Mr.?
 18 MR. POWERS: Powers.
 19 BY MS. DONOVAN:
 20 Q. Powers in person?
 21 A. I met with him yesterday.
 22 Q. Okay. And when did you speak to

Page 13

1 Mr. Powers by telephone?
 2 A. That would have been mid April.
 3 Q. Was that after you submitted your reply
 4 declaration, sir? And I'll represent to you your
 5 reply declaration was submitted on April 19th.
 6 A. That was before I submitted my reply
 7 declaration.
 8 Q. Yesterday in your in-person meeting, was
 9 anyone else present other than Mr. Powers?
 10 A. No one else was present.
 11 Q. Okay. And during your telephone
 12 conversation or telephonic meeting with counsel, were
 13 there -- was anyone else participating in that
 14 telephonic meeting?
 15 A. There were -- there was an associate of
 16 Dr. -- of Mr. Powers that was also present.
 17 Q. Do you remember the associate's name?
 18 A. I couldn't remember Mr. Powers' name.
 19 Q. He's going to try not to take that
 20 personally.
 21 MR. POWERS: I will try.
 22

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1 BY MS. DONOVAN:
 2 Q. Okay. And your meeting yesterday in
 3 person with Mr. Powers, about how long did you meet
 4 for?
 5 A. Possibly four hours.
 6 Q. In preparing for your deposition, other
 7 than counsel, did you meet with any nonattorneys
 8 either in person or by telephone, to your knowledge?
 9 A. Other than the associate -- Mr. Powers'
 10 associate, I have not met with another person.
 11 Q. Okay. So you have not had any telephonic
 12 conversations with someone named Dr. Ian McKeague?
 13 A. No, I haven't.
 14 Q. Okay. And not -- no in-person meetings
 15 with Dr. McKeague either, correct?
 16 A. No.
 17 Q. Okay. And you've not had any in-person or
 18 telephonic meetings with a Dr. Robert Stoner; is that
 19 correct?
 20 A. I have not.
 21 Q. Okay.
 22 Sir, I'm placing in front of you a copy of

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1 Wockhardt Exhibit 1104, and I see that you, in fact,
 2 have a copy of that in front of you. Do you recognize
 3 this document, sir?
 4 A. I do.
 5 Q. This is your reply declaration that's been
 6 submitted in this matter, correct?
 7 A. That is correct.
 8 Q. Okay. If you could look at the last page
 9 of Exhibit 1104, please, sir. The very last page.
 10 It's --
 11 A. On the back.
 12 Q. Yes. Is that your signature that appears
 13 on the very last page of Exhibit 1104?
 14 A. That is.
 15 Q. Okay. You signed your declaration on
 16 April 14th, 2017; is that correct, sir?
 17 A. That is correct.
 18 Q. Were additional changes made to the reply
 19 declaration after you signed it on April 14th, 2017?
 20 A. Not that I'm aware of.
 21 Q. Okay. Is WCK 1104, your reply
 22 declaration, an accurate statement of the reply

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1 opinions you have reached in this case?
 2 A. It is an accurate reflection of my
 3 opinions, yes.
 4 Q. And do you have any corrections that you'd
 5 like to make to -- today to Wockhardt Exhibit 1104?
 6 A. I do not.
 7 Q. Okay. And did you write your reply
 8 declaration yourself, sir?
 9 A. I wrote it in conjunction with my
 10 attorneys.
 11 Q. Who prepared the first draft of the
 12 declaration, sir?
 13 A. My attorneys prepared the first draft.
 14 Q. And about how many drafts were prepared,
 15 to your recollection?
 16 MR. POWERS: Objection, relevance.
 17 THE WITNESS: At least two drafts were
 18 prepared.
 19 BY MS. DONOVAN:
 20 Q. Okay. And about how much time did you
 21 spend in preparing your reply declaration?
 22 A. I spent maybe eight hours.

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