UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

WOCKHARDT BIO AG,
PETITIONER,
vs.
JANSSEN ONCOLOGY, INC.,
PATENT OWNER.

CASE IPR2016-01582
PATENT 8,822,438

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TUESDAY, MARCH 7, 2017

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VIDEOTAPED DEPOSITION of PAUL A. GODLEY, M.D., PH.D., MPP, taken at the offices of Sterne Kessler Goldstein Fox, 1100 New York Avenue NW, Suite 600, Washington, D.C., beginning at 9:06 a.m., before Nancy J. Martin, a Registered Merit Reporter, Notary in and for the District of Columbia.

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EXHIBITS PREVIOUSLY MARKED





WASHINGTON, D.C., TUESDAY, MARCH 7, 2017; 9:06 A.M.

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THE VIDEOGRAPHER: Good morning. My name is Solomon Francis, representing Veritext. Today's date is March 7, 2017. The time is approximately 9:06 a.m. This deposition is being held by the law offices of Sterne, Kessler, Goldstein & Fox, located at 1100 New York Avenue, Northwest, Washington, D.C. and is taken by counsel for the patent owner. Caption of this case is Wockhardt Bio AG, Petitioner, v. Janssen Oncology, Inc., Patent Owner. This case is being held in the United States Patent and Trademark Office. Case No. IPR2016-01582. The name of the witness is Dr. Paul A. Godley.

At this time will counsel present please identify themselves and the parties they represent.

MR. KRAUSE: Todd Krause of Sidley Austin for patent owner, Janssen.

MR. POWERS: Ralph Powers, III, Sterne, Kessler, Goldstein & Fox for Wockhardt.

MR. GALLO: Christopher Gallo from Sterne, Kessler, Goldstein & Fox for Wockhardt.

THE VIDEOGRAPHER: At this time our court reporter, Nancy Martin, representing Veritext, will swear the witness and we can proceed.

PAUL A. GODLEY, M.D., PH.D.,
having been first sworn,
was examined and testified as follows:

EXAMINATION

BY MR. KRAUSE:

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

REDACTED

Q. Have you ever been deposed before?

A. I have.

Q. There are a few points that I'd like to review before we get started. If I ask a question that isn't clear or you didn't hear me, please let me know so I can ask the question again. If you answer, I'll assume that you understood and heard my question. Okay?

A. Yes.

Q. 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. And we'll try to take breaks about every hour or so, but please let me know if you need a break.



I'll finish up my line of questions that I'm on, and then we can take a break. Okay?

A. Yes.

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

A. Not that I know of.

MR. KRAUSE: I'm handing you a document that's been marked as -- I apologize. I don't have additional copies, but I'm sure you have a copy.

A document that's been previously marked as Wockhardt Exhibit 1002.

(Previously marked Exhibit 1002 was handed to the witness.)

BY MR. KRAUSE:

Q. Is this your declaration?

A. It appears to be.

Q. Would you like to review it to confirm?

A. I would.

(The witness reviewed Exhibit 1002.)

BY MR. KRAUSE:

Q. Is this your declaration?

A. It is.

Q. And is that your signature on the last page of the declaration?

A. It is.



Q. Is the declaration marked as Wockhardt 1002 an accurate statement of the opinions that you've reached in this case?

A. Yes, it is.

Q. Doctor, we'll be talking a lot about a person of ordinary skill in the art today. When I refer to a person of ordinary skill in the art, or POSA, P-O-S-A, I'm referring to the person as you've defined it in your expert report. Is that understood?

A. I understand.

Q. And when we talk about that person's knowledge, it refers to that person's knowledge as of August 25, 2006. Is that also understood?

A. That is understood.

Q. What is metastatic castration-resistant prostate cancer?

(The witness further reviewed Exhibit 1002.)

THE WITNESS: So it doesn't appear I define it directly, but "metastatic" implies that the cancer has spread beyond the region around the prostate to usually bone or lymph node. "Castrate resistance" implies a prostate cancer is no longer responding to our typical hormonal strategies of antiandrogen withdrawal. So by definition --

REPORTER MARTIN: I'm sorry. Can you speak



up just a little bit, sir. "is no longer responding to typical" --

THE WITNESS: Antiandrogen. Antiandrogens. And so by definition, resistant to castration, and castration is this withdrawal of androgens.

BY MR. KRAUSE:

Q. And is metastatic castration-resistant prostate cancer sometimes referred to as "MCRPC"?

A. Yes, it is.

Q. As of August 25, 2006, the prognosis for patients with MCP- -- let me start that again.

As of August 25, 2006, the prognosis for patients with MCRPC was poor, and treatment focused on palliative care; is that correct?

A. That is correct.

Q. What treatment options would a person of ordinary skill in the art use in August 25, 2006 to treat MCRPC?

A. So these would typically be patients who have failed Lupron. So they've failed first-line therapy, which makes the metastatic castrate resistant. And then they would receive, potentially, an antiandrogen, like Casodex or flutamide. They would then, failing that, potentially get ketoconazole and hydrocortisone.

And, potentially, failing that, they may get

hydrocortisone alone or mitoxantrone chemotherapy agent.

Q. So is it fair to say, then, that the first-line therapies were hormonal treatments? Is that right?

A. So your question was treatment of metastatic castrate-resistant prostate cancer. So this would be after --

Q. I see.

A. -- hormonal treatment.

Q. Okay. So hormonal treatment would precede this?

A. Right. So in their failure of hormonal treatment would meet the criteria for castrate resistant. So even though your question started with castrate resistant, I did mention that they would have gotten something like Lupron or a bilateral orchiectomy first. After that, then their next treatment would be their first castrate -- metastatic castrate-resistant prostate cancer treatment, would likely be an antiandrogen, hydrocortisone and ketoconazole, potentially prednisone ketoconazole, potentially prednisone alone, a drug like mitoxantrone or another chemotherapy drug. Docetaxel was also available at that time.



Q. I think in your report you talk about docetaxel?

A. Yes.

Q. So and docetaxel is a chemotherapy; is that right?

A. Yes.

Q. Where would the use of chemotherapy fit into kind of the landscape of therapies that a person of skill in the art would use for the treatment of prostate cancer in this 2006 time frame?

A. There was, I think, incentives on the parts of physician to delay the use of chemotherapy because it's much less convenient for the patient who would have to come in every three weeks instead of every months, and the chemotherapy side effects tended to be more dramatic.

And so there was a tendency to shift -- even though chemotherapy could be used earlier in these patients, it shifted later because you keep patients at home more and use oral therapies. And the antiandrogens were oral, the ketoconazole and prednisone were also oral. So there was a tendency to shift patients to use oral, oral hormonal treatments earlier.

The advantage of both mitoxantrone and docetaxel are that they're pretty effective in patients who have symptoms. So if you have a patient who is symptomatic, then the tendency would be to move chemotherapy up in your treatment paradigm because it's pretty well established the patient can have pretty dramatic palliation of their symptoms.



Q. I see. And what is -- I apologize if you touched on this before, but what is "androgen deprivation therapy"?

A. So androgen deprivation therapy is the analog of being castrate resistant. Prostate cancer as a disease feeds on androgens so that withdrawal of androgens can elicit a remarkable response. A guy named Hopps won the noble prize by figuring out in 1960, figuring out that castrating men with metastatic prostate cancer led to a dramatic, prolonged sort of response in their cancer.

So that -- we haven't gotten too far away from that, that it's clear that taking hormones either by bilateral orchiectomy or by -- with chemical like Lupron, removing hormones can have a dramatic effect in patients with metastatic prostate cancer.

The problem that we face now is it doesn't last. And so a year later or two years later, you're faced with a patient who has, again, increasing



prostate cancer, your energy withdrawal therapy, either the castration or Lupron has stopped working, and now you need a sort of second line of therapy that would be effective in patients that are no longer responding to this antiandrogen withdrawal.

Q. And that's where the physician would start using chemotherapy if they didn't decide to use it earlier; is that correct?

MR. POWERS: Objection. Form.

THE WITNESS: The -- there are a couple choices.

BY MR. KRAUSE:

Q. Okay.

A. So the prevailing theory at the time was that there are additional androgens that are driving the prostate cancer after essentially eliminated androgens coming from the testicles, that there are additional androgens that are driving the prostate cancer, and the next step would be to eliminate those androgens and potentially get another response of the prostate cancer.

And so there was a focus for decades on how to effectively eliminate adrenal androgens, and that's where drugs like -- well, Casodex has a different mechanism that's an antiandrogen, but drugs like

ketoconazole had come out to eliminate the synthesis of androgens coming from the adrenal gland.

And that -- those are also effective, not as dramatic as the initial treatment, but they're also effective and they're also limited in terms of how long they'll be effective.

So after maybe trying an antiandrogen, which blocks androgens at the receptor sites on prostate cancer cells, and after blocking adrenal androgens, then, typically you're ready for chemotherapy, which is a bigger deal in a number of ways, both for the patient and in terms of side effects.

Q. Okay. I think you just referred to blocking adrenal androgens, and I think you mentioned ketoconazole, and you said, "drugs like ketoconazole." What other drugs were physicians using to try to block the adrenal androgens?

MR. POWERS: Objection. Form.

THE WITNESS: Aminoglutethimide is a drug that similarly blocks --

REPORTER MARTIN: I'm sorry. What was --

THE WITNESS: Aminogluthethimide.

Works similarly in ablating adrenal steroid hormone synthesis and certainly abiraterone was known to be a drug that had a similar effect on adrenal



androgens.

BY MR. KRAUSE:

Q. Any others that you can think of?

MR. POWERS: Objection. Form.

THE WITNESS: Those are the ones that come to mind.

BY MR. KRAUSE:

Q. Okay. And in August of 2006 a person of ordinary skill in the art would have known that the combination of docetaxel and prednisone was a standard of care for patients who progressed on androgen deprivation therapy; is that right?

A. That is correct.

Q. And just so I kind of understand the language here, the first-line therapy, those would be the antiandrogens, and then the second-line would be the -- blocking the adrenal androgens?

MR. POWERS: Objection. Form.

BY MR. KRAUSE:

Q. Can you describe that.

A. The first-line would be, essentially, treatment of hormone-sensitive disease, and that takes several forms, but all of it is withdrawal of androgens.

The second step, much broader, is the



treatment of metastatic castrate-resistant disease, and that can take on many forms that I discussed, antiandrogens, drugs that inhibit steroid hormone synthesis, various chemotherapy agents, and they're all mixed together in this category and can be used -- and they've been moved back and forth in the treatment paradigm, depending on what exactly the issues are with that particular patient and their preferences.

Q. And the combination of docetaxel and prednisone is a standard of care for patients that progressed on the androgen deprivation therapy; right?

A. Yes.

Q. But I think you indicated earlier, again it would depend on the patient profile as to when that combination might be used in the treatment of patients?

A. Correct. And it's not uncommon -- it would not be uncommon for patients to say they don't want chemotherapy, and if you have some intermediate therapy that will keep their disease in check, that that's what they would prefer. So that's not uncommon.

Q. And was the combination of docetaxel and prednisone combined -- approved for the use -- let me start that again.



Was the combination of docetaxel and prednisone approved for the use of prostate cancer around 2004?

A. Yes.

Q. And was it increasingly used by the time of 2006?

MR. POWERS: Objection. Form. Relevant.

THE WITNESS: That is my understanding.

BY MR. KRAUSE:

Q. And is that because the combination of docetaxel and prednisone was the first and only known treatment for prostate cancer that provided a survival benefit?

MR. POWERS: Objection. Form. Relevance.

THE WITNESS: That is true. Up until that time, drugs had been approved for prostate cancer but only docetaxel and prednisone had demonstrated, to that point, a survival benefit.

BY MR. KRAUSE:

Q. So none of the drugs that had been used before the approval of docetaxel and prednisone had a survival benefit?

A. Correct.

Q. And that was also true as of August of 2006, docetaxel, prednisone were the only therapy that

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