

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

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WOCKHARDT BIO AG, :

:

Petitioner, :

:

vs. : Case No.

:

: IPR2016-01582

JANSSEN ONCOLOGY, INC., :

:

Patent Owner. :

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Washington, D.C.

Friday, April 21, 2017

VIDEOTAPED Deposition of:

ROBERT D. STONER, Ph.D.,

the witness, was called for examination by counsel for the Patent Owner, pursuant to notice, commencing at 10:01 a.m., at the law offices of Sterne, Kessler, Goldstein & Fox P.L.L.C., before Dawn A. Jaques, CSR, CLR, and Notary Public in and for the District of Columbia.

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 21
 22 VIDEOGRAPHER: Larry Newman

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1 PROCEEDINGS
 2 THE VIDEOGRAPHER: We are now on the
 3 record. My name is Larry Newman. I am a
 4 videographer for Golkow Technologies.
 5 Today's date is Friday, April 21st,
 6 2017, and the time is 10:01 a.m. This video
 7 deposition is being held in Washington, D.C., in
 8 the matter of Wockhardt Bio AG versus Janssen
 9 Oncology Incorporated, and this is in the
 10 U.S. Patent and Trademark Office, Patent and
 11 Trademark -- Patent Trademark and Appeal Board,
 12 Cause No. IPR2016-01582. Our deponent today is
 13 Robert D. Stoner, Ph.D.
 14 And, Counsel, would you please
 15 identify yourselves and state whom you represent?
 16 MR. ZEGGER: My name is Paul Zegger.
 17 I'm with the law firm of Sidley Austin, and I'm
 18 representing the Patent Owner.
 19 MR. VARUGHESE: Dennis Varughese from
 20 the law firm of Sterne, Kessler, Goldstein & Fox,
 21 on behalf of Petitioner Wockhardt, and with me
 22 today is Krishan Thakker, also Sterne Kessler.

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1 I-N-D-E-X
 2 WITNESS: PAGE:
 3 ROBERT D. STONER, Ph.D.
 4 Examination by Mr. Zegger 5
 5
 6
 7 E-X-H-I-B-I-T-S
 8 (No new exhibits marked)
 9
 10 PREVIOUSLY MARKED EXHIBITS REFERRED TO
 11 JANSSEN EXHIBIT NUMBER PAGE
 12 2155 85
 13
 14
 15 WOCKHARDT EXHIBIT NUMBER PAGE
 16 1031 64
 17 1077 8
 18 1103 7
 19 1114 51
 20
 21
 22

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1 THE VIDEOGRAPHER: Would our -- our
 2 court reporter is Dawn Jaques, and will now swear
 3 in the witness.
 4 THE REPORTER: Raise your right hand,
 5 sir.
 6 (The witness was sworn in by the reporter.)
 7 MR. VARUGHESE: Just one second. My
 8 realtime's not working.
 9 THE REPORTER: Can we go off?
 10 THE VIDEOGRAPHER: The time is 10:02.
 11 We'll go off the video record.
 12 (Pause in the proceedings.)
 13 THE VIDEOGRAPHER: The time is
 14 10:04 a.m. Back on the video record.
 15 Whereupon,
 16 ROBERT D. STONER, Ph.D.,
 17 was called as a witness, after having been
 18 first duly sworn by the Notary Public,
 19 was examined and testified as follows:
 20 EXAMINATION BY COUNSEL FOR THE PATENT OWNER
 21 BY MR. ZEGGER:
 22 Q Good morning, sir.

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1 A Good morning.
 2 Q Sir, do you dispute that Zytiga® has
 3 had over \$4 billion in sales since it was
 4 launched?
 5 MR. VARUGHESE: Objection, lacks
 6 foundation.
 7 THE WITNESS: From the materials I've
 8 seen, I don't dispute that.
 9 BY MR. ZEGGER:
 10 Q Do you think that Janssen regrets
 11 bringing Zytiga to market?
 12 MR. VARUGHESE: Objection, vague and
 13 ambiguous, lacks foundation.
 14 THE WITNESS: I have no idea how to
 15 answer that question. I don't -- I haven't seen
 16 any evidence on the profitability of Zytiga®.
 17 I've seen evidence on sales and market
 18 share, but that doesn't tell me necessarily that
 19 the product has been overall profitable for
 20 Janssen.
 21 BY MR. ZEGGER:
 22 Q Do you seriously think that Janssen

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1 regrets bringing Zytiga® to market?
 2 MR. VARUGHESE: Objection,
 3 argumentative, vague and ambiguous.
 4 THE WITNESS: As I said, I can't
 5 answer that question.
 6 BY MR. ZEGGER:
 7 Q Let me hand you what has been marked
 8 as Wockhardt Exhibit 3 -- I'm sorry, Wockhardt
 9 Exhibit 1103. Is this your reply declaration in
 10 this proceeding?
 11 A It appears to be, yes.
 12 Q That's your signature on the last
 13 page?
 14 A It is.
 15 Q You signed on April 18th, 2017?
 16 A Yes, I did.
 17 Q And do pages 2 through 5 contain a
 18 complete list of the materials you considered?
 19 A Yes, with the caveat in footnote 1
 20 there that the table includes materials considered
 21 in my initial declaration only if they are
 22 specifically cited in my reply.

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1 So, you know, this is a continuation
 2 of the work I did in the initial declaration.
 3 Q Okay. You mentioned your initial
 4 declaration. Let me put before you what has been
 5 marked as Wockhardt Exhibit 1077, and can you
 6 confirm whether this is your initial declaration
 7 in connection with this IPR?
 8 A Yes, it is.
 9 Q Now, is it correct that you were
 10 deposited back on February 10th of this year in
 11 connection with your initial declarations?
 12 A Correct.
 13 Q How much work have you done in
 14 connection with this case since that time?
 15 A I've done considerable work.
 16 Q Can you give me an estimate in terms
 17 of hours?
 18 A Certainly more than 50 hours.
 19 Somewhere between 50 and 100 hours.
 20 Q Has somebody assisted you with your
 21 reply declaration?
 22 A There was editing suggestions from the

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1 lawyers. There is citations that were offered by
 2 the lawyers. There was a back-and-forth after I
 3 produced the first draft of the report.
 4 Q Did you undertake any analysis of your
 5 own?
 6 A Certainly.
 7 Q Could you look at your reply
 8 declaration, paragraph 6. Are you there?
 9 A I am.
 10 Q Does that set forth some of the legal
 11 standards that you were provided in connection
 12 with this matter?
 13 A That's correct.
 14 Q The last sentence of paragraph 6
 15 states that you understand that to establish a
 16 proper nexus between a claimed invention and the
 17 commercial success of a product, quote, "a
 18 Patent Owner must offer proof that the sales were
 19 a direct result of the unique characteristics of
 20 the claimed invention, and not a result of
 21 economic and commercial factors unrelated to the
 22 quality of the patented subject matter," close

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1 quote. Did I read that correctly?
 2 A Correct.
 3 Q Is that your understanding of the
 4 legal standard?
 5 A That is.
 6 Q And was that provided to you by
 7 Wockhardt's lawyers?
 8 MR. VARUGHESE: Objection. In
 9 answering this question, I caution the witness not
 10 to divulge any confidential communications with
 11 counsel, but you can answer that yes or no.
 12 THE WITNESS: I've worked on a number
 13 of these commercial success cases before, and I
 14 generally know this to be the standard. That
 15 precise wording, presumably a function of my
 16 initial wording and any editing that was done by
 17 the lawyers.
 18 BY MR. ZEGGER:
 19 Q Okay. Is that generally referring to
 20 the nexus requirement?
 21 A Yes.
 22 Q Is it your understanding that there

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1 can ever be a presumption of nexus in the context
 2 of the obviousness inquiry here?
 3 MR. VARUGHESE: Objection, calls for
 4 speculation, calls for legal conclusion.
 5 THE WITNESS: That's a legal aspect
 6 that I'm probably not in a good position to
 7 respond to.
 8 BY MR. ZEGGER:
 9 Q All right. Well, in paragraph 6, you
 10 are setting forth your understanding of the legal
 11 requirements for commercial success, correct?
 12 A Correct.
 13 Q And you're discussing specifically the
 14 requirement for nexus, right?
 15 A Yes.
 16 Q So my question is whether you have an
 17 understanding as to whether there can ever be a
 18 presumption of nexus in this context?
 19 MR. VARUGHESE: Objection, calls for a
 20 legal conclusion, calls for speculation.
 21 THE WITNESS: I believe I've heard
 22 that there are situations where there can be a

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1 presumption, but I have no idea whether those --
 2 whether that has any import in the present matter.
 3 MR. ZEGGER: All right. And, Counsel,
 4 the coaching objections have to stop. You can
 5 object to the form, but no coaching, no speaking
 6 objections, and you understand that.
 7 MR. VARUGHESE: So, Mr. Zegger, I
 8 disagree with your characterization of my
 9 objections. I'm stating my objections and the
 10 grounds for them. They were no different than the
 11 objections that Sidley has lodged in other
 12 depositions in this proceeding. You can look at
 13 the transcripts.
 14 MR. ZEGGER: I don't know when it has
 15 happened in other depositions. I'm just saying
 16 that your objections here are improper.
 17 MR. VARUGHESE: I disagree.
 18 BY MR. ZEGGER:
 19 Q Sir, did you assume that there was a
 20 presumption of nexus here in this case?
 21 A I made no presumption in that regard
 22 one way or another.

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1 Q Well, is it correct that you, in your
 2 reply declaration, criticized the analysis of
 3 Dr. Velturo in this case?
 4 A That's correct.
 5 Q Okay. Did you undertake your own
 6 independent analysis of nexus?
 7 A In the course of my criticism of
 8 Dr. Velturo's analysis of nexus, I made quite
 9 clear what my conclusions were with respect to
 10 nexus.
 11 Q Well, did you do an independent study
 12 to undertake how much of the sales of Zytiga® were
 13 due to the patented invention here?
 14 A I myself did not do a study that
 15 apportion the success -- purported success of
 16 Zytiga® to the various aspects of -- that were
 17 important in its success, but I concluded that one
 18 could not attribute that success to the patented
 19 invention.
 20 Q Well, did you yourself attempt to
 21 apportion the degree of Zytiga® demand that was
 22 attributable to the patented invention compared to

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1 unclaimed features?
 2 A Yes, in the sense that I believe that
 3 the success -- I concluded that the success of --
 4 any commercial success of Zytiga® was a function
 5 of the independent anticancer effect of
 6 abiraterone, the independent anticancer effect of
 7 prednisone, the ability of prednisone to fight the
 8 side effects of the administration of abiraterone,
 9 the tablet form of Zytiga®, and potentially other
 10 unclaimed features as well with no indication that
 11 there is any nexus to the claimed invention.
 12 So that's apportionment, 100 percent
 13 to zero.
 14 Q I don't understand your last comment,
 15 apportionment 100 percent to zero.
 16 A To the claimed versus the unclaimed.
 17 100 percent to the unclaimed, and zero percent to
 18 the claimed.
 19 Q Where does that study appear in your
 20 reply declaration?
 21 A In my statements that there's no
 22 evidence that there's any -- in the statements and

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1 evidence that I presented or that I relied on
 2 indicating that there's no nexus between the
 3 success, purported success of Zytiga®, and the
 4 '438 patent, so that says no means zero.
 5 And my discussion of all the other
 6 unclaimed reasons that there was commercial
 7 success, they are apportioned 100 percent.
 8 Q Okay. Are you saying that it's your
 9 opinion in this matter that zero percent of
 10 Zytiga®'s sales, success, is due to the
 11 combination of abiraterone acetate and prednisone?
 12 A That's not what I said. I said it was
 13 due to the synergistic effect of those two -- of
 14 the combination of those two.
 15 None of it is due to the synergistic
 16 effect or the added effect of adding prednisone
 17 specifically to abiraterone to -- to develop an
 18 effect that goes beyond the individual effects of
 19 prednisone and abiraterone.
 20 Q Other than criticizing Dr. Vellturo's
 21 work, what study did you conduct in order to reach
 22 that conclusion?

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1 A I'm perfectly happy to discuss -- I
 2 mean, I have a 40-page report. There's a lot of
 3 evidence to discuss there if you want to.
 4 Q Okay. I see where you've criticized
 5 Dr. Vellturo in your reply report. I'm asking if
 6 you can show me in your reply declaration a study,
 7 an independent study that you undertook, to
 8 apportion the percentage of commercial success of
 9 Zytiga® that's due to the patented invention?
 10 MR. VARUGHESE: Objection, lacks
 11 foundation.
 12 THE WITNESS: I present a lot of
 13 evidence here in the discussions of the various
 14 parties that were bringing the invention -- that
 15 were bringing abiraterone forward towards
 16 commercialization that indicate that there was --
 17 that there was no belief that there was a synergy
 18 that was responsible for the commercial success.
 19 For example, I discuss the label of
 20 abiraterone, which is the best indicator of the
 21 belief of the FDA and what makes the drug -- and
 22 how the drug should be administered and what makes

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1 the drug work, and there's no mention in that of
 2 an additive effect of prednisone that -- sorry, a
 3 synergistic effect of prednisone that goes beyond
 4 the ability of prednisone to offset side effects.
 5 That's what the -- that's what the label talks
 6 about.
 7 BY MR. ZEGGER:
 8 Q You understand that the label for
 9 Zytiga® is a combination therapy of abiraterone
 10 acetate and prednisone?
 11 A Correct.
 12 Q Okay. And the '438 patent claims a
 13 combination therapy of abiraterone acetate and
 14 prednisone, correct?
 15 A That's correct.
 16 Q Could you look at paragraph 10 of your
 17 reply declaration?
 18 A Did I look at it or --
 19 Q Could you.
 20 A Oh, sure, yes.
 21 Q Okay. And there you mention that
 22 commercial success analysis requires an analysis

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