

1
2 UNITED STATES PATENT AND TRADEMARK OFFICE
3 BEFORE THE PATENT TRIAL AND APPEAL BOARD
4 CASE IPR 2016-01332
5 Patent 8,822,438
6

7 MYLAN PHARMACEUTICALS, INC.)
Petitioner)
8 vs.)
JANSSEN ONCOLOGY, INC.,)
9 Patent Owner)

10
11 Videotaped Deposition of Ivan T. Hofmann
12 Washington, D.C.

13
14 April 26, 2017

15
16 9:01 a.m.

17
18 Reported by: Bonnie L. Russo

19 Job No. 2600768
20

21 Veritext Legal Solutions

Mid-Atlantic Region

1250 Eye Street NW - Suite 350

22 Washington, D.C. 20005

Page 2

1 Videotaped Deposition of Ivan T. Hofmann held
 2 at:
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 4
 5
 6 Perkins Coie
 7 700 13th Street, N.W.
 8 Washington, D.C.
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1 Pursuant to Notice, when were present on behalf
 2 of the respective parties:
 3 APPEARANCES:
 4 On behalf of the Petitioner:
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 Also Present:
 Michael Gay, Videographer

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1 C O N T E N T S
 2 EXAMINATION OF IVAN T. HOFMANN PAGE
 3 BY MR. ZEGGER 5
 4
 5 EXHIBITS
 6
 7 PREVIOUSLY MARKED EXHIBITS
 8 Exhibit 1012 USPTO Response
 9 Exhibit 1015 Notice of Allowance
 10 and Fee(S) Due
 11 Exhibit 1016 Notice of Allowance
 12 and Fee(S) Due
 13 Exhibit 1017 Declaration of
 14 Ivan T. Hofmann, CPA/CFF,CLP
 15 Exhibit 1134 Reply Declaration of
 16 Ivan T. Hofmann
 17 Exhibit 1136 Deposition of
 18 Christopher A. Velturo, Ph.D.
 19 4-5-17
 20 Exhibit 2157 Affidavit of
 21 Christopher Butler
 22 (Exhibits included with transcript.)

Page 5

1 P R O C E E D I N G S
 2
 3 THE VIDEOGRAPHER: We are going on
 4 the record.
 5 The time now is 9:01.
 6 This marks the beginning of Disk No.
 7 1 for the videotaped deposition testimony of
 8 Ivan T. Hofmann in the matter of Mylan
 9 Pharmaceuticals, Inc., et al, versus Janssen
 10 Oncology, Inc. This case is pending in the
 11 United States Patent and Trademark Office, Case
 12 No. IPR 2016-01332. Today's date is April 26,
 13 2017.
 14 This deposition is being taken at
 15 700 13th Street, Northwest, Washington, D.C.
 16 Will all attorneys present please
 17 identify themselves and who they represent.
 18 MR. ZEGGER: I'm Paul Zegger with
 19 the firm Sidley Austin for the patent owner,
 20 Janssen Oncology, Inc.
 21 MR. SWANSON: Robert Swanson from
 22 Perkins Coie for the petitioner Mylan.

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1 MR. WHITE: Brandon White from
2 Perkins Coie for the Mylan petitioner.
3 MS. LIN: Sharon Lin from Winston &
4 Strawn for the co-petitioners, Activist, Teva,
5 West-Ward, DRL and Amneal.
6 THE VIDEOGRAPHER: My name is
7 Michael Gay, I'm with Golkow Technologies. Our
8 court reporter today is Bonnie Russo also with
9 Golkow Technologies and will now swear in our
10 witness.
11 IVAN T. HOFMANN,
12 being first duly sworn, to tell the truth, the
13 whole truth and nothing but the truth,
14 testified as follows:
15 EXAMINATION BY COUNSEL FOR THE PATENT OWNER
16 BY MR. ZEGGER:
17 Q. Mr. Hofmann, do you dispute that
18 Zytiga has had over \$4 billion in sales since
19 it was launched?
20 A. I think the gross sales have been on
21 the order of what your question suggests
22 according to IMS data.

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1 Q. What is Zytiga prescribed for?
2 A. Well, I think it's labeled for
3 metastatic castrate resistant prostate cancer
4 both pre and post chemotherapy.
5 Q. And that's sometimes referred to as
6 mCRPC in short; is that right?
7 A. Yes, sir.
8 Q. What drugs does Zytiga compete with
9 based on your understanding?
10 A. Well, I think, you know, broadly, it
11 competes with a variety of drugs for the
12 treatment of prostate cancer including Xtandi
13 as well as others.
14 Q. Well, does it -- does Zytiga compete
15 with all prostate cancer drugs?
16 A. I think -- I think as I understand
17 it, and again, I am not a clinician but as I
18 understand it, people with -- who present with
19 prostate cancer go in and out of different
20 therapies and at different times, yes. People
21 look at the armamentarium of what is available
22 to treat prostate cancer and Zytiga is part of

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1 that armamentarium.
2 Q. What drugs, other than Xtandi, do
3 you understand compete in the market for mCRPC?
4 MR. SWANSON: Objection. Vague.
5 THE WITNESS: Well, I mean, I think
6 that that is the primary competitor these days.
7 I think that there are other products that are
8 used, like I said, that are listed within a
9 variety of Janssen documents. There's
10 different sets of competing products that are
11 looked at at different times but they include a
12 variety of products.
13 BY MR. ZEGGER:
14 Q. Is there a relevant market for
15 purposes of evaluating commercial success, the
16 mCRPC market?
17 A. Well, I think we talked about this
18 last time we met. I think that there are
19 different ways that one can look at the
20 competing products and I think that certainly
21 MRCPC [sic] is one way to look at it but I
22 think that that is a narrow focus.

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1 I think as I said in my answer a few
2 moments ago, there is reasons to look at
3 broader competing products and broader -- you
4 know, really what we are talking about is the
5 patients that present with prostate cancer and
6 there are different ways to deal with that.
7 Q. Have you seen any evidence that
8 Zytiga is prescribed for conditions other than
9 mCRPC?
10 A. I am not sure I have seen specific
11 documents that address that one way or the
12 other.
13 Q. In your reply declaration, do you
14 set forth Zytiga's market share in the mCRPC
15 market?
16 A. Among others. Well, when you say my
17 "declaration," I have issued two declarations.
18 I talk about the market share relative to a
19 variety of competitive data sets.
20 Q. Well, you mentioned your
21 declarations.
22 Let me put before you what has been

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1 identified as Mylan Exhibit 1017.
2 Is that your opening declaration in
3 this IPR proceeding?
4 A. That's my opening declaration. Just
5 looked at the cover page but...
6 Q. We discussed that at your prior
7 deposition.
8 A. We did, yes.
9 Q. Let me put before you what has been
10 identified as Mylan Exhibit 1134.
11 Is that your reply declaration in
12 this matter?
13 A. It appears to be, yes.
14 Q. Is that your signature on Page 25?
15 A. Yeah, it looks like a
16 black-and-white version, but yeah.
17 Q. Signed on April 19 of this year,
18 2017?
19 A. I did.
20 Q. And does Paragraph 4 and Attachment
21 A1 contain a complete list of materials you
22 considered in connection with your reply

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1 declaration?
2 MR. SWANSON: Objection. Form.
3 THE WITNESS: I think that A1 in
4 Paragraph 4 lists the documents that I cite
5 herein. I think as we talked about at my last
6 deposition, I have also been tracking other
7 parallel IPRs and I reviewed materials that
8 were included in those IPRs.
9 BY MR. ZEGGER:
10 Q. What IPRs have you been tracking?
11 A. The Amerigen IPR and then the
12 Wockhardt IPR.
13 Q. Have you read the expert
14 declarations of McDuff and Stoner in the
15 Amerigen and Wockhardt IPRs?
16 MR. SWANSON: Object to form.
17 THE WITNESS: I have.
18 BY MR. ZEGGER:
19 Q. How much time did you spend on the
20 present matter since your deposition on
21 February 7th, 2017?
22 A. I don't have a precise amount of

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1 time off the top of my head.
2 Q. Do you have an approximate
3 estimation?
4 A. It would be dozens of hours but I
5 don't have a specific time, no.
6 Q. Looking at your reply declaration,
7 is there anything in there that would indicate
8 what you think the market share is for Zytiga
9 in the mCRPC market?
10 MR. SWANSON: Object to form.
11 THE WITNESS: Well, I think between
12 my two declarations, I do discuss market share
13 with various data sets. I mean, part of the
14 critique I have of Dr. Vellturo is that he
15 discusses a very narrow market and when one
16 looks at it relative to patients who present at
17 various stages of prostate cancer, one gets
18 different market shares based on available data
19 sets.
20 BY MR. ZEGGER:
21 Q. Well, do you set forth in either of
22 your declarations, the initial one or the reply

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1 one, what you think the market share is for
2 Zytiga in the relevant market?
3 MR. SWANSON: Object to form.
4 THE WITNESS: Well, I think that,
5 you know, as a backdrop, I mean my role here is
6 to look at what Vellturo puts forth. I think I
7 have provided some greater context than
8 Vellturo provides with respect to market share,
9 but I haven't asserted commercial success. I
10 haven't asserted market share in the way that
11 he has.
12 I think that the market share
13 metrics that I provide in my opening
14 declaration and then reiterated in my reply
15 declaration provide, you know, greater context
16 to the performance of Zytiga relative to other
17 available treatments for prostate cancer.
18 BY MR. ZEGGER:
19 Q. Do you see your role in the present
20 matter as critiquing Dr. Vellturo?
21 MR. SWANSON: Object. Vague.
22 THE WITNESS: Well, I mean, I think

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1 my role was to -- as I explain in my opening
2 declaration as well as my rebuttal declaration,
3 that my role was to respond to Dr. Velturo's
4 assertions. In my opening declaration, it was
5 to respond to the assertions made by Janssen
6 with respect to alleged commercial success and
7 nexus.

8 I don't think that my role was
9 limited to critiques of Dr. Velturo. I think
10 it was looking at the record and the assertions
11 made by the patent holder with respect to
12 claimed commercial success and nexus relative
13 to the performance of Zytiga.

14 BY MR. ZEGGER:

15 Q. Well, did you undertake on your own
16 to independently figure out what the market
17 share is for Zytiga in the relevant market?
18 MR. SWANSON: Object to form.
19 THE WITNESS: I mean, that is
20 certainly part of the information that I -- I
21 considered. I looked at what Janssen asserted
22 in their prosecution of the patent. I looked

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1 at what Dr. Velturo put forth in his
2 declaration and I analyzed the relative
3 performance of Zytiga as explained in my two
4 declarations.

5 BY MR. ZEGGER:

6 Q. Well, for example, do you have
7 anything in your reply declaration that would
8 indicate what the Zytiga market share was for
9 2016?
10 MR. SWANSON: Object to form.
11 THE WITNESS: I don't know that I
12 specifically address 2016 in the data set other
13 than if it's in the Velturo data set. I think
14 that, you know, again, my response and reply
15 was in reference to the patent prosecution
16 files as well as the assertion filed by
17 Velturo.

18 BY MR. ZEGGER:

19 Q. Are you offering any alternative
20 numbers for Zytiga's market share for 2016?
21 MR. SWANSON: Object to form.
22 BY MR. ZEGGER:

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1 Q. Other than the ones that Velturo
2 presented in his report?
3 MR. SWANSON: Object to form.
4 THE WITNESS: I don't think I did do
5 any sort of alternative mathematical
6 calculation the way that I did in my opening
7 declaration relative to the data sets that were
8 provided to the USPTO.

9 BY MR. ZEGGER:

10 Q. In your opening report, did you set
11 forth your understanding of the legal standards
12 relative to commercial success?
13 MR. SWANSON: Object to form.
14 THE WITNESS: I did. Sorry.
15 BY MR. ZEGGER:

16 Q. And did you apply those same legal
17 standards in connection with your reply
18 declaration?
19 MR. SWANSON: Object to form.
20 THE WITNESS: I did.
21 BY MR. ZEGGER:

22 Q. Did you have an understanding as to

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1 whether there are circumstances under which a
2 nexus between commercial success and a patent
3 is presumed?
4 MR. SWANSON: Objection. Vague.
5 THE WITNESS: I mean, I am not a
6 legal expert. I am not providing legal
7 opinions. I understand there has been some,
8 you know, that there are legal arguments and
9 aspects of that. I think my opinions are laid
10 out as explained in my two declarations.

11 BY MR. ZEGGER:

12 Q. Well, did you consider whether a
13 nexus should be presumed in this case?
14 A. Yeah, I think that -- relative to
15 whether it's presumed or not, my opinions stand
16 on their own. The fact is that the existence
17 of the blocking patent, the existence of all
18 the evidence that shows a lack of nexus
19 relative to the patent-in-suit and the
20 marketplace performance of Zytiga, regardless
21 of whether there is a presumed nexus stands.
22 But I will leave the presumption issue to

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