

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

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5 MYLAN PHARMACEUTICALS, INC.,  
6 TEVA PHARMACEUTICALS USA,  
7 INC., and AKORN INC.,

8 Petitioners,

9 vs.

10 ALLERGAN, INC.,

11 Patent Owner.

12 - - - - - +

13 Case IPR2016-01127 (U.S. 8,685,930 B2)

14 Case IPR2016-01128 (U.S. 8,629,111 B2)

15 Case IPR2016-01129 (U.S. 8,642,556 B2)

16 Case IPR2016-01130 (U.S. 8,633,162 B2)

17 Case IPR2016-01131 (U.S. 8,648,048 B2)

18 Case IPR2016-01132 (U.S. 9,248,191 B2)

19 Deposition of IVAN T. HOFMANN, CPA/CFF, CLP

20 Washington, D.C.

21 July 14, 2017

22 9:02 a.m.

23 Job No. LA-133840

24 Pages 1 - 102

25 Reported by: Michele E. Eddy, RPR, CRR, CLR

Page 2

1 Deposition of IVAN T. HOFMANN, CPA/CFF, CLP, held  
 2 at the offices of:  
 3 WILSON SONSINI GOODRICH & ROSATI  
 4 1700 K Street, Northwest  
 5 Fifth Floor  
 6 Washington, D.C. 20006  
 7 (202) 973-8800  
 8 Pursuant to Notice, before Michele E.  
 9 Eddy, Registered Professional Reporter, Certified  
 10 Realtime Reporter, and Notary Public in and for  
 11 the District of Columbia.  
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 12 S. Maness, Ph.D.  
 13 Exhibit 2044 NDA 208073 - Xiidra 21  
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1 A P P E A R A N C E S  
 2  
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Page 5

1 P R O C E E D I N G S  
 2 Washington, D.C.  
 3 July 14, 2017  
 4 - - -  
 5 IVAN T. HOFMANN, CPA/CFF, CLP,  
 6 having been duly sworn, testified as follows:  
 7 EXAMINATION BY COUNSEL FOR PATENT OWNER ALLERGAN  
 8 BY MR. OAKES:  
 9 Q Good morning.  
 10 A Good morning.  
 11 Q Would you please state your full name  
 12 for the record.  
 13 A Ivan T. Hofmann.  
 14 Q Can you please provide your current job  
 15 title, Mr. Hofmann.  
 16 A I'm a vice president and managing  
 17 director at Gleason IP.  
 18 Q You understand the testimony you give  
 19 today is under oath?  
 20 A I do.  
 21 Q You understand that the testimony that  
 22 you provide today can be submitted to the PTAB?  
 23 A I do.  
 24 Q You'll provide honest and truthful  
 25 answers today, right?

Page 6

1 A Yes.

2 Q If you answer any of my questions, I'm

3 going to assume that you understood the question.

4 Is that fair?

5 A Yes, I'll do my best.

6 Q Is there any reason, either medical or

7 otherwise, that would prevent you from giving

8 complete and accurate testimony today?

9 A No, sir.

10 Q Mr. Hofmann, you understand that Mylan

11 has filed IPR petitions challenging the validity

12 of the six patents listed in the Orange Book as

13 covering Restasis, right?

14 A Correct.

15 Q And you understand that Mylan filed

16 those petitions because Mylan seeks to make a

17 generic version of Restasis, correct?

18 A Correct.

19 Q Do you believe that the issue of

20 commercial success is relevant to Mylan's

21 arguments that the patents are obvious?

22 A I mean, I'm not a lawyer or legal

23 expert. My understanding is that the issue of

24 commercial success does come up as one of the

25 potential objective indicia of nonobviousness with

Page 7

1 respect to validity of patents.

2 Q You were not asked to submit a

3 declaration discussing commercial success in the

4 initial IPR petitions Mylan filed. Right?

5 A I was not.

6 Q And you, in fact, did not submit any

7 declarations regarding commercial success with the

8 initial IPR petitions Mylan filed. Right?

9 A And I'm typically not. It's usually in

10 response to the patent holder asserting commercial

11 success.

12 Q You did not submit a declaration with

13 the initial -- let me withdraw that.

14 You did not prepare a declaration to be

15 submitted along with Mylan's initial IPR petition.

16 Correct?

17 A No, sir.

18 Q When were you first contacted to provide

19 testimony in this proceeding?

20 A It would have been very late May, early

21 June of this year.

22 Q Late May, early June of 2017.

23 A Correct.

24 Q You have provided an opinion in this

25 proceeding that the commercial performance of

Page 8

1 Restasis does not provide objective indicia of

2 nonobviousness in this case. Correct?

3 A Correct.

4 Q And that is because, in your view, there

5 is not a nexus between the commercial performance

6 of Restasis and the features recited in the

7 claims. Correct?

8 A Well, I mean, I defer to the entirety of

9 my declaration. I think there are many reasons I

10 feel that way, including, you know, the blocking

11 patents, and I'm sure we'll get into everything,

12 but among them is the lack of nexus.

13 Q You have not provided an opinion that

14 the Restasis sales and revenues indicate a lack of

15 commercial success. Right?

16 A Well, I think I have provided an

17 opinion -- when you use the term "commercial

18 success," that has a certain meaning in a patent

19 case. I don't disagree that the product has

20 experienced significant sales and profits, and I

21 haven't said otherwise.

22 Q You don't disagree that the product has

23 experienced significant sales and profits.

24 Correct?

25 A Correct.

Page 9

1 Q You're aware that Restasis' gross sales

2 were over 1.7 billion dollars in 2015?

3 MS. PHILLIPS: Objection. Foundation.

4 A I don't have the numbers in front of me.

5 And, like I've said, I think gross sales isn't a

6 good metric. I think looking at net sales and

7 some other metrics, after accounting for other

8 things, are more appropriate.

9 Q Did you review the Restasis profit and

10 loss statements as part of your testimony in this

11 proceeding?

12 A I did.

13 Q You understand that Restasis has been a

14 profitable product for Allergan every year since

15 it launched in 2003?

16 A According to the product P&L that they

17 produced, that's so, yes.

18 Q Do you dispute that Allergan -- withdraw

19 that.

20 Do you dispute Dr. Maness' opinion that

21 Restasis has provided a positive net present

22 value?

23 A Again, all of these positive metrics, I

24 haven't -- I don't have evidence that says

25 otherwise. However, I have opinions that are

Page 10

1 explained in my declaration.

2 Q Why don't we -- I don't want to -- I'll

3 just give this to you now so you're free to refer

4 to it.

5 A Okay.

6 Q This is Exhibit 1041, I believe, in each

7 of the respective IPR petitions. It's the reply

8 declaration of Ivan T. Hofmann.

9 (Exhibit 1041 was previously marked and

10 referred to.)

11 Q Mr. Hofmann, can you confirm that the

12 declaration we handed you that's been submitted as

13 Exhibit 1041 is, in fact, the reply declaration

14 you submitted in these proceedings?

15 A Just quickly flipping through it, it

16 does appear to be.

17 Q If you look at the front page of your

18 declaration, you see there's six IPR cases listed

19 there?

20 A Yes.

21 Q Is it your understanding that the

22 identical declaration from you is submitted in

23 each of the six proceedings?

24 A That's my understanding.

25 Q I'm going to not make a distinction

Page 11

1 today between the various proceedings, the actual

2 IPRs. If you feel that there needs to be a

3 distinction, please let me know. Okay?

4 A Will do.

5 Q Were you asked to provide an opinion

6 that Restasis hasn't experienced significant sales

7 and profits?

8 MS. PHILLIPS: Objection. Form.

9 A I don't -- I mean, I was asked to

10 analyze and respond to the Maness declaration and

11 provide my independent objective opinions.

12 Q Have you reviewed Mylan's reply brief,

13 which cites to your declaration?

14 A I don't believe I have. That would have

15 been filed the same day?

16 Q Correct.

17 A No, I have not.

18 Q Have you spoken with Dr. Andrew Calman

19 regarding your opinions in this proceeding?

20 A Not in this proceeding.

21 Q Have you spoken with Dr. Amiji with

22 respect to your opinions in this proceeding?

23 A No, sir.

24 Q Have you spoken with Dr. Bloch with

25 respect to your opinions in this proceeding?

Page 12

1 A No.

2 Q Has -- does the declaration which we

3 have -- that's been submitted as Exhibit 1041

4 contain all of the opinions -- all of your

5 opinions regarding commercial success?

6 A It's my best effort to bring together

7 all of my opinions on this issue, yes.

8 Q I want to look on the front page of your

9 declaration. Under -- the last sentence of the

10 footnote, it states that "The word-for-word

11 identical papers filed in each proceeding

12 identified in the caption pursuant to the Board's

13 scheduling order."

14 Do you see that?

15 A Yes.

16 Q You understand that to mean that this

17 identical declaration was filed in each of the six

18 proceedings?

19 A That's my understanding.

20 Q If you could turn, please, Mr. Hofmann,

21 to page 7 of your declaration. I want to focus

22 you in particular on footnote 6.

23 A Okay.

24 Q You are not a medical doctor, correct?

25 A Yes.

Page 13

1 Q You're not an ophthalmologist?

2 A Correct.

3 Q You're not an optometrist?

4 A Correct.

5 Q You are not a clinician. Correct?

6 A Correct.

7 Q You are not -- withdraw that.

8 Are you aware of the definition of a

9 person of ordinary skill in the art that has been

10 proffered by the technical experts in these

11 proceedings?

12 A I've reviewed it. I don't have it

13 memorized.

14 Q You're not a person of ordinary skill

15 pursuant to the definition that's been offered by

16 the technical experts in these proceedings, right?

17 A No, sir.

18 Q You are not an expert in formulation

19 pharmaceuticals. Right?

20 A Correct.

21 Q You are not an expert in the formulation

22 of ophthalmic drugs. Right?

23 A No, sir.

24 Q You are not an expert in dry eye

25 disease. Right?

Page 14

1 A No.

2 Q And you're not an expert in the

3 treatment of dry eye disease.

4 A No, sir.

5 Q You're not an expert in interpreting

6 patent claims related to pharmaceutical

7 formulations, right?

8 A No.

9 Q You are not an expert in interpreting

10 patent claims related to clinical features of

11 pharmaceutical formulations, right?

12 A No, I'm not.

13 Q In footnote 6, you say that -- you cite

14 your understanding of technical issues to various

15 sources for those technical understandings as

16 identified throughout this declaration. Is that

17 correct?

18 A Yes.

19 Q So it is fair, for purposes of today and

20 it's fair for the board to consider the -- your

21 sources of statements and opinions you give in the

22 reports to be what's cited in the footnotes.

23 Right?

24 A I've done my best effort there, sure.

25 Q Where you rely on Dr. Calman for

Page 15

1 information, you've cited to him in the footnotes?

2 A That's why I say I've done my best

3 effort. I do cite to Dr. Calman in many

4 instances.

5 Q When you rely on Dr. Amiji for

6 information, you likewise would cite to his report

7 or testimony for that proposition?

8 A Yes. I mean, like I said, I've done my

9 best efforts. Maybe we'll go through examples.

10 Q When the Board is reviewing your

11 testimony, can they -- let me withdraw that.

12 When the Board is reviewing your

13 testimony, is it fair for them to look to the

14 footnotes for the sources of the information

15 you're relying on for particular opinions?

16 A Of course.

17 Q If we could turn to paragraph 12, which

18 is on the same -- which is on page 7. The last

19 sentence on that page, you state that "Restasis is

20 a topical immunomodulator indicated to increase

21 tear production in patients whose tear production

22 is presumed to be suppressed due to ocular

23 inflammation" -- continuing to the next page --

24 "associated with keratoconjunctivitis sicca

25 (KCS)." Is that correct?

Page 16

1 A Yes.

2 Q Your understanding is that Restasis

3 increases the production of natural tears?

4 A Again, I'm not a technical expert or

5 clinician, but that's my understanding.

6 Q And you're aware that Restasis is the

7 only product approved to increase natural tear

8 production, correct?

9 A I believe that Xiidra is as well.

10 Q Your understanding is that Xiidra is

11 approved to --

12 A Maybe I'm misremembering the label.

13 Q I think we can get there a little later.

14 A Okay.

15 Q So you have a couple different opinions.

16 I'm going to try to take them in buckets.

17 A Sure.

18 Q One of your opinions is that -- let me

19 back up.

20 Your declaration responds to the

21 declaration Dr. Maness submitted with -- in

22 connection with Allergan's opposition to the IPR

23 petitions?

24 A Correct.

25 Q One of your opinions is that -- this

Page 17

1 begins in paragraph 43 of your declaration. One

2 of your opinions is that Dr. Maness fails to

3 analyze Restasis in the relevant market. Correct?

4 A Correct.

5 Q Do you understand Dr. Maness' opinion to

6 be that Restasis is in its own market?

7 A That's my understanding of his opinion.

8 Q And you disagree with that definition.

9 Right?

10 A Correct.

11 Q You would agree that Dr. Maness does --

12 he does define the relevant market as only

13 Restasis.

14 A Correct. I disagree with his definition

15 of the relevant market.

16 Q But you agree that he has provided a

17 definition?

18 A Being Restasis only, yes, that's his

19 opinion.

20 Q Now, you in -- beginning in paragraph, I

21 believe, 46 of your declaration and extending

22 through, say, paragraph 53, you list a number of

23 products which you say are used to treat dry eye

24 disease or to treat the symptoms of dry eye

25 disease. Correct?

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