

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

3 \_\_\_\_\_  
4 MYLAN PHARMACEUTICALS, INC., )  
5 Petitioner, )  
6 vs. )  
7 ALLERGAN, INC., )  
8 PATENT OWNER. )

9 \_\_\_\_\_  
10 DEPOSITION OF DANIEL BLOCH, Ph.D.

11 \_\_\_\_\_

12 8:45 a.m.  
13 July 14, 2017  
14 701 Fifth Avenue, Suite 5100  
15 Seattle, Washington

16  
17 CASE IPR2016-01127, PATENT 8,685,930  
18 CASE IPR2016-01128, PATENT 8,629,111  
19 CASE IPR2016-01129, PATENT 8,642,566  
20 CASE IPR2016-01130, PATENT 8,633,162  
21 CASE IPR2016-01131, PATENT 8,648,048  
22 CASE IPR2016-01132, PATENT 9,248,191

23

24

25 REPORTED BY: Pat Lessard, CCR #2104

Page 2

A P P E A R A N C E S

1

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E X A M I N A T I O N

1

2 ATTORNEY PAGE

3 BY MR. KANE: 4

4

E X H I B I T I N D E X

5

6 No. DESCRIPTION PAGE

7 Exhibit 2078 Center for Drug Evaluation and 95

8 Research Medical Review(s).

9 Exhibit 2079 Document titled "Ophthalmology 77

10 Volume 107, Number 7, July 2000."

11 Exhibit 2080 QuickCalcs Unpaired test 85

12 results.

13 Exhibit 2081 QuickCalcs Unpaired test 86

14 results.

15

REFERRED EXHIBIT INDEX

16

17 Exhibit 1040 Declaration. 7

18 Exhibit 1043 Curriculum Vitae of Daniel A. 8

19 Bloch, Ph.D.

20 Exhibit 2027 Report marked 074. 44

21 Exhibit 1004 Excerpt. 48

22 Exhibit 1007 Sall publication. 77

23 Exhibit 2008 Portion of the Restasis label. 92

24

25

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1 DANIEL BLOCH, being duly sworn, testified

2 upon oath, as follows:

E X A M I N A T I O N

3

4 BY MR. KANE:

5 Q. Good morning, Dr. Bloch.

6 A. Good morning.

7 Q. Could you state your full name for the

8 record.

9 A. Daniel, middle initial A, last name Bloch

10 spelled with an H.

11 Q. What's your current business address?

12 A. My current business address?

13 Q. Yes.

14 A. 8987 East Tanque, spelled T A N Q U E. And

15 then another word Verde, V E R D E. And then a pound

16 sign 309-387. Tucson, Arizona 85749.

17 I've given you that. That's my mailing

18 address. I have an office at Stanford but I live in

19 Tucson and my letterhead has that address on it, my

20 Tucson address.

21 Q. Thank you. Have you been deposed before?

22 A. Yes.

23 Q. How many times, approximately?

24 A. A dozen.

25 Q. So you've been through the drill before but

Page 5

1 I'll just kind of give you the ground rules again.

2 A. Okay.

3 Q. So I'm going to be asking questions. You're

4 going to be providing the answers. Your counsel may

5 have some objections at some points along the way.

6 Our court reporter here is going to be

7 taking down everything that we say, so it's important

8 that -- a couple things. One, it seems like you may

9 be a fast talker and I'm definitely a fast talker, so

10 we both should try to maybe slow down to help her out.

11 Another thing is I'll do my best to let you

12 finish your answer before I start speaking again and,

13 likewise, you should let me finish my questions before

14 you start speaking so that she can get that down.

15 Okay?

16 A. Sure.

17 Q. If I don't ask a question that you

18 understand or is confusing to you please let me know

19 and I'll try to clarify for you. Okay?

20 A. Okay.

21 Q. And if you answer the question I'm going to

22 assume that you understood the question. All right?

23 A. Yes.

24 Q. That's another thing, you have to answer

25 verbally "Yes" and "No," not uh-huhs or huh-uhs or

<p style="text-align: right;">Page 6</p> <p>1 nods of the head or shakes of the head. She can't get 2 that down, so that's a good point to remember. 3 Finally, we'll take periodic breaks roughly, 4 usually about an hour or so of questions and then let 5 everybody stretch their legs and what have you. 6 If you need a break -- 7 A. I'll let you know. 8 Q. -- let me know. 9 A. Okay. 10 Q. Very good. Is there any reason that you 11 can't give accurate and truthful testimony today? 12 A. No. 13 Q. You understand that you're under oath and 14 the testimony you are giving is under oath and is 15 admissible in court? 16 A. I do understand, yes. 17 Q. You were talking over me there. You've got 18 to slow down and let me finish my question. Okay? 19 A. Yes. 20 Q. What did you do to prepare for your 21 deposition today? 22 A. I read over materials that are pertinent to 23 or included in my declaration and I met with counsel. 24 Q. When did you meet with counsel? 25 A. Yesterday for several hours as well as the</p>	<p style="text-align: right;">Page 8</p> <p>1 Is that right? No? I'm not really quite 2 sure. Sorry. 3 Q. The signature is June 30th. 4 A. All right. So it had to be early in June. 5 Q. Okay. How much time did you spend working 6 on the declaration? 7 A. Many hours. I don't really have an estimate 8 with me. Certainly more than 50. 9 Q. And did you draft the declaration yourself 10 or how did that process work? 11 A. Yes, I did. 12 Q. So you typed the words yourself? 13 A. No. Counsel -- counsel prepared the 14 formatting of the declaration and they aided me in 15 figures, formatting and things of that nature, but I 16 wrote the text. 17 Q. How did you write the text? Did you type it 18 in some sort of document and send it to counsel? 19 A. Yeah. Yeah, we went back and forth. 20 Q. Okay. I'll hand you what's previously been 21 marked as Exhibit 1034. 22 Do you recognize that document? 23 A. It appears to be a version of my CV. Yes. 24 Q. I see it's dated November 1, 2016. 25 A. Yes, I see that, too.</p>
<p style="text-align: right;">Page 7</p> <p>1 day before. 2 Q. Did you speak to anyone other than counsel 3 about the deposition? 4 A. No. 5 Q. I'm going to hand you, Dr. Bloch, what's 6 been marked as Exhibit 1040. 7 A. Okay. 8 Q. Do you recognize that document? 9 A. Yes, this is my declaration, a copy of my 10 declaration. 11 Q. And on page 35, that's your electronic 12 signature? 13 A. Yes, it is. 14 Q. And if you look at the front cover you'll 15 see that there are a total of six IPRs listed. 16 Do you see that? 17 A. Right. 18 Q. And you provided the same declaration or one 19 deposition for all six IPRs? 20 A. That's my understanding why they're listed 21 here. 22 Q. When did you begin working on this 23 declaration? 24 A. Sometime early in June -- no, sometime early 25 in July, I think.</p>	<p style="text-align: right;">Page 9</p> <p>1 Q. Was it accurate as of that date? 2 A. Yes. 3 Q. Have there been any changes to your CV in 4 the meantime? 5 A. There are some minor ones, I believe. There 6 has been at least one manuscript that was submitted 7 that has been accepted, so that would be a change. 8 Otherwise, I don't think I changed -- I 9 would have changed anything. I think that's probably 10 the only change of substance, maybe. 11 Q. What was the nature of that manuscript? 12 A. Oh, it had to do with an intervention of a 13 pharmaceutical company having to do with artificial 14 protection of too much scarring as a result of back 15 surgery on the spine. 16 Q. When you say "intervention," what do you 17 mean? 18 A. They have to cut you open and put this tube 19 in here where they are surgically trying to help you 20 with your debilitation. 21 Q. Thank you. And looking at the front of your 22 CV -- I may have said 1034 before but it's actually 23 Exhibit 1043, if I misspoke -- I saw you got a BS from 24 Stanford in statistics and a Ph.D. from Johns Hopkins 25 in statistics?</p>

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1 A. That's correct.

2 Q. Has your employment history been focused on

3 statistics?

4 A. Yes. Well, in terms of the academic part of

5 my career.

6 I've been self-employed as a contractor as

7 well. That's a completely different profession.

8 Q. What kind of activities did you undertake as

9 a contractor?

10 A. I was a general contractor in California. I

11 built homes.

12 Q. Really.

13 A. Custom homes, things of that nature. That's

14 why there's a gap between 1972 and 1984 on that front

15 page.

16 Q. Prior to -- well, let me step back. You're

17 obviously aware this IPR, or these are IPRs and they

18 relate to a proceeding going on in the Patent Office,

19 correct?

20 A. Yes, I've been told that.

21 Q. You also understand that there's a District

22 Court litigation going on in Marshall, Texas?

23 A. Yes.

24 Q. And you've been engaged to work on the

25 litigation as well?

Page 11

1 A. Yes, I have.

2 Q. Prior to being engaged with respect to the

3 dispute regarding Restasis, had you done any work

4 related to ophthalmology?

5 A. Well, that's a very broad question. As a

6 biostatistician, I've interacted with people at

7 Stanford that have done studies with eye tissues.

8 I have consulted for startup companies

9 having to do with devices that they've had for the

10 eye.

11 Most recently with the startup company,

12 actually in Tucson, Arizona, where they have a device

13 where they can snake something in the back of the eye

14 to help ocular, macular degeneration.

15 So, you know, broadly, yes, I have been

16 involved with ocular-type things. And with

17 specifically with this compound, you know.

18 Q. And by the compound, you're talking about

19 cyclosporin?

20 A. Well, what is it called. Restasis?

21 Q. Yes.

22 A. R E S T A S I S.

23 Q. Yes. That's the brand name. Cyclosporin is

24 the active ingredient.

25 So have you done any work related to

Page 12

1 treatment of dry eye or KCS?

2 A. When you say have I done any work, I've

3 advised people. I had a colleague at Stanford who has

4 dry eye and she asked me to -- at the time that she

5 got that diagnosis to peruse the literature to help

6 her understand, you know, what the evidence is of one

7 thing perhaps working better than another.

8 So that was a case that was -- it wasn't

9 through a pharmaceutical company, it was just a

10 private kind of thing.

11 But otherwise, I think with dry eye, I don't

12 recall that being a subject matter that I've been

13 involved with.

14 Q. Okay.

15 A. Excuse me.

16 Q. As part of your professional career as a

17 biostatistician, have you been involved with the

18 approval of drugs by FDA?

19 A. Yes.

20 Q. Have you assisted in review of the

21 submissions to FDA?

22 MR. PARMELEE: Objection; form.

23 Q. (By Mr. Kane) Have you assisted?

24 A. What was the question you asked me? I lost

25 my train of thought when the objection came in.

Page 13

1 Q. My question was have you assisted in

2 submissions to the FDA?

3 A. Yes.

4 Q. Have you assisted in review of submissions

5 made to the FDA?

6 A. Yes. But not as an employee of the FDA.

7 Q. What was your role in review of submissions

8 made to the FDA?

9 A. Well, it varied depending upon what the

10 submission was. A Phase I submission would be a very

11 different submission than a Phase III preliminary

12 trial that was done to get approval.

13 Q. I guess my question was directed at, if you

14 weren't an employee of the FDA, why were you reviewing

15 submissions made to the FDA?

16 A. Because of my expertise in biostatistics the

17 company asks me to do this sometimes.

18 Q. Have you ever been involved or engaged by

19 FDA to review any submissions?

20 A. No.

21 Q. You've never been on an FDA advisory panel?

22 A. I have been, yes.

23 Q. What does that consist of?

24 A. Again, that's a very varied topic.

25 For example, one meeting was a group of

<p style="text-align: right;">Page 14</p> <p>1 somewhere around 30 of us met with higher-ups in the 2 statistical personnel of the FDA, biologics, devices 3 and drugs, where the discussion had to do with missing 4 data in submissions.</p> <p>5 And the FDA wanted advice in terms of how 6 they should handle that broadly but also more 7 specifically how much missing data it would be okay to 8 have and that was a very lively discussion.</p> <p>9 So that's just a specific example of the 10 kind of functions that the FDA uses advisory boards 11 for if it's biostatistical in nature.</p> <p>12 <b>Q. How long have you been involved with FDA 13 statistical advisory boards?</b></p> <p>14 A. I'm not currently on the advisory board. 15 You'd have to go to my CV. I think I might have the 16 dates there. I don't actually know.</p> <p>17 <b>Q. Okay. Why don't we do that.</b></p> <p>18 A. I don't know if it's here. Is it here? I'm 19 just looking for it.</p> <p>20 Well, 1995 to 2006, it's number eleven.</p> <p>21 <b>Q. Right. Okay.</b></p> <p>22 A. It was in that time frame.</p> <p>23 <b>Q. Okay. And that's a special government 24 employee, they pay you to be on the advisory board or 25 advisory panel?</b></p>	<p style="text-align: right;">Page 16</p> <p>1 A. Yes, probably. That's right.</p> <p>2 <b>Q. Okay. So you understand that FDA has 3 statisticians who review clinical data in connection 4 with a drug approval process?</b></p> <p>5 A. Yes, more than an understanding. Yes, I 6 know that's true. Yes.</p> <p>7 <b>Q. And have you interacted with those 8 statisticians?</b></p> <p>9 A. Yes.</p> <p>10 <b>Q. In what capacities?</b></p> <p>11 A. Well, again, that's fairly varied. I've 12 been on conference calls with companies discussing 13 what the FDA statisticians had concerns with respect 14 to the -- with the investigational plan that had been 15 submitted to the FDA. So there was a discussion about 16 the content that way, long distance.</p> <p>17 I have given lectures at the FDA to 18 statisticians and interacted with them directly in 19 that way. Those lectures have been mostly having to 20 do with introducing to them some of the newer things 21 that were going on in statistics that I had expertise 22 with in terms of how they could apply it to their 23 needs.</p> <p>24 So it's a variety of ways I've interacted 25 with statisticians at the FDA.</p>
<p style="text-align: right;">Page 15</p> <p>1 A. I said including FDA statistical advisory 2 panel. And I was a special government employee also 3 working with the Veterans Administration hospital in 4 Palo Alto.</p> <p>5 The way the Veterans Administration performs 6 many very high level clinical trials.</p> <p>7 Excuse me, I'm going to get some water.</p> <p>8 In fact, some of the best clinical trials 9 that are done in this country are through the VA 10 system, where their subjects in the VA are veterans.</p> <p>11 And these protocols are actually headed by 12 statisticians, unlike many other grants which are 13 headed by PIs which are specialists in the particular 14 field.</p> <p>15 And I was the adviser to the VA on the 16 planning and execution of those trials. And there are 17 VA centers throughout the country, five or six, that 18 are involved in these clinical trials that are funded 19 through the government.</p> <p>20 So I was a special government employee for 21 that. I don't believe I got paid but they had to 22 designate me somehow to be involved.</p> <p>23 <b>Q. I see. And is that -- looking at your 24 professional activities, it's number nine there, is 25 that what you were referring to?</b></p>	<p style="text-align: right;">Page 17</p> <p>1 <b>Q. Okay. And do they use those statistical 2 panels, statistical advisory panels, for instance, to 3 stay abreast of current statistical methods?</b></p> <p>4 MR. PARMELEE: Objection; form.</p> <p>5 A. I think -- well, I don't know if they use it 6 specifically for that purpose, but those features are 7 how statistics, you know, continues to evolve and will 8 come out when you're at an advisory panel because 9 people will bring up newer methods that perhaps could 10 be used.</p> <p>11 <b>Q. (By Mr. Kane) When you've given lectures to 12 the FDA regarding statistics, what format or context 13 did that come up in?</b></p> <p>14 A. I can recall one lecture which had to do 15 with presenting to them -- it's a mouthful -- it's 16 called non-parametric regression, non-parametric 17 regression methods, which they wanted to use -- I'm 18 sorry.</p> <p>19 I haven't had this frog in my throat all 20 week and now I have to have it.</p> <p>21 <b>Q. That's the way it goes.</b></p> <p>22 A. And they were hoping to be able to use that 23 methodology in their post-marketing surveillance 24 program, and that's a fairly critical part of what 25 they do. But that's, you know, it speaks for itself.</p>

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