UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS, INC.,)

Petitioner,)

vs.)

ALLERGAN, INC.,)

PATENT OWNER.)

DEPOSITION OF DANIEL BLOCH, Ph.D.

8:45 a.m.

July 14, 2017

701 Fifth Avenue, Suite 5100

Seattle, Washington

CASE IPR2016-01127, PATENT 8,685,930

CASE IPR2016-01128, PATENT 8,629,111

CASE IPR2016-01129, PATENT 8,642,566

CASE IPR2016-01130, PATENT 8,633,162

CASE IPR2016-01131, PATENT 8,648,048

CASE IPR2016-01132, PATENT 9,248,191

REPORTED BY: Pat Lessard, CCR #2104

A P P E A R A N C E S

FOR THE PETITIONER:
MR. MICHAEL J. KANE
Fish & Richardson
3200 RBC Plaza
60 South Sixth Street
Minneapolis, MN 55402
612.335.5070
kane@fr.com

FOR THE RESPONDENT:
MR. STEVEN W. PARMELEE
MS. GRACE A. WINSCHEL
Wilson Sonsini Goodrich & Rosati
701 Fifth Avenue, Suite 5100
Seattle, WA 98104-7036
206.471.2083
sparmelee@wsgr.com
MS. JACQUELINE ALTMAN
Wilson Sonsini Goodrich & Rosati
12235 El Camino Real, Suite 200
San Diego, CA 92130-3002
858.350.2300
jacqueline.altman@wsgr.com

E X A M I N A T I O N

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

REFERRED EXHIBIT INDEX

DANIEL BLOCH, being duly sworn, testified upon oath, as follows:

E X A M I N A T I O N

BY MR. KANE:

Q. Good morning, Dr. Bloch.

A. Good morning.

Q. Could you state your full name for the record.

A. Daniel, middle initial A, last name Bloch spelled with an H.

Q. What's your current business address?

A. My current business address?

Q. Yes.

A. 8987 East Tanque, spelled T A N Q U E. And then another word Verde, V E R D E. And then a pound sign 309-387. Tucson, Arizona 85749.

I've given you that. That's my mailing address. I have an office at Stanford but I live in Tucson and my letterhead has that address on it, my Tucson address.

Q. Thank you. Have you been deposed before?

A. Yes.

Q. How many times, approximately?

A. A dozen.

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

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

A. Okay.

Q. So I'm going to be asking questions. You're going to be providing the answers. Your counsel may have some objections at some points along the way.

Our court reporter here is going to be taking down everything that we say, so it's important that -- a couple things. One, it seems like you may be a fast talker and I'm definitely a fast talker, so we both should try to maybe slow down to help her out.

Another thing is I'll do my best to let you finish your answer before I start speaking again and, likewise, you should let me finish my questions before you start speaking so that she can get that down. Okay?

A. Sure.

Q. If I don't ask a question that you understand or is confusing to you please let me know and I'll try to clarify for you. Okay?

A. Okay.

Q. And if you answer the question I'm going to assume that you understood the question. All right?

A. Yes.

Q. That's another thing, you have to answer verbally "Yes" and "No," not uh-huhs or huh-uhs or

Page 6

nods of the head or shakes of the head. She can't get that down, so that's a good point to remember.

Finally, we'll take periodic breaks roughly, usually about an hour or so of questions and then let everybody stretch their legs and what have you.

If you need a break --

A. I'll let you know.

Q. -- let me know.

A. Okay.

Q. Very good. Is there any reason that you can't give accurate and truthful testimony today?

A. No.

Q. You understand that you're under oath and the testimony you are giving is under oath and is admissible in court?

A. I do understand, yes.

Q. You were talking over me there. You've got to slow down and let me finish my question. Okay?

A. Yes.

Q. What did you do to prepare for your deposition today?

A. I read over materials that are pertinent to or included in my declaration and I met with counsel.

Q. When did you meet with counsel?

A. Yesterday for several hours as well as the

Page 7

day before.

Q. Did you speak to anyone other than counsel about the deposition?

A. No.

Q. I'm going to hand you, Dr. Bloch, what's been marked as Exhibit 1040.

A. Okay.

Q. Do you recognize that document?

A. Yes, this is my declaration, a copy of my declaration.

Q. And on page 35, that's your electronic signature?

A. Yes, it is.

Q. And if you look at the front cover you'll see that there are a total of six IPRs listed.

Do you see that?

A. Right.

Q. And you provided the same declaration or one deposition for all six IPRs?

A. That's my understanding why they're listed here.

Q. When did you begin working on this declaration?

A. Sometime early in June -- no, sometime early in July, I think.

Page 8

Is that right? No? I'm not really quite sure. Sorry.

Q. The signature is June 30th.

A. All right. So it had to be early in June.

Q. Okay. How much time did you spend working on the declaration?

A. Many hours. I don't really have an estimate with me. Certainly more than 50.

Q. And did you draft the declaration yourself or how did that process work?

A. Yes, I did.

Q. So you typed the words yourself?

A. No. Counsel -- counsel prepared the formatting of the declaration and they aided me in figures, formatting and things of that nature, but I wrote the text.

Q. How did you write the text? Did you type it in some sort of document and send it to counsel?

A. Yeah. Yeah, we went back and forth.

Q. Okay. I'll hand you what's previously been marked as Exhibit 1034.

Do you recognize that document?

A. It appears to be a version of my CV. Yes.

Q. I see it's dated November 1, 2016.

A. Yes, I see that, too.

Page 9

Q. Was it accurate as of that date?

A. Yes.

Q. Have there been any changes to your CV in the meantime?

A. There are some minor ones, I believe. There has been at least one manuscript that was submitted that has been accepted, so that would be a change.

Otherwise, I don't think I changed -- I would have changed anything. I think that's probably the only change of substance, maybe.

Q. What was the nature of that manuscript?

A. Oh, it had to do with an intervention of a pharmaceutical company having to do with artificial protection of too much scarring as a result of back surgery on the spine.

Q. When you say "intervention," what do you mean?

A. They have to cut you open and put this tube in here where they are surgically trying to help you with your debilitation.

Q. Thank you. And looking at the front of your CV -- I may have said 1034 before but it's actually Exhibit 1043, if I misspoke -- I saw you got a BS from Stanford in statistics and a Ph.D. from Johns Hopkins in statistics?

Page 10

A. That's correct.
Q. Has your employment history been focused on statistics?
A. Yes. Well, in terms of the academic part of my career.
I've been self-employed as a contractor as well. That's a completely different profession.
Q. What kind of activities did you undertake as a contractor?
A. I was a general contractor in California. I built homes.
Q. Really.
A. Custom homes, things of that nature. That's why there's a gap between 1972 and 1984 on that front page.
Q. Prior to -- well, let me step back. You're obviously aware this IPR, or these are IPRs and they relate to a proceeding going on in the Patent Office, correct?
A. Yes, I've been told that.
Q. You also understand that there's a District Court litigation going on in Marshall, Texas?
A. Yes.
Q. And you've been engaged to work on the litigation as well?

Page 11

A. Yes, I have.
Q. Prior to being engaged with respect to the dispute regarding Restasis, had you done any work related to ophthalmology?
A. Well, that's a very broad question. As a biostatistician, I've interacted with people at Stanford that have done studies with eye tissues.
I have consulted for startup companies having to do with devices that they've had for the eye.
Most recently with the startup company, actually in Tucson, Arizona, where they have a device where they can snake something in the back of the eye to help ocular, macular degeneration.
So, you know, broadly, yes, I have been involved with ocular-type things. And with specifically with this compound, you know.
Q. And by the compound, you're talking about cyclosporin?
A. Well, what is it called. Restasis?
Q. Yes.
A. R E S T A S I S.
Q. Yes. That's the brand name. Cyclosporin is the active ingredient.
So have you done any work related to

Page 12

treatment of dry eye or KCS?
A. When you say have I done any work, I've advised people. I had a colleague at Stanford who has dry eye and she asked me to -- at the time that she got that diagnosis to peruse the literature to help her understand, you know, what the evidence is of one thing perhaps working better than another.
So that was a case that was -- it wasn't through a pharmaceutical company, it was just a private kind of thing.
But otherwise, I think with dry eye, I don't recall that being a subject matter that I've been involved with.
Q. Okay.
A. Excuse me.
Q. As part of your professional career as a biostatistician, have you been involved with the approval of drugs by FDA?
A. Yes.
Q. Have you assisted in review of the submissions to FDA?
MR. PARMELEE: Objection; form.
Q. (By Mr. Kane) Have you assisted?
A. What was the question you asked me? I lost my train of thought when the objection came in.

Page 13

Q. My question was have you assisted in submissions to the FDA?
A. Yes.
Q. Have you assisted in review of submissions made to the FDA?
A. Yes. But not as an employee of the FDA.
Q. What was your role in review of submissions made to the FDA?
A. Well, it varied depending upon what the submission was. A Phase I submission would be a very different submission than a Phase III preliminary trial that was done to get approval.
Q. I guess my question was directed at, if you weren't an employee of the FDA, why were you reviewing submissions made to the FDA?
A. Because of my expertise in biostatistics the company asks me to do this sometimes.
Q. Have you ever been involved or engaged by FDA to review any submissions?
A. No.
Q. You've never been on an FDA advisory panel?
A. I have been, yes.
Q. What does that consist of?
A. Again, that's a very varied topic.
For example, one meeting was a group of

Page 14

somewhere around 30 of us met with higher-ups in the statistical personnel of the FDA, biologics, devices and drugs, where the discussion had to do with missing data in submissions.

And the FDA wanted advice in terms of how they should handle that broadly but also more specifically how much missing data it would be okay to have and that was a very lively discussion.

So that's just a specific example of the kind of functions that the FDA uses advisory boards for if it's biostatistical in nature.

Q. How long have you been involved with FDA statistical advisory boards?

A. I'm not currently on the advisory board. You'd have to go to my CV. I think I might have the dates there. I don't actually know.

Q. Okay. Why don't we do that.

A. I don't know if it's here. Is it here? I'm just looking for it.

Well, 1995 to 2006, it's number eleven.

Q. Right. Okay.

A. It was in that time frame.

Q. Okay. And that's a special government employee, they pay you to be on the advisory board or advisory panel?

Page 15

A. I said including FDA statistical advisory panel. And I was a special government employee also working with the Veterans Administration hospital in Palo Alto.

The way the Veterans Administration performs many very high level clinical trials.

Excuse me, I'm going to get some water.

In fact, some of the best clinical trials that are done in this country are through the VA system, where their subjects in the VA are veterans.

And these protocols are actually headed by statisticians, unlike many other grants which are headed by PIs which are specialists in the particular field.

And I was the adviser to the VA on the planning and execution of those trials. And there are VA centers throughout the country, five or six, that are involved in these clinical trials that are funded through the government.

So I was a special government employee for that. I don't believe I got paid but they had to designate me somehow to be involved.

Q. I see. And is that -- looking at your professional activities, it's number nine there, is that what you were referring to?

Page 16

A. Yes, probably. That's right.

Q. Okay. So you understand that FDA has statisticians who review clinical data in connection with a drug approval process?

A. Yes, more than an understanding. Yes, I know that's true. Yes.

Q. And have you interacted with those statisticians?

A. Yes.

Q. In what capacities?

A. Well, again, that's fairly varied. I've been on conference calls with companies discussing what the FDA statisticians had concerns with respect to the -- with the investigational plan that had been submitted to the FDA. So there was a discussion about the content that way, long distance.

I have given lectures at the FDA to statisticians and interacted with them directly in that way. Those lectures have been mostly having to do with introducing to them some of the newer things that were going on in statistics that I had expertise with in terms of how they could apply it to their needs.

So it's a variety of ways I've interacted with statisticians at the FDA.

Page 17

Q. Okay. And do they use those statistical panels, statistical advisory panels, for instance, to stay abreast of current statistical methods?

MR. PARMELEE: Objection; form.

A. I think -- well, I don't know if they use it specifically for that purpose, but those features are how statistics, you know, continues to evolve and will come out when you're at an advisory panel because people will bring up newer methods that perhaps could be used.

Q. (By Mr. Kane) When you've given lectures to the FDA regarding statistics, what format or context did that come up in?

A. I can recall one lecture which had to do with presenting to them -- it's a mouthful -- it's called non-parametric regression, non-parametric regression methods, which they wanted to use -- I'm sorry.

I haven't had this frog in my throat all week and now I have to have it.

Q. That's the way it goes.

A. And they were hoping to be able to use that methodology in their post-marketing surveillance program, and that's a fairly critical part of what they do. But that's, you know, it speaks for itself.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.