

1 UNITED STATES PATENT AND TRADEMARK OFFICE

2

3 BEFORE THE PATENT TRIAL AND APPEAL BOARD

4

5 MYLAN PHARMACEUTICALS INC.,

6 Petitioner

7

v.

8

ALLERGAN, INC.,

9

Patent Owner

10

11 Case IPR2016-01127

12 Patent 8,685,930

13 Case IPR2016-01128

14 Patent 8,629,111

15 Case IPR2016-01129

16 Patent 8,642,556

17 Case IPR2016-01130

18 Patent 8,633,162

19 Case IPR2016-01131

20 Patent 8,648,048

21 Case IPR2016-01132

22 Patent 9,248,191

23

24 DEPOSITION OF MANSOOR AMIJI, Ph.D.

25 Wednesday, February 22, 2017 9:10 a.m.

Page 2

1 Fish & Richardson P.C.
 2 One Marina Park Drive, Boston, MA 02210
 3
 4 Reported by:
 5 Janet Sambataro, RMR, CRR, CLR
 6 JOB NO. LA-115711
 7
 8
 9 February 22, 2017
 10 9:10 a.m.
 11
 12
 13 Deposition of MANSOOR AMIJI, PH.D., held
 14 at the offices of Fish & Richardson P.C., One
 15 Marina Park Drive, Boston, Massachusetts,
 16 pursuant to Agreement before Janet Sambataro, a
 17 Registered Merit Reporter, Certified Realtime
 18 Reporter, Certified LiveNote Reporter, and a
 19 Notary Public within and for the Commonwealth of
 20 Massachusetts.
 21
 22
 23
 24
 25

Page 3

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Page 4

I N D E X

2 WITNESS DIRECT CROSS REDIRECT
 3 MANSOOR AMIJI, Ph.D.
 4 By Ms. Coletti 5
 5
 6
 7 PREVIOUSLY MARKED EXHIBITS

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P R O C E E D I N G S

2 MANSOOR AMIJI, Ph.D.,
 3 having been duly sworn, after presenting
 4 identification in the form of a driver's license,
 5 deposes and says as follows:
 6 DIRECT EXAMINATION
 7 BY MS. COLETTI:
 8 Q. Good morning, Dr. Amiji.
 9 A. Good morning.
 10 Q. Can you please state and spell your
 11 name for the record.
 12 A. Mansoor, spelled M-A-N-S-O-O-R, middle
 13 initial M., as in Mary, last name A-M-I-J-I.
 14 Q. And can you please state your business
 15 address.
 16 A. Northeastern University, 360 Huntington
 17 Avenue, Boston, Massachusetts 02115.
 18 Q. Now, before I get started into the
 19 substance of today's deposition, I'll go over a
 20 few ground rules.
 21 I believe you've been deposed before. Is
 22 that right?
 23 A. Yes.
 24 Q. So you probably know some of these, but
 25 I'll go over them anyway.

Page 6

1 You understand you're under oath. The court
 2 reporter just swore you in. Right?
 3 A. Yes.
 4 Q. And you understand that any testimony
 5 that you give today can be used in the IPR
 6 proceeding that we're here today talking about.
 7 You understand that. Right?
 8 A. Yes.
 9 Q. And you understand that the testimony
 10 that you give today is the same as if you were
 11 giving it in court.
 12 Do you understand that as well?
 13 A. Yes.
 14 Q. And so you understand that it's
 15 important to testify completely and truthfully
 16 and accurately. Right?
 17 A. Yes.
 18 Q. Because our court reporter here is
 19 recording our conversation, it's important that
 20 you verbalize your answers, so "yes" or "no" as
 21 opposed to nodding or shaking your head. Do you
 22 understand that?
 23 A. Yes.
 24 Q. And it's important that we don't speak
 25 over each other. So I will try to let you finish

Page 7

1 an answer before I ask my next question, and I'd
 2 ask that you allow me to finish my question
 3 before you give your answer. Is that okay?
 4 A. Yes.
 5 Q. Your attorney may object from time to
 6 time, but unless for some reason he instructs you
 7 not to answer the question, do you understand
 8 you're obligated to answer my question as best
 9 you can?
 10 A. Yes.
 11 Q. If one of my questions is confusing or
 12 if you need some clarification, please let me
 13 know and I'll try to rephrase it. Okay?
 14 A. Yes.
 15 Q. So then is it fair to assume that if
 16 you answer my question, that you've understood
 17 it?
 18 A. Yes.
 19 Q. Dr. Amiji, is there any reason, medical
 20 or otherwise, that you can't give complete,
 21 truthful and accurate testimony today?
 22 A. No.
 23 Q. And if that ever changes during the
 24 course of the day, if you start to feel ill, just
 25 let me know. Is that okay?

Page 8

1 A. Sure.
 2 Q. Now, I think you said already you have
 3 been deposed before. Is that correct?
 4 A. Yes.
 5 Q. About how many times?
 6 A. Five or six times.
 7 Q. And always as an expert witness or in
 8 other capacities as well?
 9 A. In some of the cases, I've -- in other
 10 capacities as well.
 11 Q. And let's talk about the expert witness
 12 work first. What sorts of cases were they? Were
 13 they all patent infringements? Were there other
 14 kinds of cases in which you testified as an
 15 expert?
 16 A. Some were patent infringement. There
 17 are also other types of cases.
 18 Q. What were the other types?
 19 A. Contract disputes.
 20 Q. Okay. What else?
 21 A. There was also one case that involved a
 22 university that was -- the plaintiffs were
 23 St. John's University, and they were suing and I
 24 was asked to serve as an expert to look at the
 25 technical aspect of the case.

Page 9

1 Q. What was the dispute about in that
 2 case? Do you recall?
 3 A. It involved patents, but not
 4 necessarily from infringement side. It was just
 5 the patents and who were the owners, the rightful
 6 owners of the patents.
 7 Q. I see. And what about cases where you
 8 were not serving as an expert witness? What
 9 sorts of cases were those? I think you said you
 10 were deposed in cases where you were not an
 11 expert witness. Is that right?
 12 A. No. I'm not sure I said that.
 13 Q. Maybe I misunderstood you, then. So in
 14 all these five or six depositions that you gave,
 15 you were always an expert witness. Is that
 16 right?
 17 A. Yes. I was asked to serve as an expert
 18 looking at the technical matters.
 19 Q. Okay. When was the last time you were
 20 deposed?
 21 A. November of last year.
 22 Q. And what did that relate to, generally?
 23 Was that a patent infringement case?
 24 A. Yes.
 25 Q. What was the technology, generally?

Page 10

1 A. It was a drug formulation patent.

2 Q. Was it a Hatch-Waxman case or ANDA

3 case?

4 A. Yes.

5 Q. Have you ever been deposed in an IPR

6 proceeding before?

7 A. No, I haven't.

8 Q. Have you ever served as an expert

9 witness in an IPR proceeding, before this one?

10 A. Yeah. I don't believe I have served on

11 an IPR proceeding before.

12 Q. In all of the cases where you were --

13 excuse me, in all of the patent cases where you

14 served as an expert witness, were they all

15 Hatch-Waxman cases?

16 A. No. As I said before, I have served on

17 cases like the St. John's case I mentioned, which

18 also involved patents, but it wasn't a

19 Hatch-Waxman case.

20 Q. But that wasn't a patent infringement

21 case? Is that right?

22 A. No. It wasn't a patent infringement.

23 Q. So limiting it just to the patent

24 infringement cases that you have served as an

25 expert on, were all of those Hatch-Waxman cases?

Page 11

1 A. Yes.

2 Q. And have you ever been an expert

3 witness in a case related to ophthalmic drugs

4 before?

5 A. No, I have not.

6 Q. Did you do anything to prepare for

7 today's deposition?

8 A. Yes.

9 Q. What did you do?

10 A. I read my declarations. I read

11 patents. I read the prosecution history. I read

12 a lot of documents.

13 Q. Did you meet with anyone to prepare for

14 today's deposition?

15 A. Yes.

16 Q. Who did you meet with?

17 A. With attorneys.

18 Q. When did you do that?

19 A. The day before yesterday and yesterday.

20 Q. For about how long?

21 A. Just a few hours both days.

22 Q. A few hours each day?

23 A. Yes.

24 Q. About how many?

25 A. Maybe five or six hours.

Page 12

1 Q. So a good chunk of the business day.

2 Is that fair?

3 A. Yeah.

4 Q. And which lawyers were present? The

5 lawyers that are here?

6 A. Yes. All three of them.

7 Q. All three of them. Was anyone else

8 present?

9 A. Mr. Parmelee was on the call yesterday,

10 just for a few -- maybe an hour or so.

11 Q. Was anyone else present in the room

12 with you and the lawyers yesterday or the day

13 before when you were preparing for the

14 deposition?

15 A. No.

16 Q. And did you speak to anyone else, other

17 than lawyers, in preparation for your deposition?

18 A. No.

19 Q. You said you read the patents, the

20 prosecution histories. What other documents did

21 you read besides those?

22 A. The declarations, my declarations. I

23 also reviewed some of the exhibits that are

24 attached to the declarations.

25 Q. Was there anything outside the

Page 13

1 declarations, the attachments, and the patents

2 that you reviewed? So anything that you didn't

3 cite in your declarations?

4 A. No.

5 Q. Okay. And did you review those on your

6 own or did you review them with the lawyers or

7 both?

8 A. Some of it I reviewed on my own.

9 Sometimes we would have some discussions, and

10 we'd do it together.

11 Q. And when did you start preparing for

12 the deposition?

13 A. Maybe about two weeks ago.

14 Q. Did you read all of your declarations

15 again or did you focus on any one in particular?

16 A. No. I read all, and specifically

17 looking at all. I also looked at the IPR

18 decision that came from the patent board.

19 Q. The institution decision?

20 A. Correct.

21 Q. Is that what you mean?

22 A. Yes.

23 Q. Do you understand, Dr. Amiji, that

24 there is a concurrent litigation going on between

25 Allergan and Mylan or Restasis in District Court?

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1 A. I was informed of that a long time ago,
 2 but I haven't really had any interactions on
 3 that.
 4 Q. Do you know anything about that
 5 litigation?
 6 A. No, I don't.
 7 Q. Have you reviewed any documents or
 8 court orders from that proceeding?
 9 A. No.
 10 Q. Has anyone talked to you about any
 11 documents or court orders from that proceeding?
 12 MR. MILLS: I'm just going to register
 13 an objection on the basis of privilege and
 14 attorney work product. And to the extent that
 15 the question inquires into any conversations with
 16 counsel, then I would instruct you to not answer
 17 with regards to conversations with counsel.
 18 MS. COLETTI: Dr. Amiji is an expert
 19 witness. There is no privilege between lawyers
 20 and an expert witness. So I think that's an
 21 improper instruction.
 22 BY MS. COLETTI:
 23 Q. So did anyone tell you anything about
 24 the Court orders or the proceedings in the
 25 District Court?

Page 15

1 A. No.
 2 MR. MILLS: Same instruction.
 3 Q. And have you asked for any documents
 4 from that proceeding? You said you didn't review
 5 anything.
 6 Have you asked for anything but not gotten
 7 it?
 8 A. No.
 9 Q. Do you know anything about Mylan's ANDA
 10 or Mylan's generic product?
 11 A. No.
 12 Q. Do you know anything about any of the
 13 other -- let me step back a minute.
 14 Do you know anything about whether there are
 15 other generic companies attempting to make
 16 generic versions of Restasis?
 17 A. No, I don't.
 18 Q. Have you been contacted by lawyers for
 19 any of the other generic companies regarding
 20 Restasis?
 21 A. No, I have not.
 22 Q. And do you know the status of Mylan's
 23 ANDA with FDA?
 24 A. No, I don't.
 25 Q. So fair to say you don't know whether

Page 16

1 Mylan's ANDA has been approved or not?
 2 A. No, I don't.
 3 Q. And you don't have any knowledge
 4 regarding any problems Mylan may or may not be
 5 having with its ANDA. Is that right?
 6 A. That's right.
 7 Q. And have you been asked to serve as an
 8 expert witness in the District Court litigation?
 9 A. No, I have not.
 10 Q. Okay. I'm going to hand you,
 11 Dr. Amiji, and I'm going to read them one by one,
 12 but these are all your declarations but so our
 13 record is clear.
 14 So first I have what has been marked as
 15 Exhibit 1002 in IPR 2016-01127, and it's your
 16 declaration related to the '930 patent.
 17 Then I'm going to hand you what's been
 18 marked as Exhibit 1002 in IPR 2016-01128. It's
 19 your declaration related to the '111 patent.
 20 MR. MILLS: Do you have copies of any
 21 of these documents?
 22 MS. COLETTI: I do. I'll hand you a
 23 whole pile in just a moment.
 24 Q. Next I have what's been marked as
 25 Exhibit 1002 in IPR 2016-01129. It's your

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1 declaration related to the '556 patent.
 2 Then I've got what has been marked as
 3 Exhibit 1002 in IPR 2016-01130. It's your
 4 declaration related to the '162 patent.
 5 Next is Exhibit 1002 in IPR 2016-01131.
 6 It's your declaration related to the '048 patent.
 7 And then finally, Exhibit 1002 in IPR 2016-01132.
 8 It's your declaration related to the '191 patent.
 9 And, Dr. Amiji, you have your six
 10 declarations in front of you? Are all of those
 11 in front of you?
 12 A. Yes.
 13 Q. For purposes of today's questioning,
 14 I'm going to focus mostly on the second document
 15 we marked. It's the one for the '111 patent. So
 16 if you'd like to reference any of the others, you
 17 have all of them. But that's the one I'm going
 18 to spend most of my time questioning on.
 19 And I see, Dr. Amiji, you have a binder of
 20 documents in front of you. What's in your binder
 21 that you brought with you today?
 22 A. So that's the same, the declarations
 23 and then the corresponding patents.
 24 Q. Okay. And is there anything in your
 25 binder that's marked up or in any way is

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