## MANSOOR AMIJI - 02/22/2017

|    | MANDOOK AMIDI 02/22/2017                  |  |  |  |  |
|----|---|--|--|--|--|
| 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  | 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 | 7 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.    |  |  |  |  |
|    |   |  |  |  |  |



|  | MANSOOR AMIJI   |                                  | - , , -  | 2                        |
|--|---|----------------------------------|--|--------------------------|
| 1  | Page 2 Fish & Richardson P.C.   | 1                                | PINDEX   | age 4                    |
| 2  | One Marina Park Drive, Boston, MA 02210   | 2                                | WITNESS DIRECT CROSS REDIRECT  |                          |
| 3  | one narina rain brive, bessess, in value  | 3                                | MANSOOR AMIJI, Ph.D.   |                          |
| 4  | Reported by:  | 4                                | By Ms. Coletti 5   |                          |
| 5  | Janet Sambataro, RMR, CRR, CLR  | 5                                | 2  |                          |
| 6  | JOB NO. LA-115711   | 6                                |  |                          |
| 7  |   | 7                                | PREVIOUSLY MARKED EXHIBITS   |                          |
| 8  |   | 8                                | Number Pag   | е                        |
| 9  | February 22, 2017   | 9                                | Exhibit 1001 44  |                          |
| 10   | 9:10 a.m.   | 10                               | Exhibit 1002 in IPR 2016-01129 16  |                          |
| 11   |   | 11                               | Exhibit 1002 in IPR 2016-01128 16  |                          |
| 12   |   | 12                               | Exhibit 1002 in IPR 2016-01129 16  |                          |
| 13   | Deposition of MANSOOR AMIJI, PH.D., held  | 13                               | Exhibit 1002 in IPR 2016-01130 17  |                          |
| 14   | at the offices of Fish & Richardson P.C., One   | 14                               | Exhibit 1002 in IPR 2016-01131 17  |                          |
| 15   | Marina Park Drive, Boston, Massachusetts,   | 15                               | Exhibit 1002 in IPR 2016-01132 17  |                          |
| 16   | pursuant to Agreement before Janet Sambataro, a   | 16                               | Exhibit 1003 18  |                          |
| 17   | Registered Merit Reporter, Certified Realtime   | 17                               | Exhibit 1004 44  |                          |
| 18   | Reporter, Certified LiveNote Reporter, and a  | 18                               | Exhibit 1006 46  |                          |
| 19   | Notary Public within and for the Commonwealth of  | 19                               | Exhibit 1007 47  |                          |
| 20   | Massachusetts.  | 20                               | Exhibit 1008 47  |                          |
| 21   |   | 21                               | Exhibit 1009 16.   | 2                        |
| 22   |   | 22                               | Exhibit 1015 10  |                          |
| 23   |   | 23                               |  |                          |
| 24   |   | 24                               |  |                          |
| 25   |   | 25                               |  |                          |
|  |   |                                  |  |                          |
| 1  | Page 3 APPEARANCES:   | 1                                | P<br>PROCEEDINGS   | age                      |
| 2  | FISH & RICHARDSON P.C.  | 2                                | MANSOOR AMIJI, Ph.D.,  |                          |
| 3  | (By Susan Morrison Coletti, Esquire)  | 3                                | having been duly sworn, after presenting   |                          |
| 4  | 222 Delaware Avenue   | 4                                | identification in the form of a driver's lice  | ranca                    |
| 5  | Wilmington, Delaware 19899  | 5                                | deposes and says as follows:   | CIISC                    |
| 6  | 302.652.5070  | 6                                | DIRECT EXAMINATION   |                          |
| 7  | coletti@fr.com  | 7                                | BY MS. COLETTI:  |                          |
| 8  | Counsel for the Petitioner  | 8                                | Q. Good morning, Dr. Amiji.  |                          |
| 9  | - and -   | 9                                | A. Good morning.   |                          |
| 10   | FISH & RICHARDSON P.C.  | 10                               | Q. Can you please state and spell you  |                          |
| 11   | (By Tasha M. Francis, Ph.D., Esquire)   | 11                               | name for the record.   | L                        |
| 12   | 3200 RBC Plaza  | 12                               | A. Mansoor, spelled M-A-N-S-O-O-R, mi  | 4416                     |
| 13   | 60 South Sixth Street   | 13                               | initial M., as in Mary, last name A-M-I-J-I.   |                          |
|  |   | 14                               |  |                          |
| 14   |   | T-4                              | Q. And can you please state your busi  | 2000                     |
|  | Minneapolis, Minnesota 55402  | 1 =                              |  | ness                     |
| 15   | 612.335.5070  | <b>15</b>                        | address.  A Northeastern University 360 Hunti  |                          |
| 15<br>16   | _   | 16                               | A. Northeastern University, 360 Hunti  |                          |
| 15<br>16<br>17   | 612.335.5070<br>Counsel for the Petitioner  | 16<br>17                         | A. Northeastern University, 360 Hunti<br>Avenue, Boston, Massachusetts 02115.  | .ngto                    |
| 15<br>16<br>17<br>18   | 612.335.5070  Counsel for the Petitioner  WILSON SONSINI GOODRICH & ROSATI  | 16<br>17<br><b>18</b>            | A. Northeastern University, 360 Hunti Avenue, Boston, Massachusetts 02115.  Q. Now, before I get started into the  | .ngto                    |
| 15<br>16<br>17<br>18   | 612.335.5070  Counsel for the Petitioner  WILSON SONSINI GOODRICH & ROSATI (By Jad Mills, Esquire)  | 16<br>17<br>18<br>19             | A. Northeastern University, 360 Hunti Avenue, Boston, Massachusetts 02115.  Q. Now, before I get started into the substance of today's deposition, I'll go over  | .ngto                    |
| 15<br>16<br>17<br>18<br>19<br>20                               | 612.335.5070  Counsel for the Petitioner  WILSON SONSINI GOODRICH & ROSATI  (By Jad Mills, Esquire)  701 Fifth Avenue, Suite 5100                                       | 16<br>17<br>18<br>19<br>20       | A. Northeastern University, 360 Hunti Avenue, Boston, Massachusetts 02115.  Q. Now, before I get started into the substance of today's deposition, I'll go ove few ground rules.   | ngto<br>er a             |
| 15<br>16<br>17<br>18<br>19<br>20<br>21                         | 612.335.5070  Counsel for the Petitioner  WILSON SONSINI GOODRICH & ROSATI (By Jad Mills, Esquire)  701 Fifth Avenue, Suite 5100  Seattle, Washington 98104             | 16<br>17<br>18<br>19<br>20<br>21 | A. Northeastern University, 360 Hunti Avenue, Boston, Massachusetts 02115.  Q. Now, before I get started into the substance of today's deposition, I'll go ove few ground rules.  I believe you've been deposed before.              | ngto<br>era              |
| 15<br>16<br>17<br>18<br>19<br>20<br>21                         | 612.335.5070  Counsel for the Petitioner  WILSON SONSINI GOODRICH & ROSATI (By Jad Mills, Esquire) 701 Fifth Avenue, Suite 5100  Seattle, Washington 98104 206.883.2554 | 16<br>17<br>18<br>19<br>20<br>21 | A. Northeastern University, 360 Hunti Avenue, Boston, Massachusetts 02115.  Q. Now, before I get started into the substance of today's deposition, I'll go over few ground rules.  I believe you've been deposed before. that right? | ngto<br>er a             |
| 14<br>15<br>16<br>17<br>18<br>19<br>20<br>21<br>22<br>23<br>24 | 612.335.5070  Counsel for the Petitioner  WILSON SONSINI GOODRICH & ROSATI (By Jad Mills, Esquire)  701 Fifth Avenue, Suite 5100  Seattle, Washington 98104             | 16<br>17<br>18<br>19<br>20<br>21 | A. Northeastern University, 360 Hunti Avenue, Boston, Massachusetts 02115.  Q. Now, before I get started into the substance of today's deposition, I'll go ove few ground rules.  I believe you've been deposed before.              | ngto:<br>e<br>er a<br>Is |



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You understand you're under oath. 1 The court 2 reporter just swore you in. Right?

> Α. Yes.

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

- Α. Sure.
- 2 Now, I think you said already you have been deposed before. Is that correct? 3
  - Α.
    - Q. About how many times?
  - Five or six times.
- 7 And always as an expert witness or in 8 other capacities as well?
- 9 A. In some of the cases, I've -- in other capacities as well. 10
  - And let's talk about the expert witness work first. What sorts of cases were they? Were they all patent infringements? Were there other kinds of cases in which you testified as an expert?
- 16 Some were patent infringement. There A. 17 are also other types of cases.
  - What were the other types?
- 19 A. Contract disputes.

owners of the patents.

- Q. Okay. What else?
- There was also one case that involved a university that was -- the plaintiffs were St. John's University, and they were suing and I was asked to serve as an expert to look at the technical aspect of the case.

Page 9 What was the dispute about in that case? Do you recall?

2 3 It involved patents, but not Α. 4 necessarily from infringement side. It was just 5 the patents and who were the owners, the rightful

- I see. And what about cases where you were not serving as an expert witness? What sorts of cases were those? I think you said you were deposed in cases where you were not an expert witness. Is that right?
  - No. I'm not sure I said that.
- 13 Maybe I misunderstood you, then. So in all these five or six depositions that you gave, 14 15 you were always an expert witness. Is that right? 16
  - Yes. I was asked to serve as an expert looking at the technical matters.
  - Okay. When was the last time you were Q. deposed?
  - A. November of last year.
- 22 And what did that relate to, generally? ٥. Was that a patent infringement case?
- 23 24
  - Α.
    - What was the technology, generally?

an answer before I ask my next question, and I'd ask that you allow me to finish my question before you give your answer. Is that okay?

- Your attorney may object from time to time, but unless for some reason he instructs you not to answer the question, do you understand you're obligated to answer my question as best you can?
- 10 Α. Yes.
- 11 If one of my questions is confusing or if you need some clarification, please let me 12 13 know and I'll try to rephrase it. Okay?
  - Α. Yes.
- 15 So then is it fair to assume that if you answer my question, that you've understood 16 17 it?
  - Α. Yes.
- Q. Dr. Amiji, is there any reason, medical 19 or otherwise, that you can't give complete, 20 21 truthful and accurate testimony today?
  - A.
- And if that ever changes during the 23 24 course of the day, if you start to feel ill, just 25 let me know. Is that okay?

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- A. It was a drug formulation patent.
- Q. Was it a Hatch-Waxman case or ANDA
- 3 case?

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- 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.
- Q. But that wasn't a patent infringement case? Is that right?
- 22 A. No. It wasn't a patent infringement.
- Q. So limiting it just to the patent infringement cases that you have served as an expert on, were all of those Hatch-Waxman cases?

- Page 12
- Q. So a good chunk of the business day. Is that fair?
- 7 77 1
  - A. Yeah.
- 4 Q. And which lawyers were present? The 5 lawyers that are here?
  - 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.
  - Q. Was anyone else present in the room with you and the lawyers yesterday or the day before when you were preparing for the deposition?
    - A. No
  - Q. And did you speak to anyone else, other than lawyers, in preparation for your deposition?
    - A. No.
  - Q. You said you read the patents, the prosecution histories. What other documents did you read besides those?
- A. The declarations, my declarations. I also reviewed some of the exhibits that are attached to the declarations.
  - Q. Was there anything outside the

Page 11

- A. Yes.
- 2 Q. And have you ever been an expert
- 3 witness in a case related to ophthalmic drugs
- 4 before?

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- 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 today's deposition?
- 15 A. Yes.
- 16 Q. Who did you meet with?
  - A. With attorneys.
- 18 Q. When did you do that?
- 19 A. The day before yesterday and yesterday.
  - Q. For about how long?
- 21 A. Just a few hours both days.
- 22 Q. A few hours each day?
- 23 A. Yes.
- Q. About how many?
  - A. Maybe five or six hours.

- Page 13 declarations, the attachments, and the patents that you reviewed? So anything that you didn't cite in your declarations?
- A. No
- Q. Okay. And did you review those on your own or did you review them with the lawyers or both?
- 8 A. Some of it I reviewed on my own. 9 Sometimes we would have some discussions, as
  - Sometimes we would have some discussions, and we'd do it together.
  - Q. And when did you start preparing for the deposition?
    - A. Maybe about two weeks ago.
    - Q. Did you read all of your declarations 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?
  - A. Correct.
- Q. Is that what you mean?
  - A. Yes.
- 23 Q. Do you understand, Dr. Amiji, that
- 24 there is a concurrent litigation going on between
  - Allergan and Mylan or Restasis in District Court?

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Page 14 I was informed of that a long time ago, 2 but I haven't really had any interactions on 3 that. Q. Do you know anything about that 4 5 litigation? No, I don't. 6 Α.

Have you reviewed any documents or court orders from that proceeding?

A. No.

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Has anyone talked to you about any documents or court orders from that proceeding?

MR. MILLS: I'm just going to register an objection on the basis of privilege and attorney work product. And to the extent that the question inquires into any conversations with counsel, then I would instruct you to not answer with regards to conversations with counsel.

MS. COLETTI: Dr. Amiji is an expert witness. There is no privilege between lawyers and an expert witness. So I think that's an improper instruction.

BY MS. COLETTI: 2.2

Α.

No.

So did anyone tell you anything about the Court orders or the proceedings in the District Court?

Mylan's ANDA has been approved or not?

No, I don't.

3 And you don't have any knowledge regarding any problems Mylan may or may not be 4 having with its ANDA. Is that right? 5

That's right.

And have you been asked to serve as an expert witness in the District Court litigation?

No, I have not.

Okay. I'm going to hand you, Dr. Amiji, and I'm going to read them one by one, but these are all your declarations but so our record is clear.

So first I have what has been marked as Exhibit 1002 in IPR 2016-01127, and it's your declaration related to the '930 patent.

Then I'm going to hand you what's been marked as Exhibit 1002 in IPR 2016-01128. It's your declaration related to the '111 patent.

MR. MILLS: Do you have copies of any of these documents?

22 MS. COLETTI: I do. I'll hand you a 23 whole pile in just a moment.

Next I have what's been marked as Exhibit 1002 in IPR 2016-01129. It's your

Page 15

MR. MILLS: Same instruction.

And have you asked for any documents from that proceeding? You said you didn't review anything.

Have you asked for anything but not gotten it?

Do you know anything about Mylan's ANDA or Mylan's generic product?

A. No.

Do you know anything about any of the other -- let me step back a minute.

Do you know anything about whether there are other generic companies attempting to make generic versions of Restasis?

No, I don't.

18 Have you been contacted by lawyers for any of the other generic companies regarding 19 Restasis? 20

No, I have not.

22 Q. And do you know the status of Mylan's ANDA with FDA? 23

24 A. No, I don't.

So fair to say you don't know whether

declaration related to the '556 patent.

Then I've got what has been marked as Exhibit 1002 in IPR 2016-01130. It's your declaration related to the '162 patent.

5 Next is Exhibit 1002 in IPR 2016-01131. It's your declaration related to the '048 patent. 6 7 And then finally, Exhibit 1002 in IPR 2016-01132. 8 It's your declaration related to the '191 patent.

And, Dr. Amiji, you have your six declarations in front of you? Are all of those in front of you?

Α.

For purposes of today's questioning, I'm going to focus mostly on the second document we marked. It's the one for the '111 patent. So if you'd like to reference any of the others, you have all of them. But that's the one I'm going to spend most of my time questioning on.

And I see, Dr. Amiji, you have a binder of documents in front of you. What's in your binder that you brought with you today?

So that's the same, the declarations and then the corresponding patents.

24 Okay. And is there anything in your 25 binder that's marked up or in any way is

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