Page 1

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

INNOPHARMA LICENSING, INC., INNOPHARMA LICENSING LLC, INNOPHARMA INC., INNOPHARMA LLC) MYLAN PHARMACEUTICALS INC. and) MYLAN INC., Petitioner,) Case No.) IPR2015-00902 VS. SENJU PHARMACEUTICAL CO., LTD.,) BAUSCH & LOMB, INC., and BAUSCH) & LOMB PHARMA HOLDINGS CORP., Patent Owner. *** CAPTION CONTINUED ***

CONFIDENTIAL SUBJECT TO THE PROTECTIVE ORDER

VIDEOTAPED DEPOSITION OF ADAM C. MYERS, Ph.D.

Wednesday, February 24, 2016

Washington, DC



Confidential - Subject to The Protective Order Adam C. Myers, Ph.D. - February 24, 2016

2 (Pages 2 to 5)

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1 2 3	IN THE UNITED STATES DIST FOR THE DISTRICT OF NEW		1 2		APPEARANCES
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	SENJU PHARMACEUTICAL CO., LTD.,) BAUSCH & LOMB INCORPORATED, and) BAUSCH & LOMB PHARMA HOLDINGS) CORP.,) Plaintiffs,) VS.		3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	BY:	the InnoPharma Petitioner and Defendants: ON & BIRD LLP 333 South Hope Street Sixteenth Floor Los Angeles, CA 90071 213.576.1000 H. JAMES ABE, ESQ. james.abe@alston.com the Patent Owner and Plaintiffs: EGAN HENDERSON FARABOW ETT & DUNNER, LLP 901 New York Avenue NW Washington, DC 20001 202.408.4000 ESTHER H. LIM, ESQ. esther.lim@finnegan.com CHIAKI FUJIWARA, ESQ. Chiaka.fujiwara@finnegan.com
20 21 22	VIDEOTAPED DEPOSITION OF ADAM C Wednesday, February 2 Washington, DC		21 22		Chiaka.fujiwara@finnegan.com
		Page 3			Page 5
1	Wednesday, February	24, 2016	1		APPEARANCES (Continued)
2	9:06 a.m.		2		
3			3	For t	he Lupin Defendants:
4			4	GOODV	VIN PROCTER LLP
5	VIDEOTAPED DEPOSITION OF ADAM C.	MYERS, Ph.D., held	5		The New York Times Building
6	at the offices of:		6		620 Eighth Avenue
7			7		New York, NY 10018
8	FINNEGAN HENDERSON FARABOW		8		212. 813. 8800
9	GARRETT & DUNNER, LLP		9	BY:	NATASHA E. DAUGHTREY, ESQ. (By Telephone)
10	901 New York Avenue NW		10		ndaughtrey@goodwinprocter.com
11	Washington, DC 20001		11		
12			12	Also	Present:
					T. J. O'Toole, Videographer
13			13		1. 0. 0 1001e, videographer
			14		1. 0. 0 1001e, videographer
13	Pursuant to notice, before Denise	• ,	14 15		1. 0. 0 1001e, Videographer
13 14	Registered Merit Reporter, Certif	ied Realtime	14 15 16		1. 0. 0 foote, videographer
13 14 15	Registered Merit Reporter, Certif Reporter, and Notary Public in an	ied Realtime	14 15 16 17		1. 0. 0 foote, videographer
13 14 15 16 17 18	Registered Merit Reporter, Certif	ied Realtime	14 15 16		1. 0. 0 foote, videographer
13 14 15 16 17 18 19	Registered Merit Reporter, Certif Reporter, and Notary Public in an	ied Realtime	14 15 16 17		1. 0. 0 foote, videographer
13 14 15 16 17 18 19 20	Registered Merit Reporter, Certif Reporter, and Notary Public in an	ied Realtime	14 15 16 17 18 19 20		1. U. U Toore, Videographer
13 14 15 16 17 18 19	Registered Merit Reporter, Certif Reporter, and Notary Public in an	ied Realtime	14 15 16 17 18 19		1. U. U Toute, Videographer



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4 5 6 7 8 9 10 11 12 13 14 15 16 17	Exhibit No. 6 Exhibit No. 7 Exhibit No. 8 Exhibit No. 9	Stability Evaluation of Bromf Drug Product Samples for Pote PROL0337648 to 700, Senju Exh Lab Notebook PROL0337631 to 6 Senju Exhibit 2247 Expert Report of Adam C. Myer Senju v. Lupin, District Cour Expert Report of Adam C. Myer Senju v. InnoPharma, District Supplemental Expert Report of Myers, Ph.D., Senju v. InnoPh District Court Supplemental Expert Report of	ancy nibit 2248 339 137 4s, Ph. D. 140 4t 4s, Ph. D. 147 5: Court case 6: Adam C. 151 harma,	5 6 7 8 9 10 11 12 13 14 15 16 17 18	Myers taken in Incorporated, Company, Limit Patent Trial Patent and Triand the relation Limited, et a heard before the District 1:14-CV-00667 the law office New York Aver February 24,	et al. versus Senju Pharmaceutical ted, et al., being heard before the and Appeal Court of the United States ademark Office, Case No. IPR2015-00902 and matter Senju Pharmaceutical Company II. versus Lupin Limited, et al., being the United States District Court for of New Jersey, Civil Action No. Y-JBS-KMW. This deposition is being held at sees of Finnegan Henderson located at 90 aue, Northwest in Washington, DC on 2016 at approximately 9:06 a.m. My name is T.J. O'Toole. I am the
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4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Exhibit No. 6 Exhibit No. 7 Exhibit No. 8 Exhibit No. 9 Exhibit No. 10	Stability Evaluation of Bromf Drug Product Samples for Pote PROLO337648 to 700, Senju Exh Lab Notebook PROLO337631 to 6 Senju Exhibit 2247 Expert Report of Adam C. Myer Senju v. Lupin, District Cour Expert Report of Adam C. Myer Senju v. InnoPharma, District Supplemental Expert Report of Myers, Ph.D., Senju v. InnoPh District Court Supplemental Expert Report of Myers, Ph.D., Senju v. Lupin, Court	ribit 2248 ris, Ph. D. 140 rt rs, Ph. D. 147 rc Court case re Adam C. 151 rarma, re Adam C. 156 District	5 6 7 8 9 10 11 12 13 14 15 16 17 18	Myers taken in Incorporated, Company, Limit Patent Trial Patent and Triand the relation Limited, et a heard before the District 1:14-CV-00667 the law office New York Aver February 24,	et al. versus Senju Pharmaceutical ted, et al., being heard before the and Appeal Court of the United States ademark Office, Case No. IPR2015-00902 and matter Senju Pharmaceutical Company II. versus Lupin Limited, et al., being the United States District Court for of New Jersey, Civil Action No. 2-JBS-KMW. This deposition is being held at these of Finnegan Henderson located at 90 and Northwest in Washington, DC on 2016 at approximately 9:06 a.m. My name is T.J. O'Toole. I am the call specialist. The court reporter is any.



Confidential - Subject to The Protective Order Adam C. Myers, Ph. D. - February 24, 2016

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4 (Pages 10 to 13)
                                               Page 10
                                                                                                           Page 12
                      Will counsel please introduce
                                                                                  MR. ABE: Yes, it's as
 1
 2 themselves and indicate which parties they
                                                             2 memorialized in the e-mails you referenced. That's
 3
    represent.
                                                               correct.
 4
                      MR. ABE: James Abe of Alston &
                                                                                 CROSS-EXAMINATION
                                                               BY MR. ABE:
 5
   Bird for the InnoPharma Defendants and Petitioner
    InnoPharma.
                                                                       Q.
                                                                            Okay. Will you state your name for the
 6
                                                             6
 7
                      MS. LIM: Esther Lim and Chiaki
                                                             7
                                                               record?
   Fujiwara with Finnegan on behalf of Plaintiffs.
                                                             8
                                                                            Adam Myers.
 8
                                                                       A.
                     THE VIDEOGRAPHER: Thank you.
 9
                                                             9
                                                                            Okay. Dr. Myers, have you been deposed
10
   Will the court reporter please swear in the witness.
                                                            10
                                                               before?
11
                                                            11
                                                                            No, I have not.
                                                                       A.
12
                  ADAM C. MYERS, Ph. D.
                                                            12
                                                                       Q.
                                                                            Okay. I'll go over some of the basic
13 called for examination, and, after having been duly
                                                            13
                                                               rules.
   sworn, was examined and testified as follows:
                                                            14
                                                                            I represent the InnoPharma entities in
14
15
                      MR. ABE: Can we go off the record
                                                            15 this case. I'll be asking questions from you and
   for a second? I don't think my realtime is working.
                                                            16 I'll expect answers. Your counsel might object, but
16
17
                      THE VIDEOGRAPHER: The time is
                                                               unless your counsel instructs you not to answer,
18
   9:07:36. Off the record.
                                                               I'll expect an answer.
19
                      (Recess - 9:07 a.m. - 9:11 a.m.)
                                                            19
                                                                       A.
                                                                            (Nods head).
                      THE VIDEOGRAPHER: On the record.
20
                                                                            You understand you're under oath to
21 The time is 9:11:33.
                                                            21 testify as if you're in a court proceeding and in
                      MR. ABE: Okay. I'll just note
22
                                                            22 court.
                                               Page 11
                                                                                                           Page 13
 1 for the record, this is the consolidated proceeding
                                                             1
                                                                            What else?
 2 for the IPR2015-00902 and the district --
                                                                            If I ask you a question and you don't
 3 corresponding District Court proceedings involving
                                                             3 understand or if it's unclear, just let me know.
 4 the same parties, also Lupin, and that it's being
                                                               I'll try to clarify. But if you answer my question,
 5 taken pursuant to an agreement that was reached
                                                               I'll assume you understood it.
                                                                            (Nods head).
   between the parties.
                                                             6
 7
                      And I will start with the IPR
                                                             7
                                                                            And also avoid talking over each other
 8 portion and I'll note when we'll switch over to the
                                                               so that the court reporter can take a cleaner
 9 District Court portion, but it's under the
                                                               record, and please respond verbally. No nodding or
10 understanding that the parties will not object to
                                                            10
                                                               uh-huhs, which are difficult to show on the record.
11 having the IPR proceeding portion of your testimony
                                                            11
                                                                       A.
                                                                            (Nods head).
12 being used for the District Court proceeding.
                                                                            And oh, yeah. If you need a break,
                                                            12
13
                      MS. LIM: Counsel, I'd like to
                                                            13 just let me know. But if I have a question pending,
14 clarify for the record --
                                                            14 I'll expect you to answer it before we go on the
15
                      MR. ABE: Sure.
                                                            15 break.
                      MS. LIM: -- that that
16
                                                            16
                                                                            Is there any reason why you cannot
17 understanding is memorialized in the e-mail
                                                               testify truthfully today?
18 correspondence between the parties, and that there
                                                            18
                                                                       A.
                                                                            No, there's no reason.
19 is a caveat for satisfying the other rules of the
                                                            19
                                                                            You're not taking any medication that
20 Federal Rules of Civil Procedure and Federal Rules
                                                            20 might impact your ability to testify accurately?
```



22 can proceed.

21 of Evidence. So subject to that clarification, we

21

22

A.

No, I am not.

Okay. And you mentioned earlier you

5 (Pages 14 to 17)

Page 14

- 1 never testified -- never been deposed before?
- 2 A. That is correct.
- 3 Q. So you never acted as an expert witness
- 4 in any -- ever in any previous matter?
- **A.** No, I have not.
- Q. Okay. Who is your current employer?
- 7 A. I'm employed by SSCI, a division of
- 8 Albany Molecular Research.
- 9 **Q.** Okay. And what is the nature of your 10 company's business?
- 11 **A.** We're a contract research company
- 12 working with the pharmaceutical industry primarily.
- 13 **Q.** By "contract research," what kind of
- 14 contract research is provided by SSCI?
- 15 **A.** We perform a variety of analytical
- 16 tests as well as chemical development support, both
- 17 in a GMP and non-GMP fashion, supporting a variety
- 18 of industries, primarily the pharmaceutical
- 19 industry.

6

- Q. When you mentioned "GMP," that refers
- $21\,$ to Good Manufacturing Practice; is that correct?
- 22 A. That is correct.

Page 16

Page 17

- A. This would be when requested by
- 2 clients. That uses the same instrumentation that
- 3 would be used for GMP.
 - **Q.** When you said non-GMP would use the
- 5 same instrumentation as GMP uses, so I'm a little
- 6 unclear.
- 7 What's the difference again?
- 8 A. The difference is primarily in the data
- 9 review side from our quality assurance department.
 - Q. Is SSCI asked to conduct testing that
- 11 is submitted to regulatory authorities, such as the
- 12 FDA?

13

- A. Yes.
- 4 Q. And for those types of requests, I
- 15 assume it would be for GMP-type services?
- 16 Or let me rephrase that.
- 17 For testing that would be submitted to
- 18 a regulatory authority like the FDA, those services
- 19 that are provided would be in compliance with the
- 20 GMP requirements?
- 21 A. That is correct.
 - Q. Dr. Myers, I understand you're

Page 15

- 1 Q. What's your understanding of GMP?
- A. GMP is a set of federal regulations
- 3 codified by the Code of Federal Regulations which
- 4 requires certain controls to be in place for
- 5 assuring quality of a drug product or drug
- 6 substance.
- 7 Q. Can you expand a little bit? What do
- 8 you mean by "controls"?
- 9 A. Controls would include items such as
- 10 instrument calibrations, facility controls such as
- 11 pest control, quality reviews, data integrity and
- 12 proper data storage.
- 13 Q. And SSCI provides support in GMP and
- 14 non-GMP fashion; is that right?
- 15 A. That is correct.
- 16 Q. When does it provide support in GMP
- 17 fashion?
- 18 A. So our facility as a whole is run as a
- 19 GMP facility. So our facility controls are GMP at
- 20 all times. We perform testing on a GMP basis as
- 21 requested by clients.
 - Q. And for non-GMP, when would that apply?

- 1 testifying regarding some testing data that was
- 2 submitted in this case; is that right?
 - A. That is correct.
- 4 Q. You understand it's not -- is it your
- 5 understanding that -- strike that.
- 6 It's your understanding that the
- 7 testing data that you've submitted in this case are
- 8 not being submitted to a regulatory authority; is
- 9 that right?

11

- 10 A. That is correct.
 - Q. You understand it's being submitted
- 12 pursuant to a lawsuit between parties regarding a
- 13 patent dispute; is that right?
- 14 **A.** Yes.
 - MS. LIM: I'd just like to
- 16 clarify. You are still referring to the Patent
- 17 Office proceeding with this witness?
- 18 MR. ABE: For this portion, that
- 19 would be fine. Yeah.
- 20 MS. LIM: Yes.
- 21 BY MR. ABE:
 - Q. For testing that is generated for such



22

22

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