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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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		Page 2			Pag	e 4
1 2 3	IN THE UNITED STATES DISTRICT FOR THE DISTRICT OF NEW JER		1 2		APPEARANCES	
4			3	For t	he InnoPharma Petitioner and Defendan	ts:
5	SENJU PHARMACEUTICAL CO., LTD.,)		4	ALSTO	N & BIRD LLP	
_	BAUSCH & LOMB INCORPORATED, and)	A N	5		333 South Hope Street	
6		A. Nos. 14-cv-00667	6		Sixteenth Floor	
7		14-cv-04149 14-cv-05144	7		Los Angeles, CA 90071	
8)	14 CV 03144	8		213. 576. 1000	
9	vs.)		9	BY:	H. JAMES ABE, ESQ.	
	LUPIN LIMITED and LUPIN)		10		james.abe@alston.com	
10	PHARMACEUTICALS, INC.,)		11			
11	Defendants.)		12	For t	he Patent Owner and Plaintiffs:	
12	vs.		13	FINNE	GAN HENDERSON FARABOW	
13	INNOPHARMA LICENSING, INC.,) C.	A. Nos.	14	GARRE	TT & DUNNER, LLP	
	INNOPHARMA LICENSING, LLC,) 1:	14-cv-06893	15		901 New York Avenue NW	
14	INNOPHARMA, INC., and) 1: INNOPHARMA, LLC,)	15-cv-03240	16		Washington, DC 20001	
15)		17		202. 408. 4000	
16	Defendants.))		18	BY:	ESTHER H. LIM, ESQ.	
17)		19		esther.lim@finnegan.com	
18	CONFIDENTIAL SUBJECT TO THE PROTECT	IVE ORDER	20	BY:	CHIAKI FUJIWARA, ESQ.	
19 20	VIDEOTAPED DEPOSITION OF ADAM C. MY	ERS. Ph.D.	21		Chiaka.fujiwara@finnegan.com	
21 22	Wednesday, February 24, 2 Washington, DC		22			
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2	9:06 a.m.		2		·	
3			3	For tl	he Lupin Defendants:	
4			4		IN PROCTER LLP	
5	VIDEOTAPED DEPOSITION OF ADAM C. MYER	S, 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	
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11	Washington, DC 20001		11			
12			12	Alsol	Present:	
13			13	•	T.J. O'Toole, Videographer	
14			14			
4.5	Pursuant to notice, before Denise D.	Vickery,	15			
15	Denistand Namit Denistan Contition	Realtime	16			
16	Registered Merit Reporter, Certified		17			
	Reporter, and Notary Public in and fo	r the District	' '			
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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? 21 of Evidence. So subject to that clarification, we 21 A. No, I am not.



22 can proceed.

22

Okay. And you mentioned earlier you

5 (Pages 14 to 17)

Page 14

- 1 never testified -- never been deposed before?
 - 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.

2

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?

10

11

14

- **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?
 - 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

DOCKET

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