

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.,)
) 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

IN THE UNITED STATES DISTRICT COURT
 FOR THE DISTRICT OF NEW JERSEY

SENJU PHARMACEUTICAL CO., LTD.,
 BAUSCH & LOMB INCORPORATED, and
 BAUSCH & LOMB PHARMA HOLDINGS
 CORP.,
 Plaintiffs,)
 C. A. Nos.
 1:14-cv-00667
 1:14-cv-04149
 1:14-cv-05144

vs.
 LUPIN LIMITED and LUPIN
 PHARMACEUTICALS, INC.,
 Defendants.)

vs.
 INNOPHARMA LICENSING, INC.,
 INNOPHARMA LICENSING, LLC,
 INNOPHARMA, INC., and
 INNOPHARMA, LLC,
 Defendants.)
 C. A. Nos.
 1:14-cv-06893
 1:15-cv-03240

CONFIDENTIAL SUBJECT TO THE PROTECTIVE ORDER
 VIDEOTAPED DEPOSITION OF ADAM C. MYERS, Ph.D.
 Wednesday, February 24, 2016
 Washington, DC

A P P E A R A N C E S

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Wednesday, February 24, 2016
 9:06 a.m.

VIDEOTAPED DEPOSITION OF ADAM C. MYERS, Ph.D., held
 at the offices of:

FINNEGAN HENDERSON FARABOW
 GARRETT & DUNNER, LLP
 901 New York Avenue NW
 Washington, DC 20001

Pursuant to notice, before Denise D. Vickery,
 Registered Merit Reporter, Certified Realtime
 Reporter, and Notary Public in and for the District
 of Columbia.

A P P E A R A N C E S (Continued)

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Also Present:
 T.J. O'Toole, Videographer

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1	I N D E X		1	E X H I B I T S (Continued)	
2			2		
3	EXAMINATION OF ADAM C. MYERS, Ph.D.	PAGE	3	EXHIBIT	DESCRIPTION PAGE
4	IPR PROCEEDING:		4	Exhibit No. 12	Bausch & Lomb Incorporated Chemical 192
5	By Mr. Abe	12	5		Specification Hidden River,
6			6		HPLC Assay for the Analysis of
7	DISTRICT COURT PROCEEDING:		7		Bromfenac in Bromfenac Ophthalmic
8	By Mr. Abe	141	8		Solutions, PROL0003907 to 928
9	By Ms. Lim	228	9	Exhibit No. 13	Reply Expert Report of Adam C. Myers, 195
10			10		Ph.D., Senju v. InnoPharma,
11			11		District Court
12			12	Exhibit No. 14	Reply Expert Report of Adam C. Myers, 199
13			13		Ph.D., Senju v. Lupin, District Court
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<p>1 Will counsel please introduce 2 themselves and indicate which parties they 3 represent. 4 MR. ABE: James Abe of Alston & 5 Bird for the InnoPharma Defendants and Petitioner 6 InnoPharma. 7 MS. LIM: Esther Lim and Chiaki 8 Fujiwara with Finnegan on behalf of Plaintiffs. 9 THE VIDEOGRAPHER: Thank you. 10 Will the court reporter please swear in the witness. 11 - - - 12 ADAM C. MYERS, Ph.D. 13 called for examination, and, after having been duly 14 sworn, was examined and testified as follows: 15 MR. ABE: Can we go off the record 16 for a second? I don't think my realtime is working. 17 THE VIDEOGRAPHER: The time is 18 9:07:36. Off the record. 19 (Recess – 9:07 a.m. – 9:11 a.m.) 20 THE VIDEOGRAPHER: On the record. 21 The time is 9:11:33. 22 MR. ABE: Okay. I'll just note</p>	<p>1 MR. ABE: Yes, it's as 2 memorialized in the e-mails you referenced. That's 3 correct. 4 CROSS-EXAMINATION 5 BY MR. ABE: 6 Q. Okay. Will you state your name for the 7 record? 8 A. Adam Myers. 9 Q. Okay. Dr. Myers, have you been deposed 10 before? 11 A. No, I have not. 12 Q. Okay. I'll go over some of the basic 13 rules. 14 I represent the InnoPharma entities in 15 this case. I'll be asking questions from you and 16 I'll expect answers. Your counsel might object, but 17 unless your counsel instructs you not to answer, 18 I'll expect an answer. 19 A. (Nods head). 20 Q. You understand you're under oath to 21 testify as if you're in a court proceeding and in 22 court.</p>
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<p>1 for the record, this is the consolidated proceeding 2 for the IPR2015-00902 and the district -- 3 corresponding District Court proceedings involving 4 the same parties, also Lupin, and that it's being 5 taken pursuant to an agreement that was reached 6 between the parties. 7 And I will start with the IPR 8 portion and I'll note when we'll switch over to the 9 District Court portion, but it's under the 10 understanding that the parties will not object to 11 having the IPR proceeding portion of your testimony 12 being used for the District Court proceeding. 13 MS. LIM: Counsel, I'd like to 14 clarify for the record -- 15 MR. ABE: Sure. 16 MS. LIM: -- that that 17 understanding is memorialized in the e-mail 18 correspondence between the parties, and that there 19 is a caveat for satisfying the other rules of the 20 Federal Rules of Civil Procedure and Federal Rules 21 of Evidence. So subject to that clarification, we 22 can proceed.</p>	<p>1 What else? 2 If I ask you a question and you don't 3 understand or if it's unclear, just let me know. 4 I'll try to clarify. But if you answer my question, 5 I'll assume you understood it. 6 A. (Nods head). 7 Q. And also avoid talking over each other 8 so that the court reporter can take a cleaner 9 record, and please respond verbally. No nodding or 10 uh-huhs, which are difficult to show on the record. 11 A. (Nods head). 12 Q. And oh, yeah. If you need a break, 13 just let me know. But if I have a question pending, 14 I'll expect you to answer it before we go on the 15 break. 16 Is there any reason why you cannot 17 testify truthfully today? 18 A. No, there's no reason. 19 Q. You're not taking any medication that 20 might impact your ability to testify accurately? 21 A. No, I am not. 22 Q. Okay. And you mentioned earlier you</p>

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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?
5 **A.** No, I have not.
6 **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.
20 **Q.** When you mentioned "GMP," that refers
21 to Good Manufacturing Practice; is that correct?
22 **A.** That is correct.

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1 **Q.** What's your understanding of GMP?
2 **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.
22 **Q.** And for non-GMP, when would that apply?

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1 **A.** This would be when requested by
2 clients. That uses the same instrumentation that
3 would be used for GMP.
4 **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.
10 **Q.** Is SSCI asked to conduct testing that
11 is submitted to regulatory authorities, such as the
12 FDA?
13 **A.** Yes.
14 **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.
22 **Q.** Dr. Myers, I understand you're

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1 testifying regarding some testing data that was
2 submitted in this case; is that right?
3 **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 **A.** That is correct.
11 **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.
15 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:
22 **Q.** For testing that is generated for such

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