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.
vs.	)	IPR2015-00902
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

IPR2015-01099
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IPR2015-01100
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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

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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.

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A P P E A R A N C E S

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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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I N D E X

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E X H I B I T S

E X H I B I T S (Continued)

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E X H I B I T S (Continued)

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P R O C E E D I N G S

- - -

THE VIDEOGRAPHER: On the record with disk No. 1 of the video deposition of Dr. Adam Myers taken in the matter of InnoPharma Licensing Incorporated, et al. versus Senju Pharmaceutical Company, Limited, et al., being heard before the Patent Trial and Appeal Court of the United States Patent and Trademark Office, Case No. IPR2015-00902, and the related matter Senju Pharmaceutical Company, Limited, et al. versus Lupin Limited, et al., being heard before the United States District Court for the District of New Jersey, Civil Action No. 1:14-CV-00667-JBS-KMW.

This deposition is being held at the law offices of Finnegan Henderson located at 901 New York Avenue, Northwest in Washington, DC on February 24, 2016 at approximately 9:06 a.m.

My name is T.J. O'Toole. I am the certified legal specialist. The court reporter is Denise Vickery. We are both here representing Gregory Edwards, LLC.

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Will counsel please introduce themselves and indicate which parties they represent.

MR. ABE: James Abe of Alston & Bird for the InnoPharma Defendants and Petitioner InnoPharma.

MS. LIM: Esther Lim and Chiaki Fujiwara with Finnegan on behalf of Plaintiffs.

THE VIDEOGRAPHER: Thank you. Will the court reporter please swear in the witness.

- - -

ADAM C. MYERS, Ph.D.

called for examination, and, after having been duly sworn, was examined and testified as follows:

MR. ABE: Can we go off the record for a second? I don't think my realtime is working.

THE VIDEOGRAPHER: The time is 9:07:36. Off the record.

(Recess - 9:07 a.m. - 9:11 a.m.)

THE VIDEOGRAPHER: On the record. The time is 9:11:33.

MR. ABE: Okay. I'll just note

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for the record, this is the consolidated proceeding for the IPR2015-00902 and the district -- corresponding District Court proceedings involving the same parties, also Lupin, and that it's being taken pursuant to an agreement that was reached between the parties.

And I will start with the IPR portion and I'll note when we'll switch over to the District Court portion, but it's under the understanding that the parties will not object to having the IPR proceeding portion of your testimony being used for the District Court proceeding.

MS. LIM: Counsel, I'd like to clarify for the record --

MR. ABE: Sure.

MS. LIM: -- that that understanding is memorialized in the e-mail correspondence between the parties, and that there is a caveat for satisfying the other rules of the Federal Rules of Civil Procedure and Federal Rules of Evidence. So subject to that clarification, we can proceed.

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MR. ABE: Yes, it's as memorialized in the e-mails you referenced. That's correct.

CROSS-EXAMINATION

BY MR. ABE:

Q. Okay. Will you state your name for the record?

A. Adam Myers.

Q. Okay. Dr. Myers, have you been deposed before?

A. No, I have not.

Q. Okay. I'll go over some of the basic rules.

I represent the InnoPharma entities in this case. I'll be asking questions from you and I'll expect answers. Your counsel might object, but unless your counsel instructs you not to answer, I'll expect an answer.

A. (Nods head).

Q. You understand you're under oath to testify as if you're in a court proceeding and in court.

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What else?

If I ask you a question and you don't understand or if it's unclear, just let me know. I'll try to clarify. But if you answer my question, I'll assume you understood it.

A. (Nods head).

Q. And also avoid talking over each other so that the court reporter can take a cleaner record, and please respond verbally. No nodding or uh-huhs, which are difficult to show on the record.

A. (Nods head).

Q. And oh, yeah. If you need a break, just let me know. But if I have a question pending, I'll expect you to answer it before we go on the break.

Is there any reason why you cannot testify truthfully today?

A. No, there's no reason.

Q. You're not taking any medication that might impact your ability to testify accurately?

A. No, I am not.

Q. Okay. And you mentioned earlier you

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never testified -- never been deposed before?
A. That is correct.
Q. So you never acted as an expert witness in any -- ever in any previous matter?
A. No, I have not.
Q. Okay. Who is your current employer?
A. I'm employed by SSCI, a division of Albany Molecular Research.
Q. Okay. And what is the nature of your company's business?
A. We're a contract research company working with the pharmaceutical industry primarily.
Q. By "contract research," what kind of contract research is provided by SSCI?
A. We perform a variety of analytical tests as well as chemical development support, both in a GMP and non-GMP fashion, supporting a variety of industries, primarily the pharmaceutical industry.
Q. When you mentioned "GMP," that refers to Good Manufacturing Practice; is that correct?
A. That is correct.

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

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A. This would be when requested by clients. That uses the same instrumentation that would be used for GMP.
Q. When you said non-GMP would use the same instrumentation as GMP uses, so I'm a little unclear.
What's the difference again?
A. The difference is primarily in the data review side from our quality assurance department.
Q. Is SSCI asked to conduct testing that is submitted to regulatory authorities, such as the FDA?
A. Yes.
Q. And for those types of requests, I assume it would be for GMP-type services?
Or let me rephrase that.
For testing that would be submitted to a regulatory authority like the FDA, those services that are provided would be in compliance with the GMP requirements?
A. That is correct.
Q. Dr. Myers, I understand you're

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testifying regarding some testing data that was submitted in this case; is that right?
A. That is correct.
Q. You understand it's not -- is it your understanding that -- strike that.
It's your understanding that the testing data that you've submitted in this case are not being submitted to a regulatory authority; is that right?
A. That is correct.
Q. You understand it's being submitted pursuant to a lawsuit between parties regarding a patent dispute; is that right?
A. Yes.
MS. LIM: I'd just like to clarify. You are still referring to the Patent Office proceeding with this witness?
MR. ABE: For this portion, that would be fine. Yeah.
MS. LIM: Yes.
BY MR. ABE:
Q. For testing that is generated for such

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