

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 ***)
)
) -----

Videotaped Deposition of:
DARYL S. PAULSON, Ph.D., M.B.A.
February 19, 2016

Page 2

1 IN THE UNITED STATES DISTRICT COURT
 2 FOR THE DISTRICT OF NEW JERSEY
 3
 4 _____)
 5 SENJU PHARMACEUTICAL CO., LTD.,)
 6 BAUSCH & LOMB INCORPORATED, and) C. A. Nos.
 7 BAUSCH & LOMB PHARMA HOLDINGS) 1:14-cv-00667
 8 CORP.,) 1:14-cv-04149
 9 Plaintiffs,) 1:14-cv-05144
 10 vs.)
 11 LUPIN LIMITED and LUPIN)
 12 PHARMACEUTICALS, INC.,)
 13 Defendants.)
 14 vs.)
 15 INNOPHARMA LICENSING, INC.,) C. A. Nos.
 16 INNOPHARMA LICENSING, LLC,) 1:14-cv-06893
 17 INNOPHARMA, INC., and) 1:15-cv-03240
 18 INNOPHARMA, LLC,)
 19 Defendants.)
 20 _____)
 21
 22 Videotaped Deposition of:
 DARYL S. PAULSON, Ph.D., M.B.A.
 February 19, 2016

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A P P E A R A N C E S

1
 2
 3 On behalf of Senju Pharmaceutical Co.,
 4 Ltd., Bausch & Lomb Incorporated and
 5 Bausch & Lomb Pharma Holdings Corp. :
 6 BRYAN C. DINER, ESQUIRE
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 14 On behalf of Lupin Limited and Lupin
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 20 New York, New York 10018
 21 212-813-8800 (P) 212-355-3333 (F)
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Page 3

1
 2 The Videotaped Deposition of DARYL S.
 3 PAULSON, Ph.D., M.B.A., was taken on Friday,
 4 February 19, 2016, commencing at 10:07 a.m. at the
 5 law offices of Finnegan Henderson Farabow Garrett
 6 & Dunner, LLP, 901 New York Avenue, N.W.,
 7 Washington, D.C., before Cappy Hallock, Registered
 8 Professional Reporter, Certified Realtime
 9 Reporter, Certified Livenote Reporter, and Notary
 10 Public in and for the District of Columbia.
 11
 12
 13
 14
 15
 16
 17
 18
 19
 20
 21 Videographer:
 22 TJ O'Toole, CLVS

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

1
 2
 3 On behalf of InnoPharma Licensing, Inc.,
 4 InnoPharma Licensing LLC, InnoPharma Inc.,
 5 InnoPharma LLC, Mylan Pharmaceuticals Inc.,
 6 and Mylan Inc. :
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 22 joe.janusz@alston.com

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|--------|---|--------|--|
| 1 | I N D E X | 1 | E X H I B I T S (Continued) |
| 2 | | 2 | |
| 3 | Deposition of Daryl S. Paulson, Ph.D., M.B.A. | 3 | PAULSON PAGE |
| 4 | February 19, 2016 | 4 | Exhibit 11 Expert Reply Report of Daryl 218 |
| 5 | | 5 | Paulson, Senju v. Lupin v. |
| 6 | EXAMINATION BY: PAGE | 6 | InnoPharma |
| 7 | Mr. Abe (IPR) 12 | 7 | Exhibit 12 Media Production and Growth 225 |
| 8 | Mr. Diner 161 | 8 | Testing Data Sheet, |
| 9 | Mr. Abe 173 | 9 | PROL0340406-0425 |
| 10 | Mr. Abe (District Court) 192 | 10 | Exhibit 13 2-14-16 TSA/SDA Equivalence 232 |
| 11 | Ms. Daughtrey 260 | 11 | Evaluation, PROL0340429 |
| 12 | -o0o- | 12 | Exhibit 14 EP General Notices 241 |
| 13 | | 13 | Exhibit 15 Media/Diluent Tracking Form 256 |
| 14 | E X H I B I T S | 14 | for Study No. 151142-203, |
| 15 | | 15 | PROL0340403-0405 |
| 16 | PAULSON PAGE | 16 | -o0o- |
| 17 | Exhibit 1 U.S. Patent No. 8,669,290, 28 | 17 | |
| 18 | InnoPharma EX1001 01-09 | 18 | |
| 19 | Exhibit 2 European Pharmacopoeia, Seventh 33 | 19 | |
| 20 | Edition, Volume 1, | 20 | |
| 21 | LUPIN068837-8854 | 21 | |
| 22 | | 22 | |
| Page 7 | | Page 9 | |
| 1 | E X H I B I T S (Continued) | 1 | P R O C E E D I N G S |
| 2 | | 2 | - - - - - |
| 3 | PAULSON PAGE | 3 | THE VIDEO OPERATOR: All right, stand by. |
| 4 | Exhibit 3 Declaration of Daryl Paulson, 51 | 4 | On the record with Disc Number 1 of the |
| 5 | Senju Exhibit 2128, | 5 | video deposition of Daryl Paulson, taken by the |
| 6 | IPR2015-00902, Pages 1-20 | 6 | defendant in the matter of Senju Pharmaceutical |
| 7 | Exhibit 4 Supplemental Expert Report of 61 | 7 | Company Limited, et al. versus Lupin Limited, et |
| 8 | Daryl Paulson, Senju Exhibit | 8 | al., being heard before the United States District |
| 9 | 2257, IPR2015-00902, Pages 1-31 | 9 | Court for the District of New Jersey, Civil Action |
| 10 | Exhibit 5 1-7-16 letter, Dragotoiu to 64 | 10 | Number 1:14-cv-00667-JBS-KMW and in the matter of |
| 11 | Myers, Senju Exhibit 2249, | 11 | InnoPharma Licensing, Incorporated, et al. versus |
| 12 | IPR2015-00902, Pages 1-65 | 12 | Senju Pharmaceuticals Company Limited, et al. |
| 13 | Exhibit 6 Addendum 4, Senju Exhibit 2250, 128 | 13 | being heard before the Patent Trial and Appeal |
| 14 | PROL0337854-7869 | 14 | Board of the United States Patent & Trademark |
| 15 | Exhibit 7 Expert Report of Daryl Paulson, 192 | 15 | Office, Case Number IPR2015-00902. |
| 16 | Senju v. InnoPharma | 16 | This deposition is being held at the Law |
| 17 | Exhibit 8 Expert Report of Daryl Paulson, 205 | 17 | Offices of Finnegan Henderson, located at 901 New |
| 18 | Senju v. Lupin | 18 | York Avenue Northwest in Washington, D.C. on |
| 19 | Exhibit 9 1-7-16 letter, Dragotoiu to 209 | 19 | February 19th, 2016 at approximately 10:08 a.m. |
| 20 | Myers, PROL0337789-7853 | 20 | My name is TJ O'Toole. I am the |
| 21 | Exhibit 10 1-7-16 letter, Dragotoiu to 214 | 21 | Certified Legal Video Specialist. The court |
| 22 | Myers, PROL0337789-7853 | 22 | reporter is Cappy Hallock. We are both here |

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1 representing GregoryEdwards LLC.
 2 Will counsel please introduce themselves
 3 and indicate which parties they represent.
 4 MR. ABE: James Abe for the InnoPharma
 5 defendants and Petitioner InnoPharma.
 6 Natasha Daughtrey from Goodwin & Procter
 7 on behalf of Lupin Limited.
 8 MR. JANUSZ: Joe Janusz with Alston &
 9 Bird also on behalf of the InnoPharma defendants.
 10 MR. DINER: Brian Diner of Finnegan
 11 Henderson representing plaintiff Senju, et al. in
 12 the District Court and Patent Owner Senju in the
 13 PTAB proceeding.
 14 THE VIDEO OPERATOR: Thank you.
 15 Will the court reporter please swear in
 16 the witness.
 17 WHEREUPON,
 18 DARYL S. PAULSON, Ph.D., M.A., M.S., M.B.A.,
 19 A Witness called for examination, having
 20 been first duly sworn, was examined and testified
 21 as follows:
 22

Page 11

1 MR. ABE: Before I go into the
 2 questioning, I just want to note I think it is
 3 clear from the case caption that was stated --
 4 THE WITNESS: Could you people speak up
 5 so I can hear you?
 6 MR. ABE: Sure. I'm sorry about that.
 7 -- that we are conducting a consolidated
 8 deposition pursuant to an agreement that the
 9 parties reached by e-mail this morning. And under
 10 the conditions in that e-mail and including that
 11 the plaintiffs Patent Owner will not object to the
 12 IPR testimony by the witness given during this
 13 consolidated deposition from being used in the
 14 District Court litigation in a manner consistent
 15 with the Federal Rules of Civil Procedure and the
 16 Federal Rules of Evidence.
 17 MR. DINER: I am just going to interject
 18 that the agreement that has been struck between
 19 the parties is that no party will object --
 20 MR. ABE: Both parties.
 21 MR. DINER: So it's bilateral?
 22 MR. ABE: Right. That's my

Page 12

1 understanding.
 2 EXAMINATION
 3 BY MR. ABE:
 4 Q Good morning, Dr. Paulson.
 5 A Good morning.
 6 Q Have you ever been deposed before?
 7 A Yes, I have.
 8 Q Okay. Well, let me go over the ground
 9 rules just quickly to refresh you of how this will
 10 work.
 11 I represent the InnoPharma entities and I
 12 will be asking questions of you today. When I ask
 13 a question I will expect you to answer it. Your
 14 counsel might object, but I will still expect you
 15 to answer it unless your counsel instructs you not
 16 to answer. Is that okay?
 17 A It's okay.
 18 Q If you don't understand a question that
 19 I'm asking, please let me know and I will try to
 20 clarify, but if you answer it I will assume you
 21 understood my question. Is that okay?
 22 A Yes.

Page 13

1 MR. DINER: James, if I can just
 2 interject, Dr. Paulson is a Vietnam War veteran,
 3 and he does have a hearing deficiency so you may
 4 see him lean into you --
 5 THE WITNESS: Yeah.
 6 MR. DINER: -- to try to hear you better.
 7 THE WITNESS: Yes, so speak up.
 8 THE VIDEO OPERATOR: Excuse me, counsel,
 9 can we go off the record for a moment?
 10 MR. ABE: Of course.
 11 THE VIDEO OPERATOR: The time is
 12 10:12:05. Off the record.
 13 (Discussion off the record.)
 14 (Recess taken - 10:12 a.m.)
 15 (After recess - 10:20 p.m.)
 16 THE VIDEO OPERATOR: Stand by.
 17 On the record, the time is 10:20:06.
 18 BY MR. ABE:
 19 Q Dr. Paulson, is there any reason you
 20 can't testify truthfully today?
 21 A No, there isn't.
 22 Q You're not taking any medication that

| | |
|---|---|
| <p style="text-align: right;">Page 14</p> <p>1 might affect your ability to testify truthfully? 2 A No. 3 Q Okay, thank you. 4 You mentioned you have been deposed 5 before. How many times? 6 A One time. 7 Q When was that? 8 A Two years ago. 9 Q Do you recall what case it was? 10 A Yes. It was a BioScience case versus 11 another woman who was suing the company, and I 12 defended as a key employee. 13 Q So you were not testifying as an expert 14 in that case? 15 A No. 16 Q And it had nothing to do with 17 preservative efficacy or -- 18 A No, nothing at all. Nothing at all. 19 Q Dr. Paulson, you have several degrees. 20 And you have a Ph.D. in microbiology, I believe? 21 A I have a Ph.D. in microbiology and 22 psychology where I combined them at Saybrook.</p> | <p style="text-align: right;">Page 16</p> <p>1 A Yes, we do. 2 Q Do you personally? 3 A Occasionally I'm involved in them. 4 Q What is your involvement? 5 A If there is problems they always ask me 6 to help solve them. 7 Q What kind of problems? 8 MR. DINER: Objection, vague. 9 Q You can answer. 10 A It could be any problem. 11 Q For example, if a procedure was not 12 followed during a test protocol? 13 MR. DINER: Objection. There is no 14 question in that. 15 MR. ABE: Let me rephrase it. 16 Q Would one of the problems be if a person 17 didn't properly follow the procedures and they 18 come to you, for example, whether that -- strike 19 that. 20 Do you have standard operating procedures 21 at the company -- 22 A Yes, we do.</p> |
| <p style="text-align: right;">Page 15</p> <p>1 Q And that was in 1992? 2 A Yes. 3 Q Is it accurate to say it's a Ph.D. in 4 human science? 5 A Well, that's what they call it. That's 6 what they call it at Saybrook. 7 Q Okay. 8 And how long have you had the company, is 9 it biolife -- 10 A BioScience Labs. 11 Q BioScience Labs? 12 A 25 years. 13 Q Is it okay if I refer to it as BSL? 14 A BSLI, BSL. 15 Q Thank you. 16 Dr. Paulson, do you conduct the 17 preservative efficacy testing in the ordinary 18 course of your business, you personally? 19 MR. DINER: Objection, vague. Compound. 20 You may answer. 21 A Yes, we do. 22 Q Your company does?</p> | <p style="text-align: right;">Page 17</p> <p>1 MR. DINER: Just let him finish his 2 question before you answer. Otherwise the record 3 is not going to be clear, and it's going to wreak 4 havoc on the poor court reporter. 5 Q Do you have a procedure for how to handle 6 deviations? 7 MR. DINER: Objection, vague. 8 Q You can answer. 9 A Yes, we do. 10 Q Do you know what the general procedure is 11 for handling deviations? 12 MR. DINER: Objection, vague. In which 13 context are you referring to? 14 MR. ABE: He says he has a standard 15 operating procedure so I just want to know what, 16 generally, it says. 17 A Quality assurance has methods in place 18 right now. 19 Q Okay. 20 I earlier asked have you done 21 preservative efficacy testing in your regular 22 course of business, and you said you -- if there</p> |

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