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	
V S .) IPR2015	-00902
SENJU PHARMACEUTICAL CO., LTD.,)	
BAUSCH & LOMB, INC., and BAUSCH)	
& LOMB PHARMA HOLDINGS CORP.,)	
Patent Owner.)	
*** CAPTION CONTINUED ***)	
)	

VIDEOTAPED DEPOSITION OF WILLIAM B. TRATTLER, M.D.

Tuesday, February 23, 2016

Miami, Florida



2 (Pages 2 to 5)

,					2 (Pages	2 to 5)
		Page 2				Page 4
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	CORP., 1:1 Plaintiffs, 1:1 Vs. 1:1 LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC., 1 Defendants. 1 Vs. 1 INNOPHARMA LICENSING, INC., 1:1	CT COURT IERSEY Nos. 4-cv-00667 4-cv-04149 4-cv-05144 Nos. 4-cv-06893 5-cv-03240 B. TRATTLER, M. D.	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	On behalf of Senj Bausch & Lomb Ind Bausch & Lomb Pha JUSTIN J. HASFORE Finnegan Hendersc 901 New York Aver Washington, D.C. 202-408-4000 (P) justin. hasford@fi On behalf of Lupi Inc.: NATASHA E. DAUGHT Goodwin Procter L The New York Time 620 Eighth Avenue New York, New Yor 212-813-8800 (P) ndaughtrey@goodwi (PRESENT BY TELEF On behalf of Inno InnoPharma LLC, N and Mylan Inc.: JOSEPH M. JANUSZ, Alston & Bird LLF Bank of America F 101 South Tryon S	Arma Holdings Corp.: (), ESQUIRE (), ESQU	
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	The Videotaped Deposition of TRATTLER, M.D. was taken on Februa commencing at 12:19 p.m. at the Da 9090 South Dadeland Boulevard, Mia before Michele Anzivino, Registere Reporter, and Notary Public in and Florida.	ry 23, 2016, deland Marriott, mi, Florida, d Professional	24 25 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	EXAMINATION BY	INDEX LIAM V. TRATTLER, M.D. -000- EXHIBITS DESCRIPTION Declaration of William D. Trattler, M.D. Declaration of William D. Trattler, M.D. Prolensa prescribing information Eight-page document previously marked Senju Exhibit 2113 Bromday prescribing information	Page 5 Page 7 Page 9 Page 11 11 20 40 53

3 (Pages 6 to 9)

					3 (Pages 6 to 9)
			Page 6		Page 8
1		E X H I B I T S (Continued)		1	THE VIDEOGRAPHER: This begins video media
2				2	disc number one, volume one. This is the
3	EXHIBIT	DESCRIPTION	PAGE	3	videotaped deposition of William V. Trattler,
4	Exhibit No. 6	Prescribing information for	57	4	that's T-r-a-t-t-l-e-r, M.D. in the matter of
5		Xibrom		5	Innopharm Licensing, Inc. et al versus Senju
6				6	Pharmaceuticals Company Limited, et al, Case Number
7	Exhibit No. 7	Prescribing information for	60	7	IPR2015-00903 and 14-CV-0667-JBS-KMW et al in the
8		bromfenac ophthalmic solution		8	United States Patent and Trademark Office before
9				9	the Patent Trial and Appeals Board and the U.S.
10	Exhibit No. 8	Document previously marked	91	10	District Court for the District of New Jersey.
11		Senju 2060		11	Today is February 23, 2016. The time is
12				12	12:19 p.m. This video deposition is taking place
13	Exhibit No. 9	Document previously marked as	93	13	at the Dadeland Marriott at 9090 South Dadeland
14		Senju Exhibit 2134		14	Boulevard, Miami, Florida. This video deposition
15				15	has been at the request of Joseph Janusz from the
16	Exhibit No. 10	Document previously marked as	99	16	law firm of Alston & Bird, LLP. My name is Jeff
17		Senju 2030		17	Menton. I am the certified legal video specialist,
18				18	and the court reporter is Michele Anzivino. We're
19	Exhibit No. 11	Curriculum vitae	102	19	from Gregory Edwards LLC.
20				20	Would counsel please state their appearance
21	Exhibit No. 12	Opening expert report	120	21	for the record and state whom you represent
22				22	starting with the noticing attorney, and then will
23	Exhibit No. 13	Reply expert report	122	23	the court reporter please swear the witness in.
24				24	MR. JANUSZ: Joe Janusz of Alston & Bird on
25	///			25	behalf of the Innopharm entities which are a
			Page 7		Page 9
			Tugo /		rugo /
		E V II I D I T O (O . : . I)		,	IDD
1		E X H I B I T S (Continued)		1	petitioner in the IPR proceedings and a defendant
2	EVILLE		DAGE	2	in the District Court litigation.
2	EXHIBIT	DESCRIPTION	PAGE	2 3	in the District Court litigation. MS. DAUGHTREY: And this is Natasha Daughtrey
2 3 4	EXHIBIT Exhibit No. 14	DESCRIPTION Document, Bates	PAGE 135	2 3 4	in the District Court litigation. MS. DAUGHTREY: And this is Natasha Daughtrey from Goodwin Proctor on defendant of the Lubin
2 3 4 5		DESCRIPTION		2 3 4 5	in the District Court litigation. MS. DAUGHTREY: And this is Natasha Daughtrey from Goodwin Proctor on defendant of the Lubin defendant in the District Court litigation.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Exhibit No. 14	DESCRIPTION Document, Bates PROL0333863 - 869 Document, Bates PROL0333854 - 862	135	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	in the District Court litigation. MS. DAUGHTREY: And this is Natasha Daughtrey from Goodwin Proctor on defendant of the Lubin defendant in the District Court litigation. MR. HASFORD: Justin Hasford of Finnegan on behalf of Senju and Bausch & Lomb in both the IPR and the District Court proceedings. Thereupon, WILLIAM V. TRATTLER, M.D., having been duly sworn or affirmed, was examined and testified as follows: THE WITNESS: Yes, I do. DIRECT EXAMINATION BY MR. JANUSZ: Q. Good morning, Dr. Trattler. How are you? A. Great, thank you. Q. I'm going to go over a few ground rules ahead of time. Ha — have you ever depose — been deposed before? A. I have, yes. Q. Okay. So I'm going to run through this quickly. I'm sure it's all stuff you've heard before.

8

4 (Pages 10 to 13)

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Page 10

- 1 **Q.** Okay. I'm going to ask you a series of 2 questions today, and I'm going to ask that those 3 questions be answered. Even though intermittently your 4 counsel may interject objections, unless he instructs 5 you not to answer the question I'd ask that you answer 6 the question.
 - **A.** 0kay.

7

17

- 9 answers so that the court reporter doesn't have any 10 trouble recording what our discussion is here today. 11 She can't effectively record head nods or shakes or 12 anything like that, so and then we'll take breaks 13 periodically throughout the day. And the only thing 14 that I'd ask and and if you need a break please 15 let me know obviously. The only thing I'd ask is that 16 if there is a question pending that you answer the
- 18 A. Perfect.
- 19 Q. Okay. Have you ever submitted an -- well,20 let me start with this actually.
- 21 MR. HASFORD: Joe, if it will speed things 22 along, we can stipulate that he's here pursuant to 23 this notice.
 - MR. JANUSZ: Very well, then.

question before we go into a break.

25 MR. HASFORD: Okay.

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- 1 been marked as Exhibits 1 and 2. We'll refer to them
- 2 here as Trattler Exhibits 1 and 2, but Trattler Exhibit
- 3 1 is Senju Exhibit 2116 in the IPR 2015-00902
- 4 proceeding. And Trattler 2 is the same Senju Exhibit
- 5 Number 2116 in the 903 proceeding.
- 6 These are your declarations that you
- 7 submitted in the IPR proceedings, correct?
 - A. Yes.
- 9 **Q.** Okay. And you understand that that the 10 opinions that — that you've offered — and just let me 11 back up a minute.
- Obviously there have been a lot of opinions,
- 3 you know, submitted in this case on -- on your behalf.
- 14 And so I'd like to try to streamline things as much as
- 15 I can. And so, you know, part of what I'm going to do
- 16 here is just to try to get you, if you're willing to,
- 17 to confirm that the opinions you offered in each of
- 18 these declarations are largely similar if that's -- if
- 19 that's something you're comfortable with.
- 20 **A.** Yes, they are.
- 21 Q. Okay. And -- okay. Now, if I can touch a
- 22 little bit on your -- on your background. You --
- 23 you're an ophthalmologist, correct?
- 24 A. Correct.
- 25 Q. Okay. And have you -- I presume you've

Page 11

1 BY MR. JANUSZ:

- 2 **Q.** Okay. So have you ever submitted a a 3 declaration in an IPR proceeding before?
 - A. No, this is my first time.
- 5 **Q.** Okay. And have you ever testified in a 6 patent case in a District Court proceeding before?
- 7 A. This is my first time, as well.
- 8 **Q.** Okay. And so you -- you have testified at a 9 deposition previously, they just weren't really patent
- 10 cases; is that correct?
 - A. Correct.
- 12 **Q.** Okay. Have you ever testified at a trial
- 13 before?

11

14

18

25

- A. Yes.
- 15 **Q.** Okay. And and none of those were related 16 to patent issues?
- 17 A. Correct.
 - Q. Okay. Were any of those related to
- 19 ophthalmic solutions containing bromfenac?
- 20 **A.** No
- 21 **Q.** Okay.
- 22 (Exhibit No. 1 marked for identification.)
- 23 (Exhibit No. 2 marked for identification.)
- 24 BY MR. JANUSZ:
 - **Q.** Dr. Trattler, you've been handed what have

- 1 performed cataract surgeries before?
 - A. Yes
- 3 **Q.** Okay. Approximately how often and we'll
- 4 start in -- in roughly a month. How -- how often
- 5 during the course of a month do you perform cataract
- 6 surgery?
- 7 A. Approximately 60 cases a month.
- 8 Q. 60 cases a month?
- A. Six-zero, yes.
- 10 Q. Six-zero? Okay.
 - And would that, you know, equate to across
- 12 all 12 months of the year?
- 13 A. Correct. You know, we're not -- we're not
- 14 very seasonal here in Miami.
- 15 Q. Right. Fair enough.
 - And and approximately when in your career
- 17 did you first perform cataract surgeries?
 - A. So during my residency. My residency was
- 19 from 1993 to 1996. So typically during my second year
- 20 of residency is when you start your first cases.
- 21 **Q.** Okay.
- 22 **A.** So in the 1994 to '95 range.
 - Q. And where was your residency?
- 24 A. At -- at Scheie Eye Institute which is in
- 25 Philadelphia, Pennsylvania. Part of the University of



16

23

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11

5 (Pages 14 to 17)

Page 16

Page 14

- 1 Pennsylvania.
- Okay. If I can have you turn to Trattler
- 3 Exhibit 1, which is your declaration in the 902 case,
- and just -- just so we are clear, on the front of
- Trattler Exhibit 1 if you look at the very bottom you
- see the case number ending in 902.
 - Yes. A.
- And so when I refer to the 902 case, that's
- 9 what I'm looking at.
- 10 A.
- Similarly with the 903 case. 11 Q.
 - So if I can direct your attention to
- 13 paragraph 41 of the declaration, and that appears at
- 14 page 13.

7

12

- 15 A. 0kay.
- And so in -- in paragraph 41 you acknowledge 17 that Prolensa is formulated -- formulated at a pH of
- 18 7.8, correct?
- 19 A. Correct.
- Q. And it's your opinion that that formulation 20
- 21 is closer to that of natural tears which you identify
- 22 as 7.4 as compared to the pH of Xibrom and Bromday
- 23 which are 8.3; is that correct?
- 24 A. Correct.
- 25 Okay. Are you aware that the pH levels of

- 1 It's your opinion that making an
 - 2 ophthalmic -- application of an ophthalmic solution
 - more comfortable for a patient would increase patient
 - compliance; is that right?
 - A. Definitely.
 - 6 Q. Okay. And -- and the idea behind that is
 - likely that obviously if a patient's more comfortable
 - with the drug that they're applying to themselves
 - they're not going to have any issues applying it; is
 - 10 that right?
 - A. Correct. If a - if a medication stings and burns on every application, they may be less likely to

 - put it into their eyes. 13
 - Okay. And so it's -- it's your opinion in 14
 - 15 this declaration -- in this -- in this paragraph of
 - your declaration that Prolensa's pH level of 7.8 being
 - 17 closer to that of natural tears being 7.4 at least in part contributes to the elimination of burning --
 - burning and stinging experienced by patients using
 - Prolensa; is that right?
 - 21 Yeah, my th -- my understanding is that that
 - would -- by being closer to the natural pH it can help,
 - and -- you know, as far as reduced burning and
 - stinging.

25

14

Q. Okay. And can you explain -- when you say it

Page 15

- 1 natural tears in humans can fluctuate beyond the 7.4
- 2 that you've identified?
- I think that, you know, pH can be affected by 4 a variety of different things, but I think the average
- is considered by most experts to be around 7.4.
- Okay. But it can -- it can go -- for 6 example, it can be lower than 7.4 in certain patients?
 - 7.4 is an -- is an average. A.
- 9
- Is -- I think that's an the understanding 10
- 11 that when we talk about, you know, patients and their
- 12 tears it's typically considered that 7.4 is the
- 13 average.

8

- 14 Q. Okay. Now, is it your opinion that -- strike
- 15 that.
- 16 It's your opinion that if -- well, let me
- 17 direct your attention to the last sentence in -- in
- 18 paragraph 41. And if you can read that out loud, it
- 19 starts with the reduced pH.
- 20 Yes. "The reduced pH and amount of
- 21 surfactant in Prolensa eliminated the burning and
- 22 stinging sensation making it more comfortable ensuring
- greater patient compliance". 23
- 24 Okay. And so let's talk generally about Q.
- 25 that.

- Page 17
- can help, can you explain what you mean by that?
- Well, obviously there are some formulations
- of medications that are at pH of 7.4 that still cause
- burning and stinging. So you can have irritating
- solutions that have a pH of 7.4. So it's a combination
- of -- of factors.
- Okay. And generally speaking, I mean, would
- your opinion be that -- obviously that there are --
- well, let me -- let me -- strike that.
- 10 Generally speaking, would your opinion be
 - that the closer you get to the natural -- the pH of
 - natural tears, the more likely a solution would be
 - comfortable for the user?
 - MR. HASFORD: Objection. Incomplete
- 15 hypothetical.
- 16 THE WITNESS: Right. So it all depends on so 17 many factors. So if we the had same solution,
- 18 potentially, and again we have to evaluate it, but
- 19 if it's closer to the natural -- you know, the pH
- 20 of -- of our natural tears is it more likely to be
- 21 comfortable. But obviously it depends on, you
- 22 know, the actual formulation, it depends on the --
- 23 what product we're looking at and all the other 24 things that go into a formulation.
 - So again, you could have formulations exactly



25

DOCKET

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