

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 WILLIAM B. TRATTLER, M.D.
Tuesday, February 23, 2016
Miami, Florida

Page 2

1 IN THE UNITED STATES DISTRICT COURT
 2 FOR THE DISTRICT OF NEW JERSEY
 3
 4
 5 SENJU PHARMACEUTICAL CO., LTD.,)
 BAUSCH & LOMB INCORPORATED, and)
 6 BAUSCH & LOMB PHARMA HOLDINGS) C. A. Nos.
 CORP.,) 1:14-cv-00667
 7) 1:14-cv-04149
 Plaintiffs,) 1:14-cv-05144
 8 vs.)
)
 9 LUPIN LIMITED and LUPIN)
 PHARMACEUTICALS, INC.,)
 10)
 Defendants.)
 11 vs.)
)
 12)
 13 INNOPHARMA LICENSING, INC.,) C. A. Nos.
 INNOPHARMA LICENSING, LLC,) 1:14-cv-06893
 14 INNOPHARMA, INC., and) 1:15-cv-03240
 INNOPHARMA, LLC,)
 15 Defendants.)
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 20 VIDEOTAPED DEPOSITION OF WILLIAM B. TRATTLER, M.D.
 21 Tuesday, February 23, 2016
 22 Miami, Florida
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1 A P P E A R A N C E S
 2
 3 On behalf of Senju Pharmaceutical Co., Ltd.,
 Bausch & Lomb Incorporated and
 4 Bausch & Lomb Pharma Holdings Corp. :
 JUSTIN J. HASFORD, ESQUIRE
 5 Finnegan Henderson Farabow Garrett & Dunner, LLP
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 7 justin.hasford@finnegan.com
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 9 On behalf of Lupin Limited and Lupin Pharmaceuticals,
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 10 NATASHA E. DAUGHTREY, ESQUIRE
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 11 The New York Times Building
 620 Eighth Avenue
 12 New York, New York 10018
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 13 ndaughtrey@goodwinprocter.com
 (PRESENT BY TELEPHONE)
 14
 15
 On behalf of InnoPharma Licensing, Inc.,
 16 InnoPharma Licensing LLC, InnoPharma Inc.,
 InnoPharma LLC, Mylan Pharmaceuticals Inc.,
 17 and Mylan Inc. :
 JOSEPH M. JANUSZ, ESQUIRE
 18 Alston & Bird LLP
 Bank of America Plaza
 19 101 South Tryon Street, Suite 4000
 Charlotte, North Carolina 28280-4000
 20 704-444-1000 (P) 704-444-1738 (F)
 joe.janusz@alston.com
 21
 22 Also present:
 23 Jeffrey Menton, CLVS
 24
 25

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1 The Videotaped Deposition of WILLIAM B.
 2 TRATTLER, M.D. was taken on February 23, 2016,
 3 commencing at 12:19 p.m. at the Dadeland Marriott,
 4 9090 South Dadeland Boulevard, Miami, Florida,
 5 before Michele Anzivino, Registered Professional
 6 Reporter, and Notary Public in and for the State of
 7 Florida.
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1 I N D E X
 2
 3 WITNESS NAME: WILLIAM V. TRATTLER, M.D.
 4
 5 EXAMINATION BY: PAGE
 6 BY MR. JANUSZ 9
 7 -o0o-
 8
 9 E X H I B I T S
 10
 11 EXHIBIT DESCRIPTION PAGE
 12 Exhibit No. 1 Declaration of William D. 11
 13 Trattler, M.D.
 14
 15 Exhibit No. 2 Declaration of William D. 11
 16 Trattler, M.D.
 17
 18 Exhibit No. 3 Prolensa prescribing 20
 19 information
 20
 21 Exhibit No. 4 Eight-page document previously 40
 22 marked Senju Exhibit 2113
 23
 24 Exhibit No. 5 Bromday prescribing 53
 25 information

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	3	videotaped deposition of William V. Trattler,	
4	Exhibit No. 6	Prescribing information for	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	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	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	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	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	19	from Gregory Edwards LLC.	
20			20	Would counsel please state their appearance	
21	Exhibit No. 12	Opening expert report	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	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		
1	E X H I B I T S (Continued)		1	petitioner in the IPR proceedings and a defendant	
2			2	in the District Court litigation.	
3	EXHIBIT	DESCRIPTION	3	MS. DAUGHTREY: And this is Natasha Daughtrey	
4	Exhibit No. 14	Document, Bates	4	from Goodwin Proctor on defendant of the Lubin	
5		PROL0333863 - 869	5	defendant in the District Court litigation.	
6			6	MR. HASFORD: Justin Hasford of Finnegan on	
7	Exhibit No. 15	Document, Bates	7	behalf of Senju and Bausch & Lomb in both the IPR	
8		PROL0333854 - 862	8	and the District Court proceedings.	
9		-o0o-	9	Thereupon,	
10			10	WILLIAM V. TRATTLER, M.D.,	
11			11	having been duly sworn or affirmed, was examined and	
12			12	testified as follows:	
13			13	THE WITNESS: Yes, I do.	
14			14	DIRECT EXAMINATION BY MR. JANUSZ:	
15			15	Q. Good morning, Dr. Trattler. How are you?	
16			16	A. Great, thank you.	
17			17	Q. I'm going to go over a few ground rules ahead	
18			18	of time. Ha -- have you ever depose -- been depose	
19			19	before?	
20			20	A. I have, yes.	
21			21	Q. Okay. So I'm going to run through this	
22			22	quickly. I'm sure it's all stuff you've heard before.	
23			23	You understand that you're under oath in giving your	
24			24	testimony today, right?	
25			25	A. Yes.	

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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.
 7 **A.** Okay.
 8 **Q.** We'll -- we're also going to need verbal
 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
 17 question before we go into a break.
 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.
 24 **MR. JANUSZ:** Very well, then.
 25 **MR. HASFORD:** Okay.

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1 BY MR. JANUSZ:
 2 **Q.** Okay. So have you ever submitted a -- a
 3 declaration in an IPR proceeding before?
 4 **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?
 11 **A.** Correct.
 12 **Q.** Okay. Have you ever testified at a trial
 13 before?
 14 **A.** Yes.
 15 **Q.** Okay. And -- and none of those were related
 16 to patent issues?
 17 **A.** Correct.
 18 **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:
 25 **Q.** Dr. Trattler, you've been handed what have

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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?
 8 **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.
 12 Obviously there have been a lot of opinions,
 13 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 13

1 performed cataract surgeries before?
 2 **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?
 9 **A.** Six-zero, yes.
 10 **Q.** Six-zero? Okay.
 11 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.
 16 And -- and approximately when in your career
 17 did you first perform cataract surgeries?
 18 **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.
 23 **Q.** And where was your residency?
 24 **A.** At -- at Scheie Eye Institute which is in
 25 Philadelphia, Pennsylvania. Part of the University of

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1 Pennsylvania.

2 **Q.** Okay. If I can have you turn to Trattler

3 Exhibit 1, which is your declaration in the 902 case,

4 and just -- just so we are clear, on the front of

5 Trattler Exhibit 1 if you look at the very bottom you

6 see the case number ending in 902.

7 **A.** Yes.

8 **Q.** And so when I refer to the 902 case, that's

9 what I'm looking at.

10 **A.** Okay.

11 **Q.** Similarly with the 903 case.

12 So if I can direct your attention to

13 paragraph 41 of the declaration, and that appears at

14 page 13.

15 **A.** Okay.

16 **Q.** 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.

20 **Q.** And it's your opinion that that formulation

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 **Q.** Okay. Are you aware that the pH levels of

Page 15

1 natural tears in humans can fluctuate beyond the 7.4

2 that you've identified?

3 **A.** I think that, you know, pH can be affected by

4 a variety of different things, but I think the average

5 is considered by most experts to be around 7.4.

6 **Q.** Okay. But it can -- it can go -- for

7 example, it can be lower than 7.4 in certain patients?

8 **A.** 7.4 is an -- is an average.

9 **Q.** Okay.

10 **A.** Is -- I think that's an the understanding

11 that when we talk about, you know, patients and their

12 tears it's typically considered that 7.4 is the

13 average.

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 **A.** Yes. "The reduced pH and amount of

21 surfactant in Prolensa eliminated the burning and

22 stinging sensation making it more comfortable ensuring

23 greater patient compliance".

24 **Q.** Okay. And so let's talk generally about

25 that.

Page 16

1 It's your opinion that making an

2 ophthalmic -- application of an ophthalmic solution

3 more comfortable for a patient would increase patient

4 compliance; is that right?

5 **A.** Definitely.

6 **Q.** Okay. And -- and the idea behind that is

7 likely that obviously if a patient's more comfortable

8 with the drug that they're applying to themselves

9 they're not going to have any issues applying it; is

10 that right?

11 **A.** Correct. If a -- if a medication stings and

12 burns on every application, they may be less likely to

13 put it into their eyes.

14 **Q.** Okay. And so it's -- it's your opinion in

15 this declaration -- in this -- in this paragraph of

16 your declaration that Prolensa's pH level of 7.8 being

17 closer to that of natural tears being 7.4 at least in

18 part contributes to the elimination of burning --

19 burning and stinging experienced by patients using

20 Prolensa; is that right?

21 **A.** Yeah, my th -- my understanding is that that

22 would -- by being closer to the natural pH it can help,

23 and -- you know, as far as reduced burning and

24 stinging.

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

Page 17

1 can help, can you explain what you mean by that?

2 **A.** Well, obviously there are some formulations

3 of medications that are at pH of 7.4 that still cause

4 burning and stinging. So you can have irritating

5 solutions that have a pH of 7.4. So it's a combination

6 of -- of factors.

7 **Q.** Okay. And generally speaking, I mean, would

8 your opinion be that -- obviously that there are --

9 well, let me -- let me -- strike that.

10 Generally speaking, would your opinion be

11 that the closer you get to the natural -- the pH of

12 natural tears, the more likely a solution would be

13 comfortable for the user?

14 **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.

25 So again, you could have formulations exactly

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