

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)
 11 Defendants.)
)
 12 vs.)
)
 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.)
)
 16
 17
 18
 19
 20 VIDEOTAPED DEPOSITION OF WILLIAM B. TRATTLER, M.D.
 21 Tuesday, February 23, 2016
 22 Miami, Florida
 23
 24
 25

Page 4

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
 901 New York Avenue, N.W.
 6 Washington, D.C. 20001-4413
 202-408-4000 (P) 202-408-4400 (F)
 7 justin.hasford@finnegan.com
 8
 9 On behalf of Lupin Limited and Lupin Pharmaceuticals,
 Inc. :
 10 NATASHA E. DAUGHTREY, ESQUIRE
 Goodwin Procter LLP
 11 The New York Times Building
 620 Eighth Avenue
 12 New York, New York 10018
 212-813-8800 (P) 212-355-3333 (F)
 13 ndaughtrey@goodwinprocter.com
 (PRESENT BY TELEPHONE)
 14
 15
 16 On behalf of InnoPharma Licensing, Inc.,
 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

Page 3

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.
 8
 9
 10
 11
 12
 13
 14
 15
 16
 17
 18
 19
 20
 21
 22
 23
 24
 25

Page 5

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

1 EXHIBITS (Continued)

2

| EXHIBIT | DESCRIPTION | PAGE |
|-------------------|---|------|
| 3 Exhibit No. 6 | Prescribing information for Xibrom | 57 |
| 4 | | |
| 5 Exhibit No. 7 | Prescribing information for bromfenac ophthalmic solution | 60 |
| 6 | | |
| 7 Exhibit No. 8 | Document previously marked Senju 2060 | 91 |
| 8 | | |
| 9 Exhibit No. 9 | Document previously marked as Senju Exhibit 2134 | 93 |
| 10 | | |
| 11 Exhibit No. 10 | Document previously marked as Senju 2030 | 99 |
| 12 | | |
| 13 Exhibit No. 11 | Curriculum vitae | 102 |
| 14 | | |
| 15 Exhibit No. 12 | Opening expert report | 120 |
| 16 | | |
| 17 Exhibit No. 13 | Reply expert report | 122 |
| 18 | | |
| 19 | | |
| 20 | | |
| 21 | | |
| 22 | | |
| 23 | | |
| 24 | | |
| 25 | /// | |

Page 8

1 THE VIDEOGRAPHER: This begins video media

2 disc number one, volume one. This is the

3 videotaped deposition of William V. Trattler,

4 that's T-r-a-t-t-l-e-r, M.D. in the matter of

5 Innopharm Licensing, Inc. et al versus Senju

6 Pharmaceuticals Company Limited, et al, Case Number

7 IPR2015-00903 and 14-CV-0667-JBS-KMW et al in the

8 United States Patent and Trademark Office before

9 the Patent Trial and Appeals Board and the U.S.

10 District Court for the District of New Jersey.

11 Today is February 23, 2016. The time is

12 12:19 p.m. This video deposition is taking place

13 at the Dadeland Marriott at 9090 South Dadeland

14 Boulevard, Miami, Florida. This video deposition

15 has been at the request of Joseph Janusz from the

16 law firm of Alston & Bird, LLP. My name is Jeff

17 Menton. I am the certified legal video specialist,

18 and the court reporter is Michele Anzivino. We're

19 from Gregory Edwards LLC.

20 Would counsel please state their appearance

21 for the record and state whom you represent

22 starting with the noticing attorney, and then will

23 the court reporter please swear the witness in.

24 MR. JANUSZ: Joe Janusz of Alston & Bird on

25 behalf of the Innopharm entities which are a

Page 7

1 EXHIBITS (Continued)

2

| EXHIBIT | DESCRIPTION | PAGE |
|------------------|-----------------------------------|------|
| 3 Exhibit No. 14 | Document, Bates PROL0333863 - 869 | 135 |
| 4 | | |
| 5 | | |
| 6 | | |
| 7 Exhibit No. 15 | Document, Bates PROL0333854 - 862 | 140 |
| 8 | | |
| 9 | -o0o- | |
| 10 | | |
| 11 | | |
| 12 | | |
| 13 | | |
| 14 | | |
| 15 | | |
| 16 | | |
| 17 | | |
| 18 | | |
| 19 | | |
| 20 | | |
| 21 | | |
| 22 | | |
| 23 | | |
| 24 | | |
| 25 | | |

Page 9

1 petitioner in the IPR proceedings and a defendant

2 in the District Court litigation.

3 MS. DAUGHTREY: And this is Natasha Daughtrey

4 from Goodwin Proctor on defendant of the Lubin

5 defendant in the District Court litigation.

6 MR. HASFORD: Justin Hasford of Finnegan on

7 behalf of Senju and Bausch & Lomb in both the IPR

8 and the District Court proceedings.

9 Thereupon,

10 WILLIAM V. TRATTLER, M.D.,

11 having been duly sworn or affirmed, was examined and

12 testified as follows:

13 THE WITNESS: Yes, I do.

14 DIRECT EXAMINATION BY MR. JANUSZ:

15 Q. Good morning, Dr. Trattler. How are you?

16 A. Great, thank you.

17 Q. I'm going to go over a few ground rules ahead

18 of time. Ha -- have you ever depose -- been deposed

19 before?

20 A. I have, yes.

21 Q. Okay. So I'm going to run through this

22 quickly. I'm sure it's all stuff you've heard before.

23 You understand that you're under oath in giving your

24 testimony today, right?

25 A. Yes.

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.
 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.

Page 11

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

Page 12

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

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

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.

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

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

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.