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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

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4 HELSINN HEALTHCARE, S.A. and
5 ROCHE PALO ALTO, LLC,

6

Plaintiffs,

7

-vs-

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DR. REDDY'S LABORATORIES, LTD.,
9 DR. REDDY'S LABORATORIES, INC.,
10 TEVA PHARMACEUTICALS USA, INC.,
and TEVA PHARMACEUTICAL
INDUSTRIES, LTD.

11

Defendants.

12

Clarkson S. Fisher United States Courthouse
402 East State Street
Trenton, New Jersey 08608
June 9, 2015

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14 **B E F O R E:**

THE HONORABLE MARY L. COOPER
UNITED STATES DISTRICT JUDGE

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23 Certified as True and Correct as required by Title 28, U.S.C.,
24 Section 753

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/S/ Regina A. Berenato-Tell, CCR, CRR, RMR, RPR
/S/ Carol Farrell, CCR, CRR, RMR, CCP, RPR, RSA

*United States District Court
Trenton, New Jersey*

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1 APPEARANCES:

2 PAUL HASTINGS

3 BY: JOSEPH O'MALLEY, ESQUIRE

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*United States District Court
Trenton, New Jersey*

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Colloquy

1 (In open court. June 9, 2015, 9:30 a.m.)

2 THE COURT: Good morning, everyone.

3 ALL: Good morning, your Honor.

4 THE COURT: You want to debate this issue that's

5 coming up as the stage of the trial shifts to plaintiffs'

6 side, or would you rather continue with the presentation of

7 defendants' side of the evidence first and get to this

8 argument in a break today?

9 MR. O'MALLEY: Your Honor, if possible, we'd like to

10 get some resolution on this so we can be planning our

11 presentation for the rest of the week.

12 THE COURT: This is one expert, maybe two, is it?

13 MR. O'MALLEY: Two.

14 THE COURT: On their side.

15 MR. DITTMANN: Two.

16 MR. O'MALLEY: Correct.

17 THE COURT: Okay. Mr. Lombardi, when would you like

18 to take this up?

19 MR. LOMBARDI: Your Honor, I will defer to DRL who's

20 going to be arguing this matter.

21 MR. SENDER: Your Honor, it really doesn't matter

22 because these are not experts that we are using, and it can be

23 deferred to the end, as far as we're concerned.

24 THE COURT: We have hours of depositions today and

25 then the defendants rest.

*United States District Court
Trenton, New Jersey*

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I N D E X

<u>WITNESS</u>	<u>VOIR DIRE</u>	<u>DIRECT</u>	<u>CROSS</u>	<u>REDIRECT</u>	<u>RECROSS</u>
(Video Deposition of Daniele Bonadeo), 5					
(Video Deposition of Roberta Canella), 38					
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RACHID BENHAMZA					
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ZOYA IVANOVA MARRIOTT					
By Mr. Bliss	150	152			
By Mr. Sender			175		

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Bonadeo - Deposition

1 MR. SENDER: That's correct, your Honor.

2 THE COURT: Okay. I would like to maintain my

3 concentration on the defendants' side of the case, and as soon

4 as they rest, I'll take up this issue.

5 MR. O'MALLEY: Thank you, your Honor.

6 MR. DITTMANN: Thank you, your Honor.

7 MR. LOMBARDI: Mr. Barker will introduce the first

8 deposition to you, Your Honor.

9 MR. BARKER: Good morning, your Honor.

10 So the first deposition we're going to play today is

11 excerpts from the deposition of Daniele Bonadeo. Dr. Bonadeo

12 is a Helsinn employee. He's one of the inventors in all the

13 patents-in-suit, and the excerpts will include designations

14 from plaintiffs and defendants, and they are approximately

15 about 40 minutes long.

16 THE COURT: That's fine, Mr. Barker. Thank you. Let

17 me just make a note before you start the tape.

18 Okay. Ready.

19 (Video played of DANIELE BONADEO as follows:)

20 Q. Good morning.

21 A. Good morning.

22 Q. Please state your name for the record.

23 A. My name is Daniele Bonadeo.

24 Q. And, Dr. Bonadeo, is that okay?

Marriott - Voir Dire

- 1 First name Zoya, Z-O-Y-A, middle name I-V-A-N-O-V-A, last name
2 Marriott, M-A-R-R-I-O-T-T.
3 THE DEPUTY CLERK: Excuse me. Before you start, do
4 you have any water?
5 MR. BLISS: Water, sure.
6 THE DEPUTY CLERK: Usually it's up there.
7 MR. BLISS: This one looks unopened.
8 THE DEPUTY CLERK: Thank you.
9 MR. BLISS: Your Honor, if I may, I have exhibit
10 binders to hand up.
11 THE COURT: Fine.
12 THE DEPUTY CLERK: Do you have one for the law clerk?
13 MR. BLISS: Yes.
14 VOIR DIRE EXAMINATION BY MR. BLISS:
15 Q. Good afternoon, Dr. Marriott.
16 A. Good afternoon.
17 Q. what kind of a doctor are you?
18 A. I have a Ph.D. in economics.
19 Q. So you're not a medical doctor?
20 A. No, I'm not.
21 Q. And you're not a patent expert?
22 A. No.
23 Q. And you're not a formulation expert?
24 A. No.
25 Q. what do you do for a living?

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Marriott - Direct

- 1 Q. what do you do as a senior manager at Cornerstone?
2 A. I conduct economic analysis for complex business
3 litigation.
4 Q. what does that typically involve?
5 A. I usually analyze data, internal company documents,
6 academic literature, devise estimation strategies as
7 appropriate.
8 Q. Have you served as a testifying expert before?
9 A. No. It's my first time.
10 Q. Has your work as an economist been focused on any
11 particular industry?
12 A. Yes. My entire professional career has been focused on
13 life sciences industry, specifically, pharmaceuticals for the
14 most part.
15 Q. Do you have any prior experience analyzing commercial
16 success in Hatch-waxman cases?
17 A. Yes. I have done so in approximately ten other matters.
18 MR. BLISS: Your Honor, we offer Dr. Marriott as an
19 expert economist on the secondary consideration of commercial
20 success.
21 MR. SENDER: I have no objection, Your Honor.
22 THE COURT: Thank you, counsel. So admitted.
23 DIRECT EXAMINATION BY MR. BLISS:
24 Q. Dr. Marriott, what is your opinion on whether Aloxi® is a
25 commercially successful product?

United States District Court
Trenton, New Jersey

Marriott - Voir Dire

- 1 A. I'm a senior manager at Cornerstone Research, which is an
2 economics and financial consulting company.
3 Q. How long have you been with Cornerstone?
4 A. Almost ten years.
5 Q. what is your role in this trial?
6 A. I am here to offer an opinion as to whether Aloxi® is a
7 commercially successful product, and, also, to examine the
8 extent of marketing expenditures for Helsinn.
9 Q. will you be offering any opinions on the patents-in-suit?
10 A. No.
11 Q. Dr. Marriott, can you please tell us about your
12 educational background?
13 A. of course. I have a Bachelor of Science degree in
14 mathematics from Novosibirsk State University in Russia, and
15 then I have a Master of Arts degree in economics from Central
16 European University in Hungary, and from there, I applied and
17 was accepted into a Ph.D. program at Boston University. And
18 five years later, I defended my dissertation and obtained my
19 doctorate in economics.
20 Q. Did you specialize in any particular branch of economics?
21 A. Yes. My area of specialization was industrial
22 organization. This is an area of economics that studies how
23 economic agents -- companies in particular -- compete, how
24 they decide which markets to enter, which products to produce,

Marriott - Direct

- 1 A. Based on the analysis I conducted, I conclude that Aloxi®
2 is, in fact, a commercially successful product.
3 Q. what indicators of commercial success did you consider in
4 forming your opinion?
5 A. I have looked into the sales, both levels and growth
6 rates for Aloxi®. I have examined sales and growth relative
7 to other drugs on the market, looked into market share, and,
8 finally, I have looked into profitability of Aloxi® to
9 Helsinn.
10 THE COURT: Okay. One moment, please.
11 Counsel, does any one of the parties have any requests
12 that any of this information be sealed as confidential?
13 MR. BLISS: I don't believe, so but --
14 MR. O'MALLEY: No, Your Honor. It's our confidential
15 information. We have no such request.
16 THE COURT: Very well. You may proceed, counsel.
17 BY MR. BLISS:
18 Q. Dr. Marriott, in your experience, are those the
19 indicators that economists typically consider in analyzing
20 commercial success?
21 A. Yes, for the most part. Profitability, sometimes it's
22 hard to establish because not all companies have
23 product-specific level data on that, but the other indicators
24 are very typical.

Marriott - Direct

- 1 products. How did you determine the relevant market for
2 Aloxi®?
- 3 A. So, in the Hatch-Waxman case, such as this one, the
4 economists typically look at relevant therapeutic category as
5 the relevant market. So this is what I've done here. I've
6 looked to see what drugs are in the relevant therapeutic
7 category. And to do so, I've looked at the company documents.
8 I've looked at how the data distinguishes between the drugs.
9 I've looked at the drug labels.
- 10 Q. And what did you conclude based on your consideration of
11 those materials?
- 12 A. So, I concluded that in this case, the relevant
13 therapeutic category was other 5-HT₃ antagonists, and, also,
14 some of the documents indicated that NK-1 antagonist, Emend,
15 can also potentially be included, so whenever I had data for
16 Emend, I've included it in the consideration.
- 17 Q. Emend is an NK-1 product?
- 18 A. Yes.
- 19 THE COURT: How do you spell that?
- 20 THE WITNESS: E-M-E-N-D.
- 21 BY MR. BLISS:
- 22 Q. Do NK-1s compete directly with 5-HT₃s?
- 23 A. So, in a sense of therapeutic -- therapeutic category,
24 they do not compete directly because they are indicated to be
25 used with other 5-HT₃ drugs.

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Marriott - Direct

- 1 THE WITNESS: But it was not a disintegrating tablet,
2 just a tablet, a pill.
- 3 THE COURT: Um-hum.
- 4 THE WITNESS: So after Zofran, after ondansetron, the
5 next product was Kytril, generic name granisetron. That one
6 was approved for CINV in December, '93. And it also went
7 generic later on.
- 8 And then the next product was Anzemet, generic name
9 dolasetron, and that one was approved for CINV in September,
10 '97.
- 11 So after Aloxi®, there were also two other 5-HT₃
12 products that were approved. One was Sancuso. That was a
13 granisetron patch. And the other one was Zuplenz, which is an
14 ondansetron oral film.
- 15 THE COURT: What is an oral film?
- 16 THE WITNESS: It's --
- 17 THE COURT: I've never heard of that.
- 18 THE WITNESS: It's a really thin film, as far as I
19 understand. I'm not a doctor.
- 20 THE COURT: Right, right, right.
- 21 THE WITNESS: And luckily, I didn't have to take it.
22 But it's a very thin film that you put on your tongue and it
23 dissolves, so I think there's some benefits because of that.
- 24 So Sancuso was approved in September, 2008 for CINV,
25 and Zuplenz was approved for CINV in July 2010. And then the

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Marriott - Direct

- 1 Q. Does your opinion depend in any way on whether NK-1
2 antagonists are included in the relevant therapeutic category?
- 3 A. No.
- 4 Q. As of the time you performed your analysis, how many
5 5-HT₃ and NK-1 products were on the market?
- 6 A. I've prepared the demonstrative if that will help.
- 7 Q. Please walk us through the products on this slide.
- 8 A. Sure.
- 9 THE COURT: So you've got 5-HT₃ antagonists and NK-1
10 antagonists on this slide, right?
- 11 THE WITNESS: Yes. That is correct.
- 12 So Aloxi®, which is the red bar, was the fourth 5-HT₃
13 on the market. It was approved for treatment of acute and
14 delayed CINV in July, 2003.
- 15 The first product on the market, the first 5-HT₃ was
16 Zofran, generic name ondansetron, and that one was approved
17 for CINV in January, '91. There was another ondansetron
18 product that was launched later on that was Zofran orally
19 disintegrating tablet, or Zofran ODT. So that one was
20 approved in January '99. Both of these drugs went generic in
21 late 2006.
- 22 THE COURT: Was the original Zofran an I.V. product?
- 23 THE WITNESS: They had both I.V. and oral
24 formulations.

Marriott - Direct

- 1 last bar, that's the NK-1 product, Emend. That one was
2 approved shortly before Aloxi® in March, 2003. And it entered
3 the market shortly thereafter.
- 4 BY MR. BLISS:
- 5 Q. How many of the 5-HT₃ --
- 6 THE COURT: When you say "approved," you're using a
7 term, "approved."
- 8 THE WITNESS: FDA approved.
- 9 THE COURT: FDA approved.
- 10 THE WITNESS: Um-hum.
- 11 THE COURT: Did they enter the market once they were
12 approved, each of these ones?
- 13 THE WITNESS: So all of them entered the market --
14 well, I should say with an exception of the oral Aloxi®, all
15 the other drugs entered the market upon being FDA approved,
16 but sometimes there was a lag, maybe a couple of months.
- 17 THE COURT: Okay. So your slide here is just showing
18 us the date of the FDA approval?
- 19 THE WITNESS: Yes.
- 20 THE COURT: Thank you, Doctor.
- 21 THE WITNESS: Yes.
- 22 BY MR. BLISS:
- 23 Q. How many of the 5-HT₃ products were approved to treat
24 delayed CINV?

Marriott - Direct

1 delayed CINV. All of the other 5-HT₃ products are approved to
2 treat acute CINV only.

3 Q. So getting back to the indicators you considered, what
4 did you find with regard to the level and growth of Aloxi®
5 dollar sales?

6 A. I have prepared another demonstrative for that.

7 Q. What does this demonstrative show?

8 A. So this demonstrative shows us annual sales of Aloxi®
9 from 2003. That's the year when it was launched on the
10 market, and through the first seven months of 2013.

11 So as you can see from this demonstrative, the first
12 full year that Aloxi® was on the market, it generated
13 \$188 million in sales, and the sales continued to grow. 2006,
14 there were 326 million. 2009 there was 434, continued to
15 grow. In 2011 for 478 million. 473 in 2012, and then that
16 last bar, that's a partial year, so that's the seven months of
17 2013 during which it generated 271 million.

18 THE COURT: And why does your chart end with that
19 first half of 2013?

20 THE WITNESS: So, I filed my expert report in
21 October, 2013. These are the data that were available at the
22 time that I was preparing my report.

23 BY MR. BLISS:

24 Q. Dr. Marriott, did you consider how Aloxi®'s dollar sales
25 compared to other products in the therapeutic category?

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Marriott - Direct

1 the market in 2007, I believe it was first quarter of 2007.

2 Q. Can you explain that last point a little more? What's
3 the significance of generic entry?

4 A. So, "generic" means from a pharmaceutical industry, when
5 generic drugs enter the therapeutic category, there is a lot
6 of pressure from the payors, from the insurance companies,
7 from Medicare, to switch patients to cheaper drugs.

8 So the fact that Aloxi® is able to not only maintain
9 the high level of sales but also to grow it over time speaks
10 to the value that patients realize from the drug.

11 Q. Did you consider the fact that, during the time period
12 covered by your analysis, Aloxi®'s peak annual sales were not
13 as high as the peak annual sales for Zofran?

14 A. Yes. It's not surprising to me really because it's a
15 well-established fact in the health economics literature, and
16 generally understood in the industry as well, that the first
17 mover in the category has an advantage. There are papers that
18 demonstrate that the first mover generally grows for longer
19 period of time, achieves higher peak levels of sales and
20 overall throughout the life cycle generates more in sales
21 compared to later entrants.

22 THE COURT: I notice that -- it's a little hard for
23 me to see when the Zofran goes generic here, just because of
24 the way the graph lines run. But does it indicate that in the
25 first quarter of 2007 is when Zofran went generic?

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Marriott - Direct

1 A. Yes. I guess one thing I wanted to mention, just to
2 summarize this whole growth, is that throughout this whole
3 time it generated \$3.6 billion. I just thought that's an
4 important number to underline here, and the sales --

5 Q. And what was the compound annual growth rate?

6 A. 12.2 percent.

7 Q. Thank you.

8 A. Sorry. And, yes, I have considered how the growth and
9 the level of sales compared to other drugs. And I have
10 demonstratives for that, as well.

11 Q. So let's look at your first sales comparison. What does
12 this demonstrative show?

13 A. So, this demonstrative shows the annual sales for Aloxi®
14 as well as other 5-HT₃ drugs and Emend, the NK-1 product from
15 2003, the year when Aloxi® was launched, through, again, the
16 first seven months of 2013.

17 So as you can see from this demonstrative, Aloxi®,
18 which is the red bar here, entered the rather crowded market.
19 There were drugs with substantial sales already on the market.
20 But already by 2004, 2005, it has overtaken many of the
21 previous entrants in terms of the levels of sale. Really, the
22 only exception was Zofran, which was the first entrant on the
23 market.

24 And the sales of Aloxi® continued to grow over time,

Marriott - Direct

1 THE WITNESS: Yes, yes.

2 THE COURT: Okay. And you've indicated that by
3 saying --

4 THE WITNESS: Actually, sorry, I take it back. I
5 think it was the last quarter of 2006 probably because if you
6 scroll down to the very top of that blue bar, there is this
7 tiny little shaded area. These are the generic ondansetron
8 sales. So I think it was approved towards the very end of the
9 year.

10 THE COURT: Oh, and so there would have
11 been branded -- what do you call them, brand or prescription?

12 THE WITNESS: Branded drug.

13 THE COURT: Branded. They are all prescription, of
14 course, whether they are generic or not?

15 THE WITNESS: Right.

16 THE COURT: But the branded sales of Zofran are
17 accompanied by a few generic sales of the Zofran generic --

18 THE WITNESS: Right.

19 THE COURT: -- in that first year where the generic
20 shows up?

21 THE WITNESS: Yes.

22 THE COURT: And then the next year which is 2007,
23 there are a few branded sales, but most of the generic Zofran
24 accounts for Zofran dollars, right?