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2 UNITED STATES DISTRICT COURT
3 FOR THE DISTRICT OF NEW JERSEY

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

7 Plaintiffs,

8 -vs-

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

14 Defendants.

15 _____
16 Clarkson S. Fisher United States Courthouse
17 402 East State Street
18 Trenton, New Jersey 08608
19 June 9, 2015

20 **B E F O R E:**

21 THE HONORABLE MARY L. COOPER
22 UNITED STATES DISTRICT JUDGE

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

25 /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

4 ERIC W. DITTMANN, ESQUIRE

5 ISAAC S. ASHKENAZI, ESQUIRE

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17 BY: JOVIAL WONG, ESQUIRE

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19 JULIA MANO JOHNSON, ESQUIRE

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21 LITE DEPALMA, GREENBERG, LLC

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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.

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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					
(Video Deposition of Riccardo Braglia), 50					
RACHID BENHAMZA					
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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?

Benhamza - Direct

- 1 Benhamza.
- 2 THE DEPUTY CLERK: Please spell your name for the
- 3 record.
- 4 THE WITNESS: It's R-A-C-H-I-D. B-E-N-H-A-M-Z-A.
- 5 DIRECT EXAMINATION BY MR. O'MALLEY:
- 6 Q. Dr. Benhamza, where do you reside?
- 7 A. I reside in Losone in Switzerland.
- 8 Q. And where do you work?
- 9 A. I work in Helsinn Healthcare in Lugano in Switzerland.
- 10 Q. what's your current position at Helsinn?
- 11 A. I am head of corporate product management inside the
- 12 commercial operations.
- 13 Q. Dr. Benhamza, can you please provide your educational
- 14 background, starting from college?
- 15 A. I am graduated in 1982 at the University of Marrakech in
- 16 Morocco in physics and chemistry. And I moved in the same
- 17 year to France in Lyon, where I was graduated in organic
- 18 chemistry, third cycle doctorate, and I moved also to
- 19 Switzerland to the University of Geneva, where I got my Ph.D.
- 20 in organic medicinal chemistry in 1989.
- 21 Q. what did you do after you received your Ph.D. in 1989?
- 22 A. A few months later, I joined Helsinn Chemicals in Biasca
- 23 in Switzerland.
- 24 Q. And that was still in 1989?
- 25 A. It was September 1989.

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Benhamza - Direct

- 1 A. I work there for three years until 1997.
- 2 Q. And what did you do when you left that company?
- 3 A. I was offered at that time to go back at that time to
- 4 Helsinn, but to work inside the licensing-out division, so I
- 5 joined Helsinn again.
- 6 Q. And that was in 1997?
- 7 A. Yes, it was September 1997.
- 8 Q. And what was your position or title when you rejoined
- 9 Helsinn again in 1997?
- 10 A. I was a licensing-out manager.
- 11 Q. And what does that mean?
- 12 A. It meant, for Helsinn, a person who will search for
- 13 partners to market our product in the different markets
- 14 worldwide. I was responsible at that time for Latin America
- 15 and for North America.
- 16 Q. Did you come to have any involvement in Helsinn's
- 17 palonosetron project?
- 18 A. Yes. I joined the project team of palonosetron in late
- 19 1989.
- 20 Q. '89?
- 21 A. No, sorry. '98.
- 22 Q. Okay. what was your title when you began working on the
- 23 palonosetron project in 1998?
- 24 A. I was still a licensing-out manager.
- 25 Q. And what were you asked to do for the project?

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Benhamza - Direct

- 1 Q. what did you do when you began working for Helsinn in
- 2 1989?
- 3 A. I was leading a small team to develop chemical processes
- 4 for the production of active pharmaceutical ingredients.
- 5 THE COURT: How many languages do you speak, Doctor?
- 6 THE WITNESS: I speak four languages.
- 7 THE COURT: what are they?
- 8 THE WITNESS: So, I speak Arabic, French, Italian and
- 9 a little bit of English.
- 10 BY MR. O'MALLEY:
- 11 Q. Did you count English?
- 12 A. If I count?
- 13 Q. Did you count?
- 14 A. English, yes. It's a very important language for our
- 15 business.
- 16 Q. Now, how long did you hold that particular position at
- 17 Helsinn at the API plant?
- 18 A. I worked at Biasca for five years.
- 19 Q. And what did you do next?
- 20 A. After that, I wanted to move to some kind of commercial
- 21 job. I wanted to start an MBA, but then I found a position as
- 22 a commercial manager in another pharmaceutical company.
- 23 Q. And what was the name of that company?
- 24 A. The name of the company was Nuova Linea.

Benhamza - Direct

- 1 A. We -- I had been asked from my management to -- to start
- 2 as soon as possible the search for a partner who can join us
- 3 for palonosetron and market the product when it will be
- 4 registered and available.
- 5 Q. while working on the palonosetron project, were you
- 6 involved with the details of the clinical trials?
- 7 A. I was not, of course, involved in the details of the
- 8 clinical trials.
- 9 Q. okay.
- 10 A. These were the clinical people, of course.
- 11 Q. while working on the palonosetron project, were you
- 12 involved with the details of the formulation development?
- 13 A. No, I was not.
- 14 Q. Now, you talked about your role was to search for a
- 15 licensing partner. Was that search directed to a particular
- 16 geographic area?
- 17 A. Yes. There was a priority set up by our management, at
- 18 that time Riccardo Braglia. He wanted us to start immediately
- 19 with searching for a partner in the United States.
- 20 The reason for that is that United States was a market
- 21 we were not present at. It was and it is the most important
- 22 pharmaceutical market, so it was very important for us to go
- 23 there. And, basically, I think it was a kind of being the
- 24 third generation, we were a family-owned company, it was a

Benhamza - Direct

- 1 Q. For himself, sir?
- 2 A. And his brother, Enrico Braglia, who was -- both of them
3 were managing directors of the company.
- 4 Q. Okay. Was Helsinn familiar with the U.S. market at this
5 time?
- 6 A. No, not at all. We were completely naive from the
7 American market. I can remember at that time that the company
8 organized some specific training for us, and they flew a dozen
9 of people working on palonosetron to join a couple of days
10 training in San Francisco. I think it was in the late '99,
11 something like that.
- 12 Q. Why was Helsinn seeking a partner in the U.S. on
13 palonosetron specifically in the late 1998 time period?
- 14 A. This is part of the licensing activity, of course, but we
15 had really to concentrate specifically in United States
16 because we -- being the biggest market, and we were working to
17 have the product coming in this market, we wanted a company
18 who can join us, work with us to make sure that we have a
19 partner for this market, but, also, to make sure that we are
20 sharing the risk of the development of the product for this
21 specific market.
- 22 Q. And what do you mean by "sharing the risk"?
- 23 A. It means that when we -- when we were setting licensing
24 agreements, those licensing agreements will trigger some
25 payments from the companies and this will help us, also, to

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Benhamza - Direct

- 1 Q. And you mentioned that took some period of years?
- 2 A. Well, when we started the first research, it was late
3 '98, beginning of 1999, and when we signed the agreement with
4 MGI Pharma, it was 2001. So it was more than a couple of
5 years of search and efforts.
- 6 Q. During that time period, from late 1998 until you signed
7 the agreement with MGI, approximately how many companies did
8 Helsinn reach out to in its search for a licensing partner for
9 palonosetron?
- 10 A. I did -- we did many, many contacts, and there were more
11 than 50 companies which we contacted.
- 12 Q. What type of companies did you contact in your search for
13 a licensing partner?
- 14 A. We -- we usually -- and also in this case, we started
15 from the big pharma because we always think that the big
16 pharma are important, have what we call the marketing
17 "muscles," you know, to make success of product.
- 18 We contacted Bristol-Myers Squibb. We contacted
19 Pharmacia, Baxter, Amgen and others, and then subsequently we
20 moved toward small companies, start-up companies who could be
21 available to partner with us.
- 22 Q. Now, how did you find the companies you contacted?
- 23 A. We -- so we attended several oncology congresses where
24 companies do exhibitions usually, so we can see which company
25 were presenting there.

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- 1 invest into our research and development at that time.
- 2 Q. Now, what did you do first when looking for a licensing
3 partner for palonosetron in the United States?
- 4 A. The first action we took was to contact Roche, who
5 licensed palonosetron to us because they had a first right of
6 refusal to be checked, so we checked with them first if they
7 were interested.
- 8 Q. And what was Roche's response?
- 9 A. Roche declined the proposal to partner in the
10 United States.
- 11 Q. What reason, if any, did Roche give for not wanting to
12 partner with Helsinn on palonosetron?
- 13 A. I don't really remember any reason given at that time,
14 but I can -- I can remember clearly that we could understand a
15 couple of years after that time that they had a different
16 strategy. In fact, Roche ended up acquiring Anzemet, which
17 was another antiemetic in United States.
- 18 Q. Okay. What did you do after Roche declined to partner on
19 palonosetron?
- 20 A. After Roche declined, then we had to start searching for
21 other companies.
- 22 Q. We'll talk about that process in a minute. Were you
23 ultimately successful in finding a licensing partner?
- 24 A. Yes. Fortunately, after several -- few years and a lot

Benhamza - Direct

- 1 I attended also several business development meetings,
2 where I can meet business development people also from other
3 companies.
- 4 But I also bought a small database, a CD, which cost at
5 that time a couple of thousand Swiss francs, with the list of
6 all the companies which potentially I could have contacted.
- 7 Q. Why did you purchase a database?
- 8 A. Well, it was -- it was late '98, beginning '99, and at
9 the time, there was no Internet on my computer. We -- you
10 know, we were a small company, and our management didn't want
11 us to have direct access to the Internet. So we had only one
12 computer in one specific room where everybody could go and use
13 it, so I had to find out other ways to find it.
- 14 Q. Now, how did you initiate contact with these companies
15 you selected to reach out to?
- 16 A. The contacts usually start by a phone call to the company
17 and asking for to talk with the business development person,
18 and maybe over the phone explain in general terms what -- why
19 I was calling, and if there is an interest I would ask to have
20 an e-mail or faxes, whatever, and then I start a contact and
21 explanation about the product.
- 22 Q. Now, you testified that you would provide some
23 explanation of the product. What form would that take?
- 24 A. So, it varies because it can go from an explanation by

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1 also, we used some small documentation, like the
2 nonconfidential profile, which we sent out to some companies.

3 And, of course, if the companies are interested, then
4 we move into the confidentiality agreement, and then we
5 provide other data, as well.

6 Q. You mention --

7 THE COURT: That's very common in the pharmaceutical
8 industry, that in order to open up any kind of detailed
9 discussions about a possible partnership, you will engage in
10 confidentiality agreements with no other obligation to each
11 other; is that right?

12 THE WITNESS: Yes, Your Honor. There was always a
13 need to give some initial information, which can raise the
14 interest at the beginning.

15 If the interest is confirmed, then, yes, we would
16 propose, we will discuss the confidentiality agreement, the
17 duration and so on, and then we move into more open
18 discussions because companies would need to see the
19 information to make their assessment.

20 BY MR. O'MALLEY:

21 Q. Now, you mentioned a nonconfidential profile. What is
22 that?

23 A. The nonconfidential profile is usually two, three pages
24 of very short description of the product. It is prepared by
25 my colleague scientists, medical communication or clinician,

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1 Do you see that?

2 A. Yes, I can see that.

3 Q. Is that a reference to this same nonconfidential profile
4 you testified about a moment ago?

5 A. Yes.

6 Q. Now, would you please turn to the next page, Plaintiffs'
7 Trial Exhibit 321.0010.

8 What is this document?

9 A. This is the nonconfidential profile of palonosetron, the
10 one we used at that time.

11 THE COURT: So, it was no secret that Helsinn had
12 acquired the worldwide rights to this molecule from Roche and
13 Syntex.

14 THE WITNESS: I -- I don't remember if we did any
15 press release, but typically an acquisition of a product is
16 not secret, Your Honor. Typically the companies will put it
17 in a press release, saying this company acquired this product
18 from this other.

19 BY MR. O'MALLEY:

20 Q. Now, again, this is the nonconfidential profile?

21 A. It is.

22 Q. And I believe you testified that you did not prepare
23 this; is that correct?

24 A. Yes. I am -- I mean, I am in the licensing-out division,
25 and it is not my duty to take care of such documents, so it is

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1 and it will describe a little bit of some pieces of every
2 aspect of the product.

3 Q. Let's please turn to Plaintiffs' Trial Exhibit 321-0009.

4 And do you recognize this document?

5 A. Yes, I do.

6 Q. And let's go to the bottom. Is this a document that was
7 sent by you?

8 A. It was a letter I sent, yes.

9 Q. And what is the date of this letter?

10 A. It's dated December 15, 1999.

11 Q. And who are you sending this letter to?

12 A. It was sent to Schwarz Pharma, a pharmaceutical company,
13 international pharmaceutical company.

14 Q. And specifically you're sending it to a Dr. Stratton; is
15 that correct?

16 A. Yes. I was contacting this person who was the
17 vice-president of corporate development, new product and
18 technology acquisitions.

19 Q. And the subject of the letter reads "licensing
20 opportunity"?

21 A. It does, yes.

22 Q. Now, in the first paragraph it states, "Following our
23 phone conversation of today, I am sending you some information
24 on our company along with the nonconfidential profile of our

Benhamza - Direct

1 done by the team.

2 THE COURT: But you can read it -- you can read it
3 and at least understand the surface of what it says, right?

4 THE WITNESS: Absolutely, your Honor, yes. Yeah, I
5 do.

6 BY MR. O'MALLEY:

7 Q. Did you provide this nonconfidential profile to every
8 company you contacted?

9 A. It was not provided to all the companies I contacted, but
10 only to the ones who had some potential interest expressed.

11 Q. Now, under pharmacokinetic profile, there's a sentence,
12 and I'll read it into the record, "Palonosetron is
13 characterized by a long-lasting half-life of approximately
14 40 hours after I.V. and oral administration and a high oral
15 bioavailability."

16 Do you see that?

17 A. Yes, I can see it.

18 Q. So, any time you sent a nonconfidential profile to a
19 potential licensing partner, it had this particular disclosure
20 of the 40-hour half-life of palonosetron?

21 A. Yes. We were very often highlighting this feature of the
22 product, which has been presented to me by my colleagues as
23 one of the important features of the product.

24 Q. Now, how did the companies respond to your offer to