

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

- - -

HEL SINN HEALTHCARE, : Civil Action
S.A., and ROCHE PALO : DOCKET NO.
ALTO, LLC, : 12-2867 (MLC)
:
Plaintiffs, : CONFIDENTIAL
:
v. :
:
DR. REDDY'S :
LABORATORIES, LTD., et :
al., :
:
Defendants. :

- - -
Friday, April 29, 2016
- - -

Videotaped deposition of DR. JOANNE BROADHEAD, taken pursuant to notice, was held at the law offices of Lerner David Littenberg Krumholz & Mentlik, 600 South Avenue West, Westfield, New Jersey, beginning at 9:46 a.m., on the above date, before Constance S. Kent, a Certified Court Reporter, Registered Professional Reporter, Certified LiveNote Reporter, and Notary Public in and for the State of New Jersey.

* * *
MAGNA LEGAL SERVICES
(866) 624-6221
www.MagnaLS.com



1 A P P E A R A N C E S:
 2 PAUL HASTINGS, LLP
 3 BY: ERIC DITTMANN, ESQUIRE
 4 200 Park Avenue
 5 New York, New York 10166
 6 212.318.6432
 7 ericdittmann@paulhastings.com
 8 Counsel for Helsinn
 9 LERNER DAVID
 10 BY: RUSSELL W. FAEGENBURG, ESQUIRE
 11 600 South Avenue West
 12 Westfield, New Jersey 07090
 13 908.654.5000
 14 rfaegenburg@lerner david.com
 15 Counsel for Dr. Reddy's

ALSO PRESENT:

11 James Li
 12
 13 Derek Rose, Video Specialist
 14
 15
 16
 17
 18
 19
 20
 21
 22
 23
 24

1	NO.	DESCRIPTION	PAGE
2	Exhibit	Patent 9,066,980	164
3	Broadhead-		
4	8		
5	Exhibit	Defendant's Contested	186
6	Broadhead-	Facts	
7	9		
8	Exhibit	Reply Expert Report of	188
9	Broadhead-	Patrick DeLuca, Ph.D.	
10	10		
11	Exhibit	Liquid Pharmaceutical	192
12	Broadhead-	Formulations of	
13	11	Palonosetron	
14	Exhibit	Rebuttal Expert Report	206
15	Broadhead-	of Gordon L. Amidon,	
16	12	Ph.D.	
17	Exhibit	Letter dated 1/3/12	214
18	Broadhead-		
19	13		
20	Exhibit	Excerpt of Formulation	226
21	Broadhead-	Book for Intravenous	
22	14	Dosage Forms	
23	Exhibit	Approval Letter	235
24	Broadhead-		
25	15		
26	Exhibit	Document dated 7/23/01,	241
27	Broadhead-	Lehmann to Talarico	
28	16		
29	Exhibit	Revised Study Report	245
30	Broadhead-	dated 8/9/02	
31	17		
32	Exhibit	Declaration of Daniele	252
33	Broadhead-	Bonadeo	
34	18		
35	24		

1 - - -
 2 I N D E X
 3 - - -
 4 Testimony of: JOANNE BROADHEAD
 5 By Mr. Dittmann 9
 6
 7 - - -
 8 E X H I B I T S
 9 - - -
 10 NO. DESCRIPTION PAGE
 11 Exhibit Expert Report 8
 12 Broadhead-
 13 1
 14 Exhibit Reply Expert Report 8
 15 Broadhead-
 16 2
 17 Exhibit Patent 6,130,208 78
 18 Broadhead-
 19 3
 20 Exhibit Abstract, Trends in 121
 21 Broadhead- Stability Testing, with
 22 4 Emphasis on Stability
 23 During Distribution and
 24 Storage
 25 Exhibit Stability Batches 136
 26 Broadhead- Manufactured by SP
 27 5 Pharmaceuticals
 28 Exhibit Pharmaceutical Dosage 142
 29 Broadhead- Forms: Parenteral
 30 6 Medications, Volume I
 31 Exhibit Medicines Compendium 149
 32 Broadhead- 2002
 33 7
 34

1	NO.	DESCRIPTION	PAGE
2	Exhibit	Portion of Reddy's NDA	261
3	Broadhead-	Submission	
4	19		
5	Exhibit	Long-term Stability	268
6	Broadhead-	Study	
7	20		
8	Exhibit	Letter dated 9/1/15	271
9	Broadhead-		
10	21		
11	Exhibit	NDA Approval Letter	274
12	Broadhead-		
13	22		
14	Exhibit	Corrected Summary,	276
15	Broadhead-	Alternate Formulations	
16	23	Tried	
17	Exhibit	Laboratory Notebook	279
18	Broadhead-		
19	24		
20	Exhibit	Laboratory Notebook	283
21	Broadhead-		
22	25		
23	Exhibit	Laboratory Notebook	284
24	Broadhead-		
25	26		
26	Exhibit	Warning Letter dated	300
27	Broadhead-	11/5/15	
28	27		
29	Exhibit	Excerpt of Laboratory	332
30	Broadhead-	Notebook	
31	28		
32	Exhibit	Excerpt of Handbook of	334
33	Broadhead-	Pharmaceutical	
34	29	Excipients, Third	
35	Edition		
36	24		

Page 6

NO.	DESCRIPTION	PAGE
1		
2	Exhibit An Examination of the	337
3	Broadhead- Decomposition of	
4	30 Dextrose Solution During	
5	Sterilization by W.T.	
6	Wing	
7	Exhibit Analytical Test Request	346
8	Broadhead- and Report	
9	31	
10	Exhibit Analytical Test Request	350
11	Broadhead- and Report	
12	32	
13	Exhibit Analytical Test Request	351
14	Broadhead- and Report	
15	33	
16	Exhibit Patent 8,729,094	377
17	Broadhead-	
18	34	
19	Exhibit Expert Report of Patrick	378
20	Broadhead- P. DeLuca, Ph.D.	
21	35	
22	Exhibit Patent 7,947,724	386
23	Broadhead-	
24	36	
25	Exhibit Exhibit 1012,	397
26	Broadhead- Declaration of Dr.	
27	37 Joanne Broadhead in	
28	Support of Petition Post	
29	Grant Review of Claims	

Page 8

(Exhibit No. Broadhead-1, Expert Report, and No. Broadhead-2, Reply Expert Report, were marked for identification.)

THE VIDEOGRAPHER: We are now on the record. This begins Videotape No. 1 in the deposition of Joanne Broadhead in the matter of Helsinn Healthcare, SA, and Roche Palo Alto, LLC, versus Dr. Reddy's Laboratories Limited, et al., in the United States District Court for the District of New Jersey, Civil Action No. 12-2867-MLC-DEA.

Today is Friday, April 29th, 2016, and the time is 9:46 AM.

This deposition is being taken at 600 South Avenue West in Westfield, New Jersey, at the request of Paul Hastings, LLP.

The videographer is Derek Rose of Magna Legal Services, and the court reporter is Connie Kent

Page 7

1	- - -		
2	DEPOSITION SUPPORT INDEX		
3	- - -		
4			
5	Direction to Witness Not to Answer		
6	Page Line Page Line Page Line		
7	14 11 266 13		
8			
9			
10	Request for Production of Documents		
11	Page Line Page Line Page Line		
12	None		
13			
14			
15	Stipulations		
16	Page Line Page Line Page Line		
17	None		
18			
19			
20	Question Marked		
21	Page Line Page Line Page Line		
22	None		
23			
24			

Page 9

of Magna Legal Services.

Will counsel and all parties present state their appearances and whom they represent.

MR. DITTMANN: Eric Dittmann, Paul Hastings, on behalf of Helsinn.

MR. FAEGENBURG: Russ Faegenburg of Lerner David on behalf of the Dr. Reddy's defendants.

THE VIDEOGRAPHER: Will the court reporter please swear in the witness?

DR. JOANNE BROADHEAD, having been first duly sworn, was examined and testified as follows:

- - -

E X A M I N A T I O N

- - -

BY MR. DITTMANN:

Q. Good morning, Dr. Broadhead.

A. Good morning.

Q. Have you been deposed

1 BY MR. DITTMANN:

2 Q. Do you understand or have
3 any understanding that there are
4 chelating agents that are used in
5 applications other than pharmaceuticals,
6 for example, detergents, industrial
7 processes?

8 A. I don't have any expertise
9 in that, but I don't doubt that that
10 would be true.

11 Q. And do you have any reason
12 to disagree there would be a large number
13 of chelating agents that could be used in
14 other processes besides pharmaceuticals?

15 A. So I'm -- my expertise is in
16 pharmaceuticals, so I -- I don't really
17 want to comment on what might be the case
18 outside the pharmaceutical field.

19 Q. Fair enough.

20 Please turn to Paragraph 95
21 of your reply report. And here you were
22 discussing Example 13 of the prior art
23 '333 patent, correct?

24 A. Yeah. I'm just reading the

1 context of that.

2 Q. Sure, take your time.

3 A. Okay.

4 Q. I want to focus you on the
5 second to last sentence of that
6 paragraph, which states:

7 "Thus, such instability was
8 an inherent feature of the prior art
9 formulation."

10 Do you see that?

11 A. Yeah.

12 Q. What did you mean when --
13 what did you mean by "instability was an
14 inherent feature"?

15 A. So -- so this is -- if you
16 go further up where it says:

17 "I understand that inherent
18 properties can be relied upon in an
19 obviousness analysis."

20 That information was
21 provided to me by Mr. Faegenburg about
22 inherent properties.

23 The -- the '980 patent
24 describes the Example 13 of the -- of the

1 '333 patent of not having the desired
2 stability of one to two years, something
3 like that. Therefore, not -- the
4 stability is an inherent feature of that
5 formulation which is described in the
6 Berger patent. That's my interpretation.

7 Q. So Example 13 had a
8 particular amount of palonosetron and
9 certain other ingredients in it, right?

10 A. That's correct.

11 Q. And that formulation has a
12 particular room temperature stability,
13 correct?

14 A. Can I -- can I see -- can I
15 just have a look at how it's described?

16 MR. FAEGENBURG: In the
17 Berger patent? Oh.

18 THE WITNESS: Yeah, maybe
19 it's the Berger patent I need to
20 look at, actually.

21 BY MR. DITTMANN:

22 Q. Well, I can represent to you
23 that the ingredients of the Berger,
24 Example 13, is at the bottom of Column 1.

1 A. Right. Okay.

2 Q. So you see that?

3 A. And somewhere in this
4 paragraph, if I can just find the right
5 place -- so yeah, the top of Column 2, it
6 states that the shelf stability is less
7 than the one to two-year period required.

8 Q. So you're going by the
9 representation in the patent in terms of
10 the stability of the Example 13
11 formulation, correct?

12 A. Yeah. But the stability
13 must be property of the formulation.

14 Q. Stability is an inherent
15 property of the formulation based on its
16 ingredients and the amounts of those
17 ingredients, correct?

18 A. So if -- I'm not quite sure
19 what you're asking me. Can you -- can
20 you just rephrase that?

21 Q. Sure.

22 The stability of a
23 formulation at any given -- any given
24 storage condition is a function of its

1 ingredients and the amounts of those
2 ingredients, right?
3 A. Yeah. Pretty much. Yeah.
4 Yeah. I'm -- there -- there are some
5 other factors that come into play. So
6 you know, for example, for a parenteral
7 product you need to be concerned about
8 sterility and that will be dependent on
9 containment closure and that sort of
10 thing as well.

11 So in terms of -- in terms
12 of -- if you want to limit it to sort of
13 chemical stability, then generally
14 speaking it will be determined by the
15 composition.

16 Q. And going back to your
17 statement that stability was an inherent
18 feature, are you referring to an inherent
19 feature being a property of the
20 formulation?

21 A. Well, yeah, in that sense,
22 I'm referring -- you know, the -- I'm --
23 based on what I understand is the patent
24 law around inherit properties, yes, I'm

1 considering the stability of that
2 formulation, to be a property of that
3 formulation.

4 Q. And that inherit property
5 you're relying upon is based on
6 information provided in the '980 patent,
7 correct?

8 A. The information about
9 stability is in the '980 patent, yes.

10 Q. Right. And you're relying
11 on that statement in the patent?

12 A. I'm relying on it for --
13 for -- where am I relying on it -- yeah,
14 to -- in this particular paragraph, that
15 would be correct, yes.

16 Q. Okay. Can we go back to our
17 Claim 5 of the '980 patent? We were
18 talking earlier about a formulation made
19 according to Claim 5.

20 Do you remember that?

21 A. Yes, I do.

22 Q. Now, talking just about the
23 ingredients in Claim 5 and the amounts,
24 would you agree that that formulation

1 would have a particular room temperature
2 stability, correct?

3 MR. FAEGENBURG: Objection,
4 vague.

5 THE WITNESS: Well, in terms
6 of the reading of the claims --

7 BY MR. DITTMANN:

8 Q. I'll strike that. I'm
9 sorry. I'll make it easier for you.
10 Maybe we'll just use the example for
11 formulation, it might be easier for you
12 for these questions. I don't want to bog
13 us down in claims for this point.

14 A. Okay.

15 Q. So the Example 4
16 formulation, which is at the bottom of
17 Column 7, right?

18 A. Yes.

19 Q. Which you understand to be
20 the Aloxi formulation?

21 A. I do understand that, yes.

22 Q. Okay. And would you agree
23 that the Example 4 formulation has a room
24 temperature stability property, correct?

1 A. Well, the -- there's no data
2 provided to show me that, and the --
3 the -- and it doesn't actually state
4 that, either, in the -- in the -- you
5 know, it describes it as a representative
6 formulation.

7 Q. I was just asking just if it
8 has a stability property, that's all.
9 I'm not asking if it's disclosed. I'm
10 asking if Example 4 -- if you made
11 Example 4 and tested it, it would have a
12 particular room temperature stability?

13 A. So you're not asking me
14 whether this has 24 months or any other
15 shelf life?

16 Q. No.

17 A. Well, as a formulation -- I
18 mean, this is -- this is a -- so this is
19 a -- you know, this is the sort of the
20 quantitative formula, you would have to
21 make it as a pharmaceutical product in a
22 vial, sterilize it and do all that.

23 But assuming that that's
24 understood, then it would have a shelf