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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 5, 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

Dr. Reddy's Laboratories, Ltd., et al.
v.
Helsinn Healthcare S.A. et al

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I N D E X

<u>WITNESS</u>	<u>VOIR</u> <u>DIRE</u>	<u>DIRECT</u>	<u>CROSS</u>	<u>REDIRECT</u>	<u>RECROSS</u>
Lee Edwin Kirsch					
By Mr. Wong	5	18			
By O'Malley				92	

1 eight asserted claims?

2 A. Yes. Claim 7 in the '219 patent really contains the
3 elements that are relevant.

4 Q. And we'll get to each of these elements in a bit, but
5 what is your general opinion regarding each of the components
6 listed here for Claim 7?

7 A. Well, it's my opinion that these elements are a
8 description or involve the description of a common -- commonly
9 used conditions and components in I.V. formulations that are
10 used for their common uses. So, in my opinion, this patent is
11 invalid because of obviousness.

12 Q. Now, have you considered who a person of ordinary skill
13 in the art would be with respect to the four patents?

14 A. Yes, I have.

15 Q. And who would that person be?

16 A. The person of ordinary skill in the art, a POSA, would be
17 a formulation scientist typically with a Ph.D. in
18 pharmaceuticals or a related field and would have a couple of
19 years of experience in developing I.V. formulations.

20 Q. Okay. Now, in your opinion, would this POSA have actual
21 experience preparing formulations at the bench?

22 A. Yes.

23 Q. And what is the scope of resources that a POSA would draw
24 upon when developing a formulation?

25 A. Well, a POSA would have their training and background,

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