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UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY

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

Plaintiffs,

-vs-

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

Defendants.

CIVIL ACTION NUMBERS:

11-3962

TRIAL

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Clarkson S. Fisher United States Courthouse  
402 East State Street  
Trenton, New Jersey 08608  
June 2, 2015

**B E F O R E:**

THE HONORABLE MARY L. COOPER  
UNITED STATES DISTRICT JUDGE

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

/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.

1 UNITED STATES DISTRICT COURT  
2 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-

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

13 Defendants.

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/S/ Carol Farrell, CCR, CRR, RMR, CCP, RPR, RSA

1 **A P P E A R A N C E S:**

2 PAUL HASTINGS

BY: JOSEPH O'MALLEY, ESQUIRE

3 ERIC W. DITTMANN, ESQUIRE

ISAAC S. ASHKENAZI, ESQUIRE

4 SAUL EWING

BY: CHARLES M. LIZZA, ESQUIRE

5 Attorneys for the Plaintiffs

6

BUDD LARNER

7 BY: STUART D. SENDER, ESQUIRE

MICHAEL H. IMBACUAN, ESQUIRE

8 H. HOWARD WANG, ESQUIRE

CONSTANCE S. HUTTNER, ESQUIRE

9 KENNETH E. CROWELL, ESQUIRE

Attorneys for the Defendant, Dr. Reddy's Laboratories

10

WINSTON & STRAWN

11 BY: JOVIAL WONG, ESQUIRE

GEORGE LOMBARDI, ESQUIRE

12 JULIA MANO JOHNSON, ESQUIRE

BRENDAN F. BARKER, ESQUIRE

13 LITE DePALMA, GREENBERG, LLC

BY: MAYRA V. TARANTINO, ESQUIRE

14 Attorneys for the Defendant, Teva

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## I N D E X

WITNESS                      DIRECT                      CROSSREDIRECT                      RECROSS

OPENING ARGUMENTS:

By Mr. Lombardi, 13

By Ms. O'Malley 61

GIORGIO CALDERARI

By Mr. Lombardi 105

1 MR. O'MALLEY: Yes, right.

2 THE COURT: -- or both?

3 MR. O'MALLEY: Yes, we believe with respect to '219,  
4 if you accept our legal argument, '219 is safe, and we're done  
5 talking.

6 Now, they have this SEC argument I'll mention on the  
7 next slide.

8 With respect to the earlier patents, these SP and  
9 Oread agreements were so-called CMO agreements. Those are  
10 service agreements. I'll talk a little bit more about that in  
11 a moment.

12 The MGI agreement was not a commercial offer for sale  
13 of the claimed invention, and why not? Because the claimed  
14 invention, as we'll point out, didn't exist at that time.  
15 They had -- Helsinn had no idea what would be approved by the  
16 FDA. They went into Phase III with two different  
17 formulations, and, furthermore, didn't know if either would be  
18 approved.

19 So at that point in time, they did not have a  
20 formulation, did not know what it would be that would be  
21 suitable for treating CINV.

22 And then, finally, the claimed inventions were not  
23 shown to work for their intended purpose before the critical  
24 date. And, finally, after that, we will show you that the  
25 Patent Office agreed with us.