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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

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 NUMBER:

11-3962

TRIAL

Clarkson S. Fisher United States Courthouse
402 East State Street
Trenton, New Jersey 08608
June 10, 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.
v.
Helsinn Healthcare S.A., et al.

1
2 UNITED STATES DISTRICT COURT
3 FOR THE DISTRICT OF NEW JERSEY

4 _____
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
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A P P E A R A N C E S:

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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>
KEITH CANDIOTTI					
By Mr. Dittman	4	14		266	
By Ms. Huttner			111		276

1 BY MR. DITTMANN:

2 Q. And just to finish and we'll move on from this section,
3 do you have an opinion as to whether a POSA in 2003 would have
4 pursued a dose that treated all PONV patients as opposed to
5 just certain subpopulation groups?

6 A. So, as I was making clear, you'd pick a drug that would
7 cover as many people as reasonably -- a dose that would cover
8 as many people as reasonably possible. It would be very
9 difficult to clinically utilize a drug that was keyed only to
10 certain subpopulations.

11 Q. Thank you.

12 So, Doctor, we have been talking so far about a PONV
13 dose. If a POSA was focused on developing a palonosetron drug
14 product to treat CINV, do you have any opinion as to the dose
15 they would have pursued?

16 A. So, even during this time period, it was known that
17 CINV -- chemotherapy is a major toxin, and the doses are
18 almost always or basically always higher, and anywhere from a
19 multiple of 2 to 10 perhaps, so if 2 milligrams, using that
20 dose, is necessary to treat a 70-kilogram person, in
21 chemotherapy, you would use multiples of that, be it 4 up to
22 20 milligrams, as it were. That would be a reasonable
23 assumption, consistent with the other known setrons at the
24 time.

25 THE COURT: Your answer assumed that the 2 milligrams

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