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

WITH SEALED PORTIONS

Clarkson S. Fisher United States Courthouse
402 East State Street
Trenton, New Jersey 08608
June 15, 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

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I N D E X

THE COURT: -- item, which would be --

THE WITNESS: Product specification, yeah.

THE COURT: And, so, although you use different words, your slides, in terms of process definition, are not that different, are they? How are they different?

THE WITNESS: No. I mean, I think the difference is that the product profile in Dr. Kirsch's definition is something that might -- like, you get a report and the formulator is charged, okay, this is what we want to do; you go make it. My position is the formulator is involved in the product profile.

THE COURT: Okay. I thought I understood that to be your point.

BY MR. DITTMANN:

Q. And just if we can focus just on PDX 709 for one moment. Just to make sure the record is clear, it's your experience that the formulator team member of this development team would be involved with all four steps seen on PDX 709, correct?

A. Yes.

Q. Now, we have talked about the first two steps a bit already in connection with your background.

With respect to this third step we see here, considering the dose, volume, clinical parameters, can you briefly describe how this work is typically accomplished in a drug development team?

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