UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

HELSINN HEALTHCARE S.A. and ROCHE PALO ALTO LLC.,	:	
Plaintiffs,	:	
	:	Civil Action No. 11-3962 (MLC)(DEA)
v.	:	Civil Action No. 11-5579 (MLC)(DEA)
	:	(consolidated)
DR. REDDY'S LABORATORIES, LTD., DR. REDDY'S LABORATORIES, INC., SANDOZ INC., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES, LTD.,	:	[redacted]
Defendants.	:	

EXPERT REPORT OF LEE KIRSCH, PH.D.

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I, Lee Kirsch, Ph.D., submit my expert report in the above-referenced case on behalf of Defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd. (collectively "Teva") and Sandoz Inc. ("Sandoz"). I reserve the right to amend or supplement my opinions in light of evidence presented by Helsinn Healthcare S.A. and Roche Palo Alto LLC (collectively "Helsinn" or "Plaintiffs"), or additional information that may be made available to me in the future. I have not yet created the exhibits or demonstratives that I expect to use to summarize or explain my opinions at trial, but they will likely include formulation summaries and presentations showing the formulation development background described in this report.

I. QUALIFICATIONS.

1. I am currently a Professor at the University of Iowa, College of Pharmacy, Division of Pharmaceutics. A complete list of my publications, presentations, professional activities, and honors that I have received are fully set forth in my *curriculum vitae*, attached hereto at Exhibit A.

2. I received a B.S. degree in Pharmacy in 1975 from Purdue University and received a Ph.D. in Pharmaceutical Chemistry in 1982 from the Ohio State University. From 1982 to 1994, I was a research scientist at Lilly Research Laboratories in the Pharmaceutical Product Development Division. During my time at Lilly, my responsibility was to develop drug formulations for new drug substances and to address formulation issues associated with marketed drug products. My particular area of focus was injectable drug product design and development, including drugs intended for intravenous and extravascular administration. During my industrial tenure, my research focus was on drug stability issues as evidenced by my publication and presentation history during this time period. In 1994, I took a position at the University of Iowa College of Pharmacy, first as an Associate Professor and then in 2010 as a full Professor. During my time at Iowa, my research has continued to focus on issues of drug product design and

development, and especially drug product stability. In addition to conducting fundamental research on drug stability phenomena, I also have had the opportunity to work on numerous industrially-supported projects, addressing various drug product performance and design issues for injectable, solid oral, topical and various other types of drug formulations. I also have had the opportunity to teach courses at Iowa, including drug degradation kinetics and mechanisms, drug stability, pharmaceutical proteins, advanced compounding, solid dosage forms, lyophilization, pharmaceutical product development, pharmacokinetics and biopharmaceutics, pharmaceutical package design and integrity, and pharmaceutical technology.

3. I have received numerous awards and honors, including the Distinguished Service Award from the Parenteral Drug Association, Jack L. Beal Post Baccalaureate Award from The Ohio State University, Fred Simon Award for the best paper in the PDA Journal of Pharmaceutical Science and Technology, Editor-in-chief for the AAPS PharmSciTech Journal, and Editor of the PDA Journal of Pharmaceutical Science and Technology.

4. I have authored or co-authored over 50 published scientific articles in the areas of pharmaceutical chemistry, drug stability, drug delivery, pharmacokinetics, pharmaceutical package integrity, and analytical chemistry. I have served as a peer-reviewer on various well-respected pharmaceutical science and technology journals, including *Journal of Pharmaceutical Science, Drug Development and Industrial Pharmacy, Pharmaceutical Research, International Journal of Pharmaceutics, PDA Journal of Pharmaceutical Science and Technology, Journal of Pharmaceutical Innovation, Pharmaceutical Development and Technology, AAPS PharmSciTech,* and *International Journal of Chemical Kinetics*.

5. In the last four years, I have testified at trial or by deposition in *AstraZeneca v. Mylan*, (10-cv-05519) (D.N.J. 2012).

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