UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

PAR PHARMACEUTICALS, INC. AND HANDA PHARMACEUTICALS, LLC, Plaintiffs, v. TAKEDA PHARMACEUTICAL CO., LTD., TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., TAKEDA PHARMACEUTICALS AMERICA, INC., AND TAKEDA PHARMACEUTICALS U.S.A., INC., Defendants.	Case No. 5:13-CV-1927 LHK (PSG) **DECLARATION OF MICHAEL MAYERSOHN, PH.D. IN SUPPORT OF DEFENDANTS' CLAIM CONSTRUCTION BRIEF** Date: June 12, 2014 Time: 1:30 p.m. Courtroom: 8, 4th Floor Judge: Hon. Lucy H. Koh
TAKEDA PHARMACEUTICAL CO., LTD., TAKEDA PHARMACEUTICALS U.S.A., INC., AND TAKEDA PHARMACEUTICALS AMERICA, INC., Plaintiffs, v. IMPAX LABORATORIES, INC., Defendant.	Case No. 5:13-CV-2416 LHK (PSG)
TAKEDA PHARMACEUTICAL CO., LTD., TAKEDA PHARMACEUTICALS U.S.A., INC., AND TAKEDA PHARMACEUTICALS AMERICA, INC., Plaintiffs, v. TWI PHARMACEUTICALS, INC., Defendant.	Case No. 5:13-CV-2420 LHK (PSG)

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EXHIBIT

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I, Michael Mayersohn, Ph.D., declare as follows:

1. I submit this declaration in support of the claim construction brief submitted by defendants Impax Laboratories, Inc., Par Pharmaceutical, Inc., Handa Pharmaceuticals LLC, and TWi Pharmaceuticals, Inc. (collectively, "Defendants").

2. In particular, I submit this declaration to provide relevant background information regarding the technology at issue in U.S. Patent No. 8,173,158 (the "'158 patent"),[1] and to set forth my opinions regarding the meaning of the disputed claim terms from the perspective of a person of ordinary skill in the pertinent art at the relevant time.

I. QUALIFICATIONS

3. The following is a brief summary of my qualifications. My qualifications are more fully set forth in my curriculum vitae, attached as Exhibit B.

4. I was awarded the degree of Bachelor of Science in Pharmacy in 1966 from Columbia University College of Pharmaceutical Sciences and a Ph.D. in Pharmaceutics from the School of Pharmacy, State University of New York at Buffalo in 1971.

5. I was licensed by the State of New York to practice pharmacy in 1967 and practiced pharmacy in Buffalo, New York from that time until 1971.

6. Following receipt of my doctoral degree, I became an Assistant Professor in the Faculty of Pharmacy at the University of Toronto in Canada and became an Associate Professor there in 1975.

7. I have been a faculty member of the College of Pharmacy at the University of Arizona in Tucson since 1976, starting as an Associate Professor. I have been a full Professor since 1983.

[1] A copy of the '158 patent is attached as Exhibit A.

8. I have been a member of the Interdisciplinary Graduate Program in Pharmacology and Toxicology, the Center for Toxicology, and the Southwest Environmental Health Sciences Center, all of which are at the University of Arizona.

9. My research interests include the general area of pharmaceutical sciences with a specialty in pharmaceutics, biopharmaceutics and pharmacokinetics, including (a) the examination of the relationship between the physical and chemical characteristics of a drug and its dosage form and the fate and performance of that drug in the body, and (b) the development of rigorous mathematical models to quantitate the kinetic processes of drug absorption, distribution, excretion, metabolism, and clinical or pharmacological response.

10. I have maintained an active research program, which has been funded by national, state and private agencies. This program has involved numerous research projects and the supervision of many graduate students, post-doctoral fellows and technicians.

11. I have conducted research studies *in vitro* to characterize the physical and chemical properties of drugs and drug dosage forms including dissolution rates, stability and binding to other compounds. These studies have included an examination of the properties of a variety of drug dosage forms, including immediate and non-immediate release oral formulations.

12. I have also conducted *in vitro* and *in vivo* studies to characterize the plasma protein binding of drugs and their metabolic properties in the presence of varying enzymatic preparations.

13. I have conducted *in situ* and whole animal studies (in mice, rats, dogs and pigs) to characterize the pharmacokinetics and pharmacodynamics of drugs and their metabolites.

14. I have conducted clinical studies in human subjects to evaluate the pharmacokinetics of selected drugs and their metabolites. In all of the above studies, I developed selective, sensitive and reliable quantitative analytical methods.

15. In addition, I have performed "theoretical" or *in silico* experiments using simulation and other mathematical/computer techniques in order to answer specific questions concerning the disposition or interaction of drugs.

16. I am a member of several professional societies and organizations, including the American Association of Pharmaceutical Scientists, the American Society for Clinical Pharmacology and Therapeutics, and the American Society of Pharmacology and Experimental Therapeutics.

17. I have reviewed and continue to review publications for several peer-reviewed journals, including the Journal of Pharmaceutical Sciences and Pharmaceutical Research.

18. I have been a member of numerous national and state grant review agencies (National Institutes of Health, Veterans Administration, *etc.*) for which I reviewed research grant applications.

19. I have published over 160 original research publications, 18 book chapters and symposia, and 15 professional/educational publications. I have given more than 65 invited presentations and contributed to over 160 submitted presentations.

20. During the years 1995-1998, I was a member of the Food and Drug Administration ("FDA") Advisory Committee for Pharmaceutical Sciences (formerly, the Generic Drug Advisory Committee). This Committee advises the FDA in setting standards for bioavailability, bioequivalence, and in resolving matters of scientific interest to the agency.

21. I served one five-year term as a member of the Dissolution and Bioavailability Expert Committee of the United States Pharmacopoeia and a subsequent five-year term as Vice Chair of the same Committee, whose name was changed to the Biopharmaceutics Expert Committee. This Committee sets standards for dissolution testing and for drugs that are incorporated into individual monographs.

22. I am also the Course Director and Instructor of "Principles of Pharmacokinetics and Toxicokinetics for the Industrial Scientist," which is sponsored by the University of Arizona and given

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