UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

~~TORRENT~~APOTEX, INC. and MYLAN PHARMACEUTICALS ~~LTD~~INC.,~~ Petitioner~~

Petitioners

v.

NOVARTIS AG AND MITSUBISHI PHARMA CORPORATION,

Patent ~~Owner~~Owners

Inter Partes Review No.: ~~2014-00784~~To Be Assigned

U.S. Patent No. 8,324,283

DECLARATION OF ~~JOHN S. KENT~~ARTHUR KIBBE, PH.D

~~Petition for Inter Partes Review~~

~~Of U.S. Patent 8,324,283~~

~~Exhibit~~

~~TORRENT – 1004~~

~~(Del)~~

(Add) Petition for Inter Partes Review Of U.S. Patent 8,324,283 Exhibit APOTEX/MYLAN – 1004

Torrent et al. v. Novartis IPR2014-00784/IPR2015-00518

I, ~~John S. Kent~~Arthur Kibbe, Ph.D., declare and state as follows:

I. QUALIFICATIONS

~~1. I am a consultant on pharmaceutical development issues with more than~~

1. I am a Professor of Pharmaceutical Sciences at the Nesbitt School of Pharmacy, Wilkes University. I am also the past Chair of the Department of Pharmaceutical Sciences in the School of Pharmacy.

~~25 years of experience in all phases of new product and formulation development.~~

2. I earned a ~~B.S.~~Bachelor of Science degree in Pharmacy from Columbia University in 1966, a Master of Science degree in Pharmacy from the University of ~~Wisconsin~~Florida in ~~1965~~1968, and ~~a~~my Ph.D. in ~~Pharmacy~~Pharmaceutics from the University of ~~Wisconsin~~Florida in ~~1969.~~

~~3. From 1969 to 1989, I worked at Syntex within the Institute of Pharmaceutical Sciences ("Syntex") (now Roche Bioscience) in various areas of pharmaceutical development and formulation. From 1969 to 1977, I served as a staff researcher in Syntex's Dosage Design Department. From 1977 to 1979, I was a senior staff researcher in the Veterinary Pharmaceutical Development Department. From 1979 to 1981, I was the head of the Pharmaceutical Development Department (Systemic and Veterinary). From 1981 to 1984, I served as the head of the Human Pharmaceutical Development Department (Systemic). I was appointed director of Syntex's pharmaceutical development in 1984. In my capacity as director of pharmaceutical development, I was responsible for the successful design and formulation of human pharmaceutical products, including numerous solid dosage forms suitable for oral administration.~~

~~4. Following my position at Syntex, I became Vice President of~~

1973. My areas of concentration at that time were pharmaceutics, pharmacokinetics and biopharmaceutics. My dissertation was on the stability of solid dosage forms.

3. I joined the faculty of the Department of Pharmaceutical Sciences at Wilkes University as its Chair in 1994. In that capacity, I oversaw the construction of the laboratory and research space in the then-new School of Pharmacy. In 2013

I stepped down as department chair but continue to teach undergraduate and professional courses in pharmaceutics (dosage form design and manufacture) and pharmacokinetics. I was chair of the faculty for the University from 2007 to 2010. I am also a member of the Pharmacy School's curriculum committee and assessment committee.

4. I have held a variety of positions in academia, industry and the government over the course of my career. My work has been largely concentrated in the fields of pharmaceutical formulation development, pharmacokinetics, pharmaceutical testing, and drug regulatory and approval processes.

~~Pharmaceutical Sciences at Allergan, Inc., a position that I held from 1990 to 2002.~~

~~While at Allergan, I supervised the research and development of new pharmaceutical products, establishing new preformulation techniques to enhance the company's formulation development. I also oversaw the areas of pharmaceutical analysis, quality assurance, and clinical manufacturing throughout the formulation process.~~

5. From ~~2002~~1972 to ~~2004~~1984, I ~~worked as a pharmaceutical development consultant on formulation development and manufacturing issues for a number of small and large pharmaceutical companies.~~was an Assistant/Associate Professor of Pharmaceutics at the School of Pharmacy of the University of Mississippi. While at the University of Mississippi, I taught undergraduate and graduate level courses in the areas of formulation design and development, pharmacokinetics, and the physical chemistry of heterogeneous systems; conducted research in those areas, among others; and served as a thesis advisor to Ph.D. candidates.

~~6. From 2004 to 2008, I served as the Vice President of Pharmaceutical Sciences in the area of technical operations at Theravance, Inc. At Theravance, I oversaw the pharmaceutical product development program primarily involving the development and manufacturing of a lyophilized injectable dosage form, Vibativ®, and supervised pharmaceutical development teams to ensure the plan for future development and drug formulation included the appropriate science, *e.g.*, QbD, Quality by Design.~~

~~7. From 2008 through the present, I have been serving as a consultant for pharmaceutical companies primarily in the areas of pharmaceutical and formulation development, and as an expert witness.~~

~~8. I am the named inventor or co-inventor of 18 pharmaceutical patents, some of which are directed to formulations of solid oral dosages.~~

6. I served as the Chief of Pharmaceutical Development Services for the National Institutes of Health (NIH) in 1984-1985. In that position, I directed a staff of 15 scientists, developed delivery systems for Phase I clinical trials and supported the internal NIH clinical research program.

7. As the Senior Director of Professional and Scientific Affairs for the American Pharmaceutical Association from 1987-1992, my responsibilities included the development of policy statements on relevant scientific issues; the representation of the Association before Congress and the Food and Drug Administration (FDA); the development and management of symposia on scientific issues; the management of various professional staff; and the

management of the Journal of Pharmaceutical Science. While with the American Pharmaceutical Association, I served as the Chair of a special panel appointed by the Commissioner of the FDA to investigate the generic drug approval process. The work of this special panel produced a report entitled "Fairness in the Generic Drug Approval Process," sometimes referred to as "The Kibbe Report."

8. My experience also extends to the pharmaceutical industry. I was the Director of Client Services for BioResearch Laboratories, Ltd. from 1985-1987, where I negotiated the protocol design and contracts for hundreds of Phase I studies and bioequivalency studies. I was also the Director of Marketing for Pharmakon Research International, Inc. from 1992-1994, where I negotiated the protocol design and contracts for numerous preclinical trials.

9. I ~~have authored and co-authored more than 30 articles on drug design and the development of drug delivery systems including solid oral dosage formulations, which have been published in peer-reviewed journals including~~am a Fellow of the Academy of Pharmaceutical Research and Science, and have served on various editorial boards. I presently serve on the Editorial Review Panel of the Journal of ~~the American Chemical Society,~~ Drug Development and Industrial Pharmacy, and as a Reviewer for the Journal of Pharmaceutical ~~Sciences~~Science and the Journal of the American Pharmacists Association.

10. I was the Chair of the FDA Pharmaceutical Sciences Advisory Committee (2002 to 2004) and its subcommittee on current good manufacturing practice (cGMP) and process analytical technology (PAT). I continued as a member of this Advisory Committee until 2006. I have also served as a scientific

consultant to the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce of the United States House of Representatives. I have also served as a member of the FDA's Generic Drug Advisory Committee.

11. I have authored or co-authored numerous papers in refereed journals, have written a number of essays and articles published in the professional press, and have made a number of presentations before national and international professional societies.

12. I co-authored the "Generic Drugs and Generic Equivalency" chapter in the Encyclopedia of Pharmaceutical Technology (1st Ed. 1993) and authored that chapter in the two subsequent editions of the Encyclopedia of Pharmaceutical Technology. As an invited guest speaker, I have lectured on the generic drug approval process.

~~10~~13. I ~~am currently a member of the American Association~~served as the Editor-in-Chief of the Handbook of Pharmaceutical ~~Scientists, and was formerly Committee Chairman of the organization from 1988 to 1989. I have also been a member of multiple organizations related to pharmaceutical development and drug design, including the Controlled Release Society and APhA Academy of Pharmaceutical Sciences. I was a member of~~Excipients (3rd Ed. 2000) and authored a number of the monographs contained therein. This is a standard reference text widely used by pharmaceutical formulators. I have served on the Steering Committee for ~~PhRMA,~~the Handbook of Pharmaceutical ~~Development Subsection, from~~Excipients since its second edition published in 1994 and continue to do so to this date. I have also authored a chapter entitled "Theory of Dissolution" in the book, Dissolution Theory, Technology & Methods, edited by Anthony Palmieri III.

~~1987 to 1989 and from 2000 to 2002. I was also elected Chairman of the Northern~~

14. During the course of my career, I have received several awards and honors, including recognition for my contributions to the training of pharmacy students. I have had the privilege of instructing students in pharmaceutical formulation for over 25 years.

~~California Pharmaceutical Discussion Group from 1977 to 1978.~~

~~11~~15. A more detailed account of my work experience, professional services, patents, publications, and other qualifications is listed in my *Curriculum Vitae,* which is attached hereto as Appendix A.

~~12~~16. I have been retained by counsel for ~~Petitioner Torrent Pharmaceuticals~~Petitioners Apotex, Inc. and~~Ltd~~Mylan Pharmaceuticals Inc. to provide an expert declaration in this action.

~~13. As set forth in more detail below, the patent at issue here, U.S. Patent No. 8,324,283, relates generally to the formulation of a solid oral dosage containing an active pharmaceutical compound and at least one excipient. Similar to the patent at issue, my previous research and industry experience focused on the design and formulation of pharmaceutical dosages suitable for oral administration including, for example, Aleve®.~~17. The opinions and conclusions I express in this declaration are based on my education, my extensive experience in this field, and my review of the materials related to this matter.

~~14~~18. I am being compensated at my customary consulting rate for my time spent on this matter, and I am also being reimbursed for reasonable expenses incurred with respect to this matter. My compensation is not contingent on the conclusions I reach herein or on the specifics of my testimony. I have no financial stake in the outcome of this proceeding.

II. MATERIALS REVIEWED

~~15~~19. In forming my opinions, I have reviewed, among other ~~things~~documents, U.S. Patent 8,324,283 ("the '283 patent") and papers filed in the Patent Office in connection with prosecution of the '283 patent, which I understand to constitute the prosecution history of the '283 patent. I have also reviewed the petition, the Board's decision and related documents in IPR2014-00784 (the "Torrent IPR"). I note that I agree with the analysis and opinions set forth by the petitioner's expert, Dr. Kent, in the declaration that was submitted in the Torrent IPR proceeding and share many of those same opinions below. Because my independent analysis of the claims and prior art led to the same conclusions as the expert in the Torrent IPR, I have incorporated many of his arguments and characterizations below as my own. A full list of materials I have considered can be found in Appendix B.

III. LEGAL STANDARDS

~~16~~20. In this section I describe my understanding of certain legal standards. ~~I~~I have been informed of these legal standards by ~~Petitioner's~~Petitioners' attorneys~~, who have supplied me with The Federal Circuit Bar Association's Model Patent Jury Instructions~~. I am not an attorney, and I am relying only on instructions from ~~Petitioner's~~Petitioners' attorneys for these legal standards. I have applied these understandings in my analysis as detailed below.

~~17. I understand that in order to receive a patent an inventor must invent or discover a new and useful process, machine, manufacture, or composition of matter.~~

~~18. I understand that patent protection may be granted for any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.~~

~~19. With respect to the level of ordinary skill in the art at the relevant times applicable to~~

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