

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RANBAXY LABORATORIES LTD and RANBAXY INC.,
Petitioners

v.

ADAMAS PHARMACEUTICALS, INC.,
Patent Owner

Inter Partes Review No.: 2015-00410

U.S. Patent No. 8,362,085

DECLARATION OF ARTHUR H. KIBBE, Ph.D.

I, Arthur H. Kibbe, Ph.D., declare and state as follows:

I. QUALIFICATIONS

1. I am a Tenured Professor in the Department of Pharmaceutical Sciences at Wilkes University Nesbitt School of Pharmacy in Wilkes-Barre, Pennsylvania. I have held this position since 1994. From 1994 to 2012, I was Chair of the Department of Pharmaceutical Sciences at Wilkes University Nesbitt School of Pharmacy.

2. My areas of expertise include drug product formulation, pharmacokinetics and biopharmaceutics. I have over 40 years of experience working directly or indirectly with the pharmaceutical industry, the Food and Drug Administration (FDA), professional and trade associations, and academia.

3. I received my Bachelor of Science in Pharmacy in 1966 from Columbia University in New York City and received both my Master of Science and Ph.D. in Pharmaceutical Sciences from the University of Florida in 1968 and 1973, respectively. My Ph.D. includes a specialty in Pharmacokinetics and Biopharmaceutics, as well as formulation design and development.

4. I am a Fellow of the Academy of Pharmaceutical Research and Science, and a member of Rho Chi Honorary Pharmaceutical Society. Since 2000, I have been a Member of the Food and Drug Administration's Scientific Advisory Committee, and I served as chairman of the committee from 2001-2004. I have also been a consultant to the Subcommittee on Oversight of the Energy and Commerce Committee of the United States Congress (1990 to 1992). I also have been a member of the FDA's

Generic Drug Advisory Committee and was Chairman of a special panel appointed by the FDA Commissioner to investigate Fairness in the Generic Drug Approval Process.

5. I was Editor-in-Chief of the *Handbook of Pharmaceutical Excipients, 3rd Edition* and also a contributing author of several monographs. I was on the Steering Committee of the *Handbook of Pharmaceutical Excipients, 2nd, 4th, 5th, and 6th Editions*. I continue to serve on the Steering Committee for upcoming editions, and continue to contribute to many of the monographs.

6. A copy of my curriculum vitae, which includes a more detailed description of my credentials and a list of my publications, is attached hereto as Appendix A.

7. I am being compensated \$500 per hour for work performed for this matter. My compensation is not dependent on the outcome of this matter.

II. MATERIALS REVIEWED

8. In forming my opinions, I have reviewed, among other things, U.S. Patent No. 8,362,085 (“the ’085 patent,” Ex. 1001) and papers filed in the U.S. Patent and Trademark Office (“PTO”) in connection with prosecution of the application that issued as the ’085 patent and the applications leading to the ’085 patent, which I understand to constitute the prosecution history of the ’085 patent. I have also relied upon my accumulated scientific knowledge and experience. I have further reviewed numerous patents and printed publications. A full list of materials I have considered can be found attached hereto as Appendix B.

III. LEGAL STANDARDS

9. In this section I describe my understanding of certain legal standards. I have been informed of these legal standards by Petitioners' attorneys. I am not an attorney, and I am relying only on instructions from Petitioners' attorneys for these legal standards. I have applied these understandings in my analysis as detailed below.

10. 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.

11. 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.

A. The Ordinarily-Skilled Artisan

12. With respect to the level of ordinary skill in the art at the relevant times applicable to the '085 patent, I understand that factors such as the education level of those working in the field, the sophistication of the technology, the types of problems encountered in the art, the prior art solutions to those problems, and the speed at which innovations are made may help establish the level of skill in the art. I also understand that one with ordinary skill has the ability to understand the technology and make modest adaptations or advances, with ordinary creativity, and is not an automaton.

13. I am advised that patents are addressed to a person who is described as having "ordinary skill in the art," who sets the standard by which patents are

interpreted and determines the extent to which they represent an improvement in the art. I have been advised that several factors may be considered in determining the level of “ordinary skill in the art,” including: the education of those who worked in the field of the invention, including the inventor and others; the nature of the challenges typically encountered in the relevant art; and how the prior art has provided solutions to those challenges.

14. It is my opinion that a person of ordinary skill in the art for the subject matter of the claims of the '085 patent would possess a relatively high level of skill. This person would have at least a Master's degree or Ph.D. degree in the field of pharmaceutical sciences or a related discipline, as well as several years of experience formulating pharmaceutically active compounds in various dosage forms, including immediate and sustained release dosage forms. If such a person were to have a higher degree of experience, that person could have a lower level of formal education. A person of ordinary skill in the art would collaborate with others who have expertise in methods of treating Alzheimer's disease and dementia. A person of ordinary skill in the art would understand the references referred to herein and have the capability to draw inferences from them.

15. I consider myself to have been an expert in the art of the '085 patent at the time of the alleged inventions claimed therein.

B. Claim Construction

16. I understand that the first step in interpreting patent claims is to properly

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