

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BRECKENRIDGE PHARMACEUTICAL, INC.,

Petitioner,

v.

NOVARTIS AG,

Patent Owner.

IPR2016-01023 and IPR2016-01103

PAR PHARMACEUTICAL, INC.,

Petitioner,

v.

NOVARTIS AG,

Patent Owner.

IPR2016-01059

ROXANE LABORATORIES, INC.,

Petitioner,

v.

NOVARTIS AG,

Patent Owner.

IPR2016-01102

Patent No. 5,665,772

**EXPERT DECLARATION OF PROFESSOR
ALEXANDER M. KLIBANOV**

I, Alexander M. Klibanov, Ph.D., declare as follows:

1. I submit this expert declaration in response to certain arguments made in the following four petitions for *inter partes* review (“IPR”) and two expert declarations cited in those petitions:

- a. Breckenridge Pharmaceutical, Inc.’s Petition For *Inter Partes* Review Of U.S. Patent No. 5,665,772 (IPR2016-01023, Paper 4) (requesting IPR of claims 1-3 and 8-10) (“**Breckenridge Pet. I**”).
- b. Breckenridge Pharmaceutical, Inc.’s Petition For *Inter Partes* Review Of U.S. Patent No. 5,665,772 (IPR2016-01103, Paper 1) (requesting IPR of claim 7) (“**Breckenridge Pet. II**”).
- c. Par Pharmaceutical, Inc.’s Petition For *Inter Partes* Review Of U.S. Patent No. 5,665,772 (IPR2016-01059, Paper 1) (requesting IPR of claim 7) (“**Par Pet.**”).
- d. Roxane Laboratories, Inc.’s Petition For *Inter Partes* Review Of U.S. Patent No. 5,665,772 (IPR2016-01102, Paper 2) (requesting IPR of claims 1-3, 7-10) (“**Roxane Pet.**”).
- e. Declaration of William L. Jorgensen, Ph.D., in Support of Petition for *Inter Partes* Review of U.S. Patent No. 5,665,772, submitted in IPR Nos. 2016-01059 (Ex. 1003), 2016-01102 (Ex. 1003), and 2016-01103 (Ex. 1003), and also submitted, but not relied upon, in

IPR2016-01023 (Ex. 1003) (“**Jorgensen Decl.**”).

- f. Declaration of Steven W. Baldwin, Ph.D., in Support of Petition for *Inter Partes* Review of U.S. Patent No. 5,665,772, submitted in IPR No. 2016-01023 (Ex. 1030) (“**Baldwin Decl.**”).

I. Qualifications

2. I am a Novartis Endowed Chair Professor of Chemistry and Bioengineering at the Massachusetts Institute of Technology (“M.I.T.”), where I have been teaching and conducting research for over 37 years.¹ In 2012-2013, I held the Roger and Georges Firmenich Endowed Chair Professorship in Chemistry and Bioengineering, and in 2007-2012, the same chaired professorship as I currently hold. Prior to that, I was a Professor of Chemistry and a Professor of Bioengineering at M.I.T., positions I held from 1988 and 2000, respectively. From 1979 to 1988, I was an Assistant Professor, then Associate Professor, and thereafter a Full Professor of Applied Biochemistry in the Department of Applied Biological Sciences (formerly the Department of Nutrition and Food Science) at M.I.T.

¹ Novartis has no say in who receives this chair or my compensation at M.I.T., and my title at M.I.T. in no way affects the content of this declaration or my opinions in this matter.

3. I obtained my M.S. in Chemistry from Moscow University in Russia in 1971 and Ph.D. in Chemical Enzymology from the same University in 1974. Thereafter, I was a Research Chemist at Moscow University's Department of Chemistry for three years. From 1977 to 1979, following my immigration to the United States, I was a Post-Doctoral Associate at the Department of Chemistry, University of California in San Diego.

4. Over the last 40+ years as a practicing chemist, I have extensively researched, published, taught, and lectured in many areas of chemistry, including biological, medicinal, physical, bioorganic, formulation, and polymer.

5. During my research career, I have earned numerous prestigious professional awards and honors. For example, I was elected to the U.S. National Academy of Sciences (considered among the highest honors that can be given to an American scientist) and also to the U.S. National Academy of Engineering (considered among the highest honors that can be given to an American engineer). I am also a Founding Fellow of the American Institute for Medical and Biological Engineering and a Corresponding Fellow of the Royal Society of Edinburgh (Scotland's National Academy of Science and Letters). In addition, I have received the Arthur C. Cope Scholar Award (for achievements in organic chemistry), the Marvin J. Johnson Award (for achievements in biochemical technology), the Ipatieff Prize (for achievements in physical chemistry, particularly

in catalysis), and the Leo Friend Award, all from the American Chemical Society, as well as the International Enzyme Engineering Prize.

6. I have published over 310 scientific papers in various areas of chemistry and am also a named inventor of 21 issued United States patents and of many pending and foreign ones. I have given some 370 invited lectures (including a number of named lectures) at professional conferences, universities, and corporations all over the world, numerous of them dealing with formulation, solubility, stability, delivery, and biological evaluation of pharmaceutically active compounds.

7. In addition to research and teaching at M.I.T., I have consulted widely for pharmaceutical, medical device, chemical, and biotechnology companies, including both innovator and generic pharmaceutical companies. I have also founded six pharmaceutical companies and have been on the scientific advisory boards and/or boards of directors of those companies and of many others. A number of these consulting, advisory, and directorship activities have dealt specifically with the formulation, solubility, stability, delivery, administration, and biological evaluation of pharmaceutically active compounds, as well as their discovery and development.

8. My curriculum vitae, which lists my professional experience and academic qualifications in greater detail, is attached hereto as Exhibit 2402.

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