

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX CORP.,
Petitioner

v.

ALCON RESEARCH, LTD.,
Patent Owner.

Case IPR2013-00428
U.S. Patent No. 8,268,299 B2

DECLARATION OF HENRY GRABOWSKI, Ph.D.

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I, Henry Grabowski, hereby declare as follows:

I. Introduction

1. I am over the age of eighteen (18) and otherwise competent to make this declaration.

2. I understand that the Patent Trial and Appeal Board has granted Apotex Corp.'s ("Apotex") petition to institute this Inter Partes Review ("IPR") regarding claims 1–28 of United States Patent No. 8,268,299 (the "'299 patent") on obviousness grounds.

A. Qualifications

3. I am currently Professor Emeritus of Economics and the Director of the Program in Pharmaceuticals and Health Economics at Duke University. I received my Bachelor of Science degree in engineering physics from Lehigh University in 1962. In 1967, I obtained a doctorate in economics from Princeton University. My academic and research specialties are in the pharmaceutical industry—health economics, economics of innovation, and government regulation.

4. I have studied the economics of the pharmaceutical industry over much of my career, and I have published numerous articles and books on this industry. I created a graduate course at Duke on economics and policy issues in the pharmaceutical industry. Under a series of grants from the National Science Foundation, I have examined the economics of pharmaceutical research and

development (“R&D”) and the effect of various government policy actions on drug innovation. I have testified several times before Congressional committees in the United States on pharmaceutical industry issues. For example, since 1994, I have testified on issues involving effective patent life and generic competition in pharmaceuticals, generic biologics, the Clinton Administration’s health reform legislation, and the federal government’s policy toward children’s vaccines.

5. I have been an advisor and consultant to the National Academy of Sciences, Institute of Medicine, Federal Trade Commission, General Accounting Office, and Office of Technology Assessment. I have also held visiting scholar appointments at the International Institute of Management in Berlin, Germany, Health Care Financing Administration in Washington, D.C., the Office of Health Economics in London, and the Centre for Medicines Research in London. Until its acquisition by Gilead Sciences in 2003, I served on the Board of Directors of Triangle Pharmaceuticals, Inc., a development-stage company that specialized in antiviral drug therapies.

6. I have done extensive research on the economics of competition in the pharmaceutical industry, including the role of patents and the importance of R&D. I have also performed several studies on pharmaceutical R&D costs and profits.

The Congressional Budget Office has used my work in this regard to analyze the effects of the Drug Price Competition and Patent Term Restoration Act (“Hatch-

Waxman Act”) on R&D returns and to analyze the proposed changes associated with the Health Security Act of 1993.

7. Exhibit AL 2008 is a copy of my curriculum vitae, which includes a more detailed description of my education and professional experience, as well as a list of my publications from the last forty years.

B. Assignment

8. I have been retained by Williams & Connolly LLP on behalf of Alcon Research, Ltd. (“Alcon”) to serve as an expert witness in this action.

9. In particular, I have been asked to opine on whether Alcon’s drug, TRAVATAN Z[®], is a commercial success, and if so, to address the factors underlying its commercial success, including whether there is a nexus between its commercial success and the features of the claimed invention. I have also been asked to opine on whether Alcon’s promotional expenditures on TRAVATAN Z[®] are in line with that of other competing products.

10. In connection with the opinions and conclusions contained within this declaration, listed below are the documents that I have reviewed and considered or created (based on data from IMS Health and Encuity Research, which I understand are being provided to Apotex) in connection with the opinions and conclusions contained within this declaration. I have also relied on my training, my years of

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