

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

ASTRAZENECA
Patent Owner.

Patent No. RE44,186

DECLARATION OF DAVID P. ROTELLA, PH.D.

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I, David P. Rotella, declare as follows:

I. QUALIFICATIONS

1. My name is David P. Rotella. I am currently the Margaret and Herman Sokol Professor of Chemistry in the Department of Chemistry and Biochemistry and in the Sokol Institute of Pharmaceutical Life Sciences at Montclair State University. I have been a member of the faculty of this university since 2011.

2. I am currently an adjunct professor in the Department of Pharmaceutical Sciences at the University of Pittsburgh, in the Center for Drug Discovery at Northeastern University, and in the Department of Medicinal Chemistry at the University of Mississippi. I have been a member of the faculty of these departments since 2010, 2010, and 2009, respectively.

3. I am currently a registered pharmacist in the Commonwealth of Pennsylvania.

4. I was formerly a research scientist at multiple pharmaceutical companies during the years 1991-2010, including at Bristol-Myers Squibb PRI, Lexicon Pharmaceuticals, and Wyeth Research/Pfizer. My industry experience focused on drug discovery and development.

5. I received my B.S. Pharm. from the University of Pittsburgh in 1981 and Ph.D. in Medicinal Chemistry from The Ohio State University in 1985. I was a Postdoctoral Scholar in the Department of Chemistry at The Pennsylvania State University from 1985 to 1987.

6. My current research focuses on protein kinase inhibitors for anti-infective and anti-inflammatory applications. Specifically, I work on the discovery of new agents useful for the potential treatment of parasitic and neurodegenerative diseases, including the synthesizing of new analogs of a lead structure as potential protein kinase inhibitors and investigation of structure-activity relationships in a product that has HSP90 inhibitor activity.

7. I have authored or co-authored more than 20 abstracts for presentation at professional meetings, 40 peer-reviewed journal articles, and seven book chapters. I have also edited or co-edited five books in the field of Medicinal Chemistry. I have received numerous honors, fellowships and awards, and am an inventor or co-inventor on seven granted patents.

8. A summary of my education, experience, publications, awards and honors, patents, publications, and presentations is provided in my CV, a copy of which is submitted separately (Ex. 1004).

II. SCOPE OF WORK

9. I understand that a petition is being filed with the United States Patent and Trademark Office for *Inter Partes* Review of U.S. Reissued Patent No. RE44,186 (hereinafter, “the ’186 patent,” Ex. 1001). I have been retained by Mylan Pharmaceuticals Inc. as a technical expert to provide opinions regarding the ’186 patent. I have reviewed the ’186 patent and relevant sections of its prosecution history in the US Patent and Trademark Office (Ex. 1006). I have also reviewed and considered other documents in arriving at my opinions, and cite them in this declaration. For convenience, documents cited in this declaration are listed

in the Appendix in Section XI.

10. I am compensated at the rate of \$500/hour for my work. I have no financial interest in the outcome of this matter.

III. OVERVIEW OF THE '186 PATENT

11. The '186 patent is entitled "Cyclopropyl-Fused Pyrrolidine-Based Inhibitors of Dipeptidyl Peptidase IV and Method" and was issued on April 30, 2013. I have been advised that the '186 patent issued from U.S. Application No. 13/308,658, which was filed on December 1, 2011, as a reissued application of U.S. Application No. 09/788,173, which was filed on February 16, 2001 and issued as U.S. Patent No. 6,395,767 on May 28, 2002. I have also been advised that U.S. Application No. 09/788,173 claims priority to U.S. Provisional Application No. 60/188,555, which was filed on March 10, 2000.

12. The '186 patent is generally directed to cyclopropyl-fused pyrrolidine-based compounds with a variety of optional substituents, as well as pharmaceutical combinations and methods for treating diabetes and additional diseases. According to the '186 patent, the "cyclopropyl-fused pyrrolidine-based compounds [of the '186 patent are] inhibitors of dipeptidyl peptidase IV [(DP-IV)] . . . for treating diabetes, especially Type II diabetes." Ex. 1001 col. 1, ll. 19-21. The '186 patent describes the mechanism by which DP-IV inhibition treats type 2 diabetes as follows: "[DP-IV] has been shown to be the primary degrading enzyme of GLP-1(7-36) in vivo . . . [t]hus, inhibition of [DP-IV] in vivo should potentiate endogenous levels of GLP-1(7-36) and . . . thus serve to ameliorate the diabetic condition." *Id.* at Col. 1, ll. 59-67.

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