UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TEVA PHARMACEUTICALS USA, INC.,
Petitioner,

v.

ASTRAZENECA
Patent Owner.

Patent No. RE44,186

DECLARATION OF RAMAIAH MUTHYALA, PH.D.

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I, Ramaiah Muthyala, declare and state as follows:

I. QUALIFICATIONS

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

2. My name is Ramaiah Muthyala. I am currently Associate Professor in the Department of Experimental Clinical Pharmacology at the University of Minnesota. I have been a member of the faculty of this university since 2006.

3. I was formerly a research scientist at multiple pharmaceutical companies during the years 1969-1999, including at Indian Drugs & Pharmaceuticals Ltd., Schering Plough, Dow Chemical Company, and 3M/Imation Corporation. My industry experience focused on drug discovery and development.

4. I received a Ph.D. in natural products from Sagar University, India in 1970 and a Ph.D. in heterocyclic chemistry from the University of East Anglia, UK in 1975. I also received an M.B.A. from St. Thomas University, MN, in 1999. I was a Postdoctoral Scholar at University of North Wales, UK, 1971-1972 and at Wayne State University, MI, 1974-1976.

5. I have authored or co-authored numerous abstracts for presentation at professional meetings, peer-reviewed journal articles, and am an inventor or co-inventor on seven U.S. patents.

6. 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. 1029).

II. SCOPE OF WORK

7. I have been retained as an expert witness on behalf of Teva Pharmaceuticals USA, Inc. ("Petitioner") for the above captioned *inter partes* review ("Teva IPR"). I am being compensated for my time in connection with this IPR at my standard consulting rate, which is $450 per hour. 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.

8. 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 understand that the '186 patent is currently subject to a previous IPR, *Mylan Pharmaceuticals Inc., v. AstraZeneca AB*, Case IPR2015-01340 (the "Mylan IPR"). I understand that Petitioner Teva seeks to become a party to the Mylan IPR. I have reviewed the materials submitted with the petition filed in the Mylan IPR, including the petition itself (IPR2015-01340, Paper 3), the Declaration of Dr. David P. Rotella (IPR2015-01340, Exhibit 1003), and the Board's Decision Instituting *Inter Partes* Review (IPR2015-01340, Paper 16). I have also reviewed and considered other documents (such as the relevant prior art) 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.

9. I note that I agree in all material respects with the analysis and

opinions set forth by the petitioner Mylan's expert, Dr. Rotella, in the declaration that was submitted in the Mylan IPR and share the same opinions below. Because my independent analysis of the claims and prior art led to the same conclusions as Dr. Rotella, coupled with the fact that the Petitioner Teva is seeking to become a party to the Mylan IPR, I have incorporated Dr. Rotella's opinions and characterizations below as my own. I do not independently address claim construction in this Declaration, because I understand that, in instituting IPR2015-01340, the Board has credited the testimony of Dr. Rotella on the views of a hypothetical person of ordinary skill in the art at the time of the invention, and has already determined that the claim terms are to be given their ordinary and customary meaning, as understood by one of ordinary skill in the art. IPR2015-01340, Paper 16. Accordingly, for purposes of this Declaration only, I will adopt the constructions set forth by Dr. Rotella in his Declaration.

10. I understand that in its Decision Instituting *Inter Partes* Review in connection with the Mylan IPR, the Board concluded that Petitioner Mylan demonstrated a reasonable likelihood of prevailing on its assertion that claims 1, 2, 4, 6-22, 25-30, 32-37 and 39-42 of the '186 patent are unpatentable. Specifically, the Board instituted review on four grounds: (1) claims 1, 2, 4, 6-11, 25-28, 32-35, 39 and 40 are obvious over Ashworth, Villhauer, Raag and Hanessian; (2) claims 12-16, 29, 30, 36, 37, 41 and 42 are obvious over Ashworth, Villhauer, Raag, Hanessian, Bachovchin and the GLUCOPHAGE Label; (3) claims 12, 17, 18 and 22 are obvious over Ashworth, Villhauer, Raag, Hanessian, Bachovchin and the XENICAL Label; and (4) claims 12 and 19-21 are obvious over Ashworth,

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