

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC. and AMNEAL
PHARMACEUTICALS LLC,

Petitioners

v.

YEDA RESEARCH AND DEVELOPMENT CO. LTD.

Patent Owner

Case No. IPR2015-00643 (8,232,250 B2)
Case No. IPR2015-00644 (8,399,413 B2)
Case No. IPR2015-00830 (8,969,302 B2)^{1, 2}

DECLARATION OF PROF. JOEL W. HAY

¹ Case Nos. IPR2015-01976, IPR2015-01980 and IPR2015-01981 have been joined with these proceedings.

² A word-for-word identical Declaration is being filed in each proceeding.

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I. INTRODUCTION

1. I, Professor Joel W. Hay, Ph.D., submit this Declaration on behalf of Mylan Pharmaceuticals Inc. and Amneal Pharmaceuticals LLC (Petitioners) in reply to the November 20, 2015 and November 25, 2015 Declaration of Henry G. Grabowski, Ph.D. (hereinafter “the Grabowski Declaration”) in the above-captioned case. I also respond to Dr. Grabowski’s testimony in his February 10, 2016 deposition (hereinafter “the Grabowski Deposition”).

2. I understand that Dr. Grabowski submitted declarations in IPR2015-00643, IPR2015-00644, and IPR2015-00830 each labelled as Exhibit 2133. I also understand that each of the three Declarations submitted by Dr. Grabowski are substantively identical. Accordingly, I address each Declaration herein.

3. A copy of my *curriculum vitae* is attached hereto as Exhibit A. A listing of legal cases where I have testified at trial or by deposition since 2012 is attached hereto as Exhibit B. A list of materials relied upon is attached here to as Exhibit C.

4. This Declaration discloses my opinions regarding, among other things, certain “secondary considerations” as they pertain to U.S. Patent Nos. 8,232,250 (the “250 patent”) (IPR2015-00643), 8,399,413 (the “413 patent”) (IPR2015-00644), and 8,969,302 (the “302 patent”) (IPR2015-00830). I refer to the pertinent patent below as the “patent at issue.”

5. My opinion is that Dr. Grabowski has not established commercial success of the Copaxone 40mg/mL formulation of glatiramer acetate or the patent at issue. It is also my opinion that none of the indicia of commercial success that Dr. Grabowski discusses have any nexus to the claims of the patent at issue.

6. I reserve the right to supplement this opinion as new or additional information becomes available to me.

7. I am being compensated for my testimony in the present case at my standard rate of \$900.00 per hour, plus any reasonable out-of-pocket expenses. No payments to me are contingent upon the outcome of this or any other hearings or litigation or upon the nature of my opinions.

II. BACKGROUND AND QUALIFICATIONS

8. In 1974, I received my B.A. in Economics, *summa cum laude*, from Amherst College. I then went on to receive my M.A. in Economics in 1975 and my M.Ph. in Economics in 1976 from Yale University. In 1980, I received my Ph.D. in Economics from Yale.

9. I am a tenured Full Professor and Founding Chair of Pharmaceutical Economics and Policy in the School of Pharmacy, with joint appointments in the Department of Economics and at the Schaeffer Center for Health Policy and Economics at the University of Southern California (USC). I also served for 15 years as the USC Project Coordinator for the Rand Evidence-Based Medicine

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