UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner

v.

YEDA RESEARCH & DEVELOPMENT CO., LTD.,
Patent Owner

U.S. Patent No. 8,399,413

Case IPR2015-00644

**EXPERT DECLARATION OF ARI GREEN, M.D.
IN SUPPORT OF PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE**

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1. I am the same Ari Green, M.D. who previously submitted a declaration in this proceeding dated February 5, 2015. I submit this expert declaration on behalf of Mylan Pharmaceuticals Inc. and Amneal Pharmaceuticals LLC to respond to certain opinions expressed in the expert declarations submitted with Patent Owner's Response to the Petition (Ex. 2129, 2134, 2135).

2. My *curriculum vitae* submitted with my original declaration is current. *See* Ex. 1004 at Ex. A.

3. In addition to the materials identified in my earlier declaration (Ex. 1004), and in addition to my experience, education, and training, I have also considered the materials cited herein and the materials identified in Exhibit A, in providing the opinions contained herein.

4. I reaffirm that my scope of work and compensation has not changed since I submitted my initial declaration in this proceeding. I have been retained by Mylan as a technical expert in this matter to provide various opinions regarding the patent at issue. I receive $1000 per hour for my services. No part of my compensation is dependent upon my opinions given or the outcome of this case. I do not have any current or past affiliation with Yeda Research & Development Co., Ltd., or the named inventor on the patent at issue.

I. SUMMARY OF OPINIONS

5. In my opinion, all claims of the patent at issue are obvious over Pinchasi in view of Flechter 2002A or the SBOA. Pinchasi discloses administration of 40 mg of glatiramer acetate ("GA") every other day. The claimed regimen is identical to Pinchasi, save for having one less dose every two weeks. This difference is minimal, and is well within GA's forgiving range. Flechter 2002A and the SBOA provide the POSA additional motivation and a reasonable expectation of success to develop a lower frequency dosing regimen. Flechter 2002A includes clinical data demonstrating that every other day administration of GA may be safe, effective, and well-tolerated. Flechter 2002A also suggests that a total weekly dose of only 70 mg may be efficacious. The SBOA includes a suggestion from an FDA reviewer as early as 1996 advocating for less frequent dosing. Especially in light of other background art—which provided additional clinical data supporting less frequent administration of GA, as well as a potentially therapeutically effective range of total weekly doses between 70 mg and 280 mg—a 40 mg three-times-weekly dosing regimen (total weekly dose of 120 mg) was obvious.

6. Further background knowledge and common sense of a POSA provided additional motivation to develop a less frequently administered dosing regimen. For example, both patients and doctors recognized that an effective GA

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