UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC., APOTEX CORP., ARGENTUM PHARMACEUTICALS LLC, ACTAVIS ELIZABETH LLC, TEVA PHARMACEUTICALS USA, INC., SUN PHARMACEUTICAL INDUSTRIES, LTD., SUN PHARMACEUTICAL INDUSTRIES, INC., AND SUN PHARMA GLOBAL FZE,

Petitioners,

v.

NOVARTIS AG,

Patent Owner.

Case IPR2017-00854[1]

U.S. Patent No. 9,187,405

REPLY IN SUPPORT OF CONTINGENT MOTION TO AMEND

Mail Stop Patent Board
Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

[1] Cases IPR2017-01550, IPR2017-01946, and IPR2017-01929 have been joined with this proceeding.

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I. PRELIMINARY STATEMENT

The proposed amendments add the closed transitional phrase "consisting of" to narrow all of the claims to a "dosing regimen consisting of a daily dosage amount of 0.5 mg" of fingolimod. The negative limitation is deleted now as it is superfluous. Petitioners oppose (Paper 62, "Opp.") by misconstruing the term "dosing regimen" in an attempt to show the claim amendments broaden the original claims. Instead of evidence, Petitioners argue based on a hypothetical that easily falls apart under scrutiny. The original claims excluded use of a loading dose, but encompassed an up-titration. "Consisting of" commands nothing be added to the dosing regimen recited in the claim, thereby resulting in a narrower scope than the original claims.

Petitioners urge that an April 2006 description of the upcoming Phase III trial for fingolimod (Chavez, Ex. 2031; Press Release, Ex. 2072, collectively "Chavez") anticipates. Chavez however does not disclose the claim preambles—Chavez describes the Phase III trial in one sentence and is silent as to whether 0.5 mg fingolimod daily will have any effect at all—and Petitioners offer no evidence to contradict the testimony from Drs. Lublin and Steinman refuting anticipation. A person of skill would understand from Chavez that fingolimod was only to be ***tested***, not that it would be useful for treating RRMS.

The amended, narrowed claims address the hindsight-driven obviousness challenges of Grounds 1 and 2 by reducing the scope of the claims such that the

broad disclosures of the art fail to make obvious the narrower claims. The amendments render Ground 3 inapplicable. The burden of persuading the Board that the amended claims are unpatentable rests with the Petitioner. *Aqua Products, Inc. v. Matal*, 872 F.3d 1290, 1327 (Fed. Cir. 2017). Here, Petitioners suffer from a failure of proof. They have no countervailing expert testimony and have not disputed key facts that support patentability of the proposed amended claims.

II. ARGUMENT

A. Claim Construction

1. Preambles Limit Claims and Prevent Redundancy

Petitioners say the preambles only inform the scope of "said subject" and do not have an efficacy requirement. This is incorrect. All RRMS patients are in need of each of the claimed methods. (Opp. at 4; Third Steinman Decl., Ex. 2096 ¶ 11.) The presumption against claim redundancy thus requires the different preambles to each have a different meaning beyond identifying the subject, as required by the Board's Institution Decision (Paper 11). Failing to accord meaning to the differences in the preambles would eliminate any differences among the claims.

The Board found that the preambles are limiting and have their "ordinary and customary meaning." (Paper 11 at 12.) Dr. Steinman says a person of skill would read the claims as having the purpose of achieving or actually achieving the specific effects recited in each of the claims: "[A] person of skill in June 2006 would read

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