

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 IPR2017-00854¹

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

CORRECTED 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

This Corrected Contingent Motion to Amend replaces the Contingent Motion to Amend filed on November 13, 2017. If any one of the original claims in U.S. Patent No. 9,187,405 is deemed unpatentable by the Board, Patent Owner Novartis AG moves the Board to take up this contingent motion and consider the respective substitute claim(s) presented here in its stead. Novartis proposes substitute claims that all include the same amendment: removing the negative limitation “absent an immediately preceding loading dose regimen” and adding the phrase “consisting of” along with some other language adjustments, to limit the dosage regimen to 0.5 mg daily of fingolimod.

The burden of persuading the Board that the amended claims are unpatentable rests with the Petitioner. On October 4, 2017, the Federal Circuit held that: “(1) the PTO has not adopted a rule placing the burden of persuasion with respect to the patentability of amended claims on the patent owner that is entitled to deference; and (2) in the absence of anything that might be entitled deference, the PTO may not place that burden on the patentee.” *Aqua Products, Inc. v. Matal*, 872 F.3d 1290, 1327 (Fed. Cir. 2017). Accordingly, Novartis sets out in **Appendix A** the amendments proposed, and the support for those amendments in the original application, which is identical to the application giving rise to the ’405 patent. Novartis also explains below how the amendments do not enlarge the scope of the

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