Paper No. ___
Filed: April 19, 2018

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 INDUSTIRES, LTD., SUN PHARMACEUTICAL INDUSTRIES, INC., AND SUN PHARMA GLOBAL FZE,
Petitioners,

v.

NOVARTIS A.G.,
Patent Owner.

IPR2017-00854[1]
Patent No. 9,187,405

PETITIONERS' SUR-REPLY REGARDING PATENT OWNER'S MOTION TO AMEND

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

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I. INTRODUCTION.

Novartis itself produced the anticipatory Chavez reference (EX2031) but failed to address Chavez in its Corrected Motion to Amend ("Mot."). Novartis's Motion also contained no claim construction section justifying requiring clinical efficacy as a claim element. Instead, Novartis simply argued that the written description support for the claims was found in "the 'Clinical Trial" example reciting a daily dosage of 0.5 mg fingolimod as one embodiment." Mot. at 2, 8; *id.*, 11 ("Clinical Trial example in the patent…is sufficient to meet 35 U.S.C. § 112."). Then, in its Reply (Paper 64), Novartis introduced new testimony and argument in support of the proposed amended claims. The Board authorized this Sur-Reply "to respond[] to arguments and citations to expert testimony expressly set forth in Patent Owner's Reply[.]" Paper 66 at 3; Paper 72 at 2.

II. THE PREAMBLES DO NOT DISTINGUISH THE PRIOR ART.

A. There Is No Claim Redundancy Issue

Novartis argues that the presumption against claim redundancy requires reading a different efficacy result or intended efficacy result into each of the independent claims beyond simply identifying need of the subject who receives the fingolimod. Reply at 2-3. But Novartis's case law applies a presumption against reading limitations from dependent claims into their independent claims to limit their plain meaning. *See Karlin Tech. Inc. v. Surgical Dynamics, Inc.* 177 F.3d 968, 971-72 (Fed. Cir. 1999); *see also Curtiss-Wright Flow Control Corp. v. Velan,*

Inc., 438 F.3d 1374, 1380-81 (Fed. Cir. 2006) ("[T]he claim differentiation tool works best in the relationship between independent and dependent claims….Beyond the independent/dependent claim scenario, this court has characterized claim differentiation more generally, i.e., as 'the presumption that each claim in a patent has a different scope.'"); *Hormone Research Found. v. Genentech, Inc.*, 904 F.2d 1558, 1567 n. 15 (Fed. Cir. 1990) ("It is not unusual that separate claims may define the invention using different terminology, especially where (as here) independent claims are involved.").

Under the plain meaning of the claims, the preamble language defines the needs of the subject receiving the fingolimod. EX2003, ¶20 (cited in Reply at 3) ("The '405 Patent claims methods for dosing fingolimod for a subject in need of certain effects."); *id.*, ¶5 (claims 1, 3, and 5 each describe a method for a subject in need of various benefits); *see also* EX1002, ¶¶15 (no data presented in '405 patent regarding efficacy of dosing regimen), 43 ("Claims 1, 3, and 5 each contain a preamble identifying 'a subject in need' of a method."); EX1047, ¶¶20-24. Novartis improperly uses claim differentiation to read limitations into the claims.

Novartis reasons that the "subject in need" category in each claim encompasses (and is therefore anticipated by) the same species of subject (actively relapsing RRMS patients). Reply at 2-3; EX2096, ¶¶9-11 (agreeing that all actively relapsing RRMS patients have each of the claimed needs). Novartis erroneously

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