Paper No. ___
Filed: March 16, 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

PETITIONER'S OPPOSITION TO PATENT OWNER'S CORRECTED MOTION TO AMEND UNDER 37 C.F.R. §42.121

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

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I. OVERVIEW OF WHY THE MOTION SHOULD BE DENIED.

Petitioner opposes Novartis's Corrected Contingent Motion to Amend (Paper 61 "Mot."). Novartis fails to satisfy the threshold requirements for amended claims. 35 U.S.C. §316(d)(3) ("An amendment under this subsection may not enlarge the scope of the claims of the patent or introduce new matter."); 37 C.F.R. §42.121(a)(2)(i)-(ii), (b)(2); 37 C.F.R. §42.20(c); *Aqua Products, Inc. v. Matal*, 872 F.3d 1290, 1305-06 (Fed. Cir. 2017) (en banc) ("For these reasons, we believe that the only reasonable reading of the burden imposed on the movant in §316(d) is that the patent owner must satisfy the Board that the statutory criteria in §316(d)(1)(a)-(b) and §316(d)(3) are met and that any reasonable procedural obligations imposed by the Director are satisfied before the amendment is entered into the IPR. Only once the proposed amended claims are entered into the IPR does the question of burdens of proof or persuasion on propositions of unpatentability come into play.").

In its February 16, 2018 Opposition to Novartis's original Motion to Amend (Paper 28), Petitioner argued Novartis had impermissibly broadened the scope of the claims by changing the claimed compound. Paper 51 at 1-2. On March 3, 2018, Novartis approached Petitioner about correcting the claimed compound to what was in the original claims. EX3009 at 3. The Board authorized Novartis to make the change to maintain clarity of the record and to conserve Board resources,

and authorized Petitioner to file an Opposition to the corrected motion within two weeks of Novartis's filing. Paper 60 at 2.[2] Petitioner agreed to file its Opposition today at the request of Novartis's attorneys.

Notwithstanding Novartis's correction, the proposed amended claims still impermissibly broaden the claims by removing the negative limitation "absent an immediately preceding loading dose regimen." Mot. 5. Novartis argues it has not broadened the claims because it replaced the negative limitation with "consisting of" language that applies to "a dosing regimen" comprised by the method. Mot. 2. However, the "consisting of" language does not prohibit the method from comprising another dosing regimen preceding the 0.5 mg dose (*e.g.*, wherein the preceding regimen is a loading dose regimen). This impermissible claim broadening requires denial of the Motion.

The Motion should also be denied because the proposed amended claims are anticipated by the prior art. For example, the proposed amended claims recite the same method that was disclosed in the prior art Chavez (EX2031) and Press Release (EX2072) references. The proposed claims are therefore anticipated and unpatentable. Pre-AIA 35 U.S.C. §102(b).

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[2] Paper 60 refers to the filing date of Paper 51 as February 22, 2018, but E2E correctly reflects the actual filing date of February 16, 2018.

The proposed substitute claims are obvious over the prior art of record. Pre-AIA 35 U.S.C. §103. The proposed amended claims do not address Ground 1 or Ground 2 of the Petition. Novartis's arguments directed to Grounds 1 and 2 merely repeat the same arguments Novartis made regarding the original claims. Those arguments fail for the same reasons here. 37 C.F.R. §42.121(a)(2)(i). The proposed amended claims also are obvious over either Ground 1 or Ground 2 in further view of Chavez or Press Release.

Each of these reasons independently suffices for denying Novartis's Motion.

II. CLAIM CONSTRUCTION

The Board interprets unexpired claims in an IPR using the "broadest reasonable construction in light of the specification of the patent in which [they] appear[]." 37 C.F.R. §42.100(b); *Cuozzo Speed Technologies, LLC v. Lee*, 136 S. Ct. 2131, 2133-36 (2016). Proposed amended claims must satisfy the written description, enablement, and definiteness requirements of 35 U.S.C. §112 and 37 C.F.R. §42.121(b).

A. "a subject in need"

The Board previously construed the preambles of independent claims 1, 3, and 5, which respectively recite a method for "reducing or preventing or alleviating relapses in Relapsing-Remitting multiple sclerosis in a subject in need thereof," for "treating Relapsing-Remitting multiple sclerosis in a subject in need thereof," and

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