IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Biocon Pharma Limited
Petitioner,

v.

Novartis Pharmaceutical Corporation
Patent Owner.

U.S. Patent No. 8,101,659 to Ksander et al.
Issue Date: January 24, 2012
Title: Methods of Treatment and Pharmaceutical Composition

Inter Partes Review No.: IPR2020-01263

Petitioner's Authorized Reply to Patent Owner's Preliminary Response

TABLE OF AUTHORITIES

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Cases

Other Authorities

§325(d) requires an examination of whether "the same or substantially the same prior art or arguments previously were presented to the Office." To begin with, Novartis does not dispute that many of the references (e.g., Gomez-Monterrey, PDR, Shetty, and Ksander) relied upon by Biocon in its Petition were not before the Examiner. Petition, 64; *Apple Inc. v. Corephotonics Ltd.,* IPR2020-00861, Paper 7 at 41(PTAB, Dec. 9, 2020). Instead, in the conclusory manner, Novartis states that based on the other art that was before the Examiner, Biocon's "arguments are substantially the same." POPR, 22-23. Rather than providing any meaningful analysis, Novartis' proof is the single, terse footnote 19. POPR, n.19.

The specific, detailed teachings from EP '072, Shetty, Gomez-Monterrey, Ksander, PDR and EP '072 are laid out in Biocon's petition. Simply because "[t]he Examiner cited the '996 Patent (Ex. 1009) and the '578 Patent (Ex. 1008) for all claim limitations" (POPR, n.19) does not mean that the specific arguments with the combinations advanced in the Petition were before the Examiner. Biocon's Petition did not rest with a simple showing that the claims limitations were present (POPR, n.19) but included specific arguments and rationales based on the combination of the specific references used Grounds 1 & 2. *Apple*, IPR2020-00861 at 41 ("Petitioner relies on different prior art (i.e., Martin, Togo, and Levey), combined in ways not contemplated during prosecution").

Turning to the Webb declaration: during prosecution, Novartis repeatedly stressed the alleged unexpected results contained therein (EX1010, pp.156, 206). The alleged unexpected results of the Webb Declaration persuaded the Examiner to allow the claims. *Id*. at p.240 (Examiner's "Reasons for Allowance"). But astonishingly, Novartis' own arguments in its POPR now undercuts the Webb Declaration's alleged unexpected results. In an effort to distinguish EP '072's teaching of synergistic effects directed to **heart failure**, Novartis' POPR now makes clear that the Webb Declaration's alleged synergistic effects are **limited only to antihypertensive effect**—something it did not feel the need to expressly explain to the Examiner (as now it does to the PTAB). POPR, 7-8; 27-31.

The '659 patent only has four claims. Claims 1, 3 and 4 of the '659 patent are not limited to any specific condition, whereas Claim 2 recites "hypertension *or heart failure*." "Evidence of secondary considerations must be reasonably commensurate with the scope of the claims." *In re Huai-Hung Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011). As Novartis explains in its POPR, its alleged unexpected results are only limited to an antihypertensive effect; Novartis has nothing to offer directed to "heart failure." Novartis's unexpected results are **not** commensurate with the scope of the claims. *Id*.

But there is more. During prosecution of the '659 patent, Novartis opportunistically (and repeatedly) told the Examiner that because of the Webb

Declaration it had "**already overcome** the *prima facie* case for obviousness, as demonstrated by the issuance of U.S. Patent 7,468,390." EX1010, pp. 156, 206. At the same time, however, Novartis neglected to inform the Examiner that the claims of the parent '390 patent recited only an "anti-hypertensive effect." EX1014, Claims 1 & 3. In contrast, the '659 patent's claims are not so limited with all but one of them not even reciting any specific condition, and with Claim 2 reciting "hypertension *or heart failure*." As Novartis concedes, the "unexpected results based on the Webb Declaration were a **key part** of the '659 Patent's prosecution." POPR, 37. Novartis' representation, however, that it had "**already overcome** the *prima facie* case for obviousness" because of the Webb Declaration in the parent '390 patent while failing to inform the Examiner of the differing claim scopes of the parent and the '659 patents was simply disingenuous.

Finally, as explained in Biocon's Petition, the PTAB routinely defers detailed consideration of any objective indicia until after institution. Petition, 59 (citing cases). The fact that Novartis has to rely so heavily on an uncontested unexpected results declaration submitted during prosecution undercuts its entire §325(d) argument. *Actavis LLC v. Abraxis Bioscience, LLC*, IPR2017-01103, Paper 7 at 8 (October 10, 2017) ("testimonial evidence that was not subject to cross-examination in determining patentability"). For all of the above reasons, Biocon's Petition should not be denied on the basis of §325(d).

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