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Filed On Behalf Of:
Novartis Pharmaceuticals Corporation

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BIOCON PHARMA LIMITED,
Petitioner,

v.

NOVARTIS PHARMACEUTICALS CORPORATION,
Patent Owner.

Case IPR2020-01263
Patent 8,101,659

NOVARTIS'S PRE-INSTITUTION SUR-REPLY

TABLE OF AUTHORITIES

Cases

Statutes

Pursuant to Board authorization (Paper 9), Novartis responds to Biocon's Reply (Paper 10, "Reply"). Nothing in Biocon's Reply compels institution.

First, Biocon complains that Novartis's § 325(d) analysis was insufficiently detailed. Reply at 1. But in contrast to *Apple Inc. v. Corephotonics Ltd*. IPR2020-00861, Paper 7 at 41 (PTAB, Dec. 9, 2020), where the petitioner cited new non-cumulative art, Biocon has not identified any material difference between the art cited in the petition and the art considered by the Examiner, let alone any art or argument that would have led the Examiner to a different conclusion on *prima facie* obviousness. Biocon's art discussing ARBs (including valsartan) and NEP inhibitors (including sacubitril) is cumulative of the art considered by the Examiner, who also found the claims *prima facie* obvious, albeit using a different combination of references.[1] Paper 7, POPR at 23–25; Ex. 1010, at 170–74, 195–99. For unexpected results, Biocon relies on EP '072, which was indisputably presented to the Office. Paper 7, POPR at 25–26. This is precisely the type of case where § 325(d) denial is appropriate.

Second, Biocon baselessly complains that the unexpected synergistic anti-hypertensive results are not commensurate in scope with the '659 patent claims,

[1] The claims ultimately were allowed for unexpected results. Ex. 1010, '659 prosecution history at 240; Paper 1, Petition at 11.

although its argument is difficult to follow. Reply at 2. Biocon ignores that claims 1–4 are composition claims. *See* Paper 1, Petition at 1 ("The challenged claims … are directed to pharmaceutical compositions…"); *see also* 43 ("Claim 2 recites the pharmaceutical composition of claim 1…"). For such claims, showing unexpected superiority for one property is sufficient to overcome a *prima facie* showing of obviousness. *In re Chupp*, 816 F.2d 643, 646 (Fed. Cir. 1987) ("Evidence that a compound is unexpectedly superior in ***one*** of a spectrum of common properties, as here, can be enough to rebut a *prima facie* case of obviousness.") (emphasis added); *In re Ackermann*, 444 F.2d 1172, 1176 (CCPA 1971). With respect to claim 2, which Biocon specifically challenges, Biocon conflates the composition claim element "amounts effective to treat . . . heart failure" with the composition's unexpected anti-hypertensive synergy.

Because a single unexpected property is sufficient to support unexpected results for all four composition claims, Biocon's suggestion that Novartis misled the Examiner about the '390 patent claims scope (Reply at 2–3) is both irrelevant and incorrect. Reply at 2–3. The prosecution history confirms the Examiner was aware of the scope of the '390 patent claims, including because she was the Examiner who allowed them ***and because she relied on them to issue a double patenting rejection***. Ex. 1015 at 1089–95; Ex. 1010 at 219. Likewise, Novartis never suggested the synergistic data was directed to heart failure (*contra* Reply at

2); Novartis described the data as showing "a synergistic, unexpected and surprising ***antihypertensive*** effect." Ex. 1010 at 156, 206 (emphasis added).

In sum, Biocon has not shown that the Examiner erred in finding unexpected results. Moreover, Biocon now surprisingly admits that the EP '072 "synergistic" results pertain to heart failure (Reply at 2), not hypertension—an admission that directly contradicts the primary argument in Biocon's Petition (Paper 1 at 5) that EP '072 and the Webb Declaration showed the "same synergistic effect." Thus, it is Biocon who is trying to mislead, not Novartis.

Finally, Biocon's suggestion that the Board should institute trial so that the Webb Declaration can be considered further (Reply at 3) is baffling, particularly as neither Biocon nor its expert have disputed that it shows anti-hypertensive synergy. As unexpected results raised during prosecution should be addressed in pre-institution papers, permitting Biocon to challenge these results for the first time in a post-institution reply would be highly prejudicial. *See* Paper 7, POPR at 36–37 (citing cases requiring petition to address unexpected results raised in prosecution); *see also id.* at 35 (distinguishing *Actavis LLC v. Abraxis Bioscience LLC*, IPR2017-01103, Paper 7 (PTAB Oct. 10, 2017)).

December 18, 2020

Respectfully submitted,

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