UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
MSN LABORATORIES PRIVATE LTD.,
and MSN PHARMACEUTICALS INC.,

Petitioner,

v.

BAUSCH HEALTH IRELAND LIMITED,

Patent Owner.

Case IPR2022-00722[1]
U.S. Patent No. 7,041,786

PATENT OWNER'S REPLY
IN SUPPORT OF ITS MOTION TO EXCLUDE

[1] IPR2023-00016 has been joined with this proceeding.

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I. EXHIBIT 1067 SHOULD BE EXCLUDED

Petitioner argues that Exhibit 1067 is an admissible "record of a public office" under FRE 803(8). Opp., 1. Petitioner is wrong. Exhibit 1067 is an incomplete and out-of-order EPO file history excerpt. Exhibit 1067 does not include the EPO's final decision upholding the plecanatide patent, which issued on September 5, 2015. Further, the applicant's October 14, 2011 submission (Ex. 1067, 138-40) is preceded by its enclosed annexes and followed by a cut-off claim list, creating confusion. Because Exhibit 1067 is not a public record but an untrustworthy excerpt, FRE 803(8) is inapplicable. FRE 803(8)(B). An EPO file history is also distinguishable from a USPTO file history, which is expressly admissible under 37 C.F.R. § 42.61.

Petitioner further argues that Exhibit 1067 is not hearsay because it was submitted not for its truth but for what was said. Opp., 3. As an initial matter, Petitioner incorrectly asserts that that the EPO found "'contradiction' in Bausch's positions about purifying uroguanylin." Opp., 3 (citing Ex. 1067, 59). The cited section does not set forth the EPO's findings; rather, it summarizes the ***opponent's*** positions. Ex. 1067, 58-59. As such, Petitioner's non-hearsay argument should be rejected. In any event, Petitioner's use of Exhibit 1067 for additional purposes does not justify its hearsay use of Exhibit 1067. Indeed, Petitioner does not dispute that it offered Exhibit 1067 for the truth of Currie's testing and results. Nor does it contend that it submitted the affidavit required by 37 C.F.R. § 42.65(b). At minimum, pages

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88-98 and 120-127 of Exhibit 1067 therefore should be excluded.

Petitioner's assertion that Currie's data should be admitted because it is more reliable than Patent Owner's data is meritless. Opp., 5. Petitioner argues that Dr. Peterson said so and "[n]o expert testimony supports Bausch's contention that Dr. Currie's submission is unreliable." *Id*. But Petitioner cited Currie's data in its Reply *for the first time*, preventing Patent Owner from providing expert testimony regarding Petitioner's reliance on Currie's data. Further, contrary to Petitioner's argument, Patent Owner did cross examine Dr. Peterson, who testified that he is not an expert in GCC receptors or receptor agonists and that he has never conducted a T84 cell bioassay. Ex. 2069, 10:6-9, 15:22-16:2, 10:15-20. Petitioner misleads the Board by arguing that "Bausch itself relies on Dr. Currie when it suits Bausch." Opp., 5 (citing POR 2, 15, 21, 24, 34, 36, 37). Patent Owner *never* cited or relied on Currie's data currently at issue (Exhibit 1067). Indeed, the cited pages refer to Exhibit 1005 (Petitioner's primary reference) and the undisputed fact that Dr. Currie selected an heat-stable enterotoxin in developing Linzess®. Fundamentally, the issue is the wholly uncorroborated data upon which Petitioner relies.

Petitioner further asserts that it provided Patent Owner with a complete copy of the EPO file history as supplemental evidence but, notably, did not file and has not filed the complete copy. Petitioner attempts to excuse its failure by pointing to the size of the file history. Opp., 7. This argument is disingenuous at best. In

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