

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 IPR2022-00722¹
U.S. Patent No. 7,041,786

PATENT OWNER'S MOTION TO EXCLUDE

¹ IPR2023-00016 has been joined with this proceeding.

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I. PRELIMINARY STATEMENT

Pursuant to 37 C.F.R. § 42.64, Patent Owner Bausch Health Ireland Limited moves to exclude the entirety of Exhibit 1067 and paragraphs 34, 149, 152-57, 160, 162-64, and 166-67 of Exhibit 1063.

II. EXHIBIT 1067 SHOULD BE EXCLUDED

Patent Owner timely objected to Exhibit 1067, an excerpt from the file history of European Patent No. 1 379 224, as incomplete under Federal Rule of Evidence (“FRE”) 106, hearsay without exception under FRE 802, and not in accordance with 37 C.F.R. § 42.65(b). Paper 40 at 1-2. Petitioner relies on Exhibit 1067 for its arguments related to Patent Owner’s objective evidence of nonobviousness, specifically unexpected results. Reply at 22-28.

A. Exhibit 1067 Is Hearsay Without Exception Under Federal Rule of Evidence 802

Exhibit 1067 should be excluded under FRE 802 because it is hearsay without exception. The file history of European Patent No. 1 379 224 contains statements, including data, made by the opponent in Europe and its witness, Mark Currie, and Petitioner relies on these statements to prove the truth of the matter Petitioner asserts, without identifying any exception to support such use. In particular, Petitioner relies on Currie’s data to assert that plecanatide—the claimed compound at issue here—and human uroguanylin do not differ “in activity, heat stability, or topoisomeric interconversion.” Reply at 23. Petitioner further asserts that “[b]ased on scientific

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