

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

Petitioners,

v.

BAUSCH HEALTH IRELAND LIMITED,

Patent Owner.

Case IPR2022-00722
Patent 7,041,786

PATENT OWNER'S SUR-REPLY

¹ IPR2023-00016 has been joined with this proceeding.

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Patent Owner respectfully submits this Sur-Reply in response to Petitioner's Reply.

I. Petitioner's Attempt to Divorce the Claimed Compound from Its Properties Is Legally Improper

Petitioner attempts to divorce the claimed compound, plecanatide, from its properties, arguing that Patent Owner's "arguments are not commensurate with its claims" because the claims do not recite "any level of potency or topoisomerism." Reply, 2. Petitioner misses the point. The question of obviousness is assessed based on what a POSA *would* have done, *not could* have done. *In re Omeprazole Patent Litig.*, 536 F.3d 1361, 1379-81 (Fed. Cir. 2008). The relevant art pertains to constipation, and a POSA seeking to make a better anti-constipation drug would have considered the properties of various prior-art compounds and would not have ignored human uroguanylin's middling potency or problematic topoisomeric instability in selecting a lead compound. Patent Owner's Response ("POR"), 28-37. Moreover, plecanatide's properties, including its unexpectedly superior potency and topoisomeric stability, cannot be ignored. *Id.*, 58-64. "From the standpoint of patent law, a compound and all of its properties are inseparable; they are one and the same thing." *In re Papesch*, 315 F.2d 381, 391 (C.C.P.A. 1963); *see also Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1086 (Fed. Cir. 2008); *In re Merchant*,

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