UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC., CELLTRION, INC.,
and APOTEX, INC.,
Petitioners

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner

Case IPR2021-00881[1]
Patent No. 9,254,338 B2

PATENT OWNER'S REPLY ON
MOTION TO EXCLUDE EVIDENCE

[1] IPR2022-00258 and IPR2022-00298 have been joined with this proceeding.

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I. The Board May Strike Petitioner's Improper New Arguments in the Context of a Motion to Exclude

PO asks the Board to exclude or strike Petitioner's new Reply arguments that expand its asserted Grounds of unpatentability. Paper 83 at 2. As explained in PO's opening brief, there is no procedural barrier to the grant of this request: On multiple occasions, and on analogous facts, the Board has treated party motions to exclude as motions to strike and has excluded arguments that exceed the permitted scope of reply. *Id.* at 3 (citing *Laboratoire Francais du Fractionnement et des Biotechnologies SA v. Novo Nordisk Healthcare AG*, IPR2017-00028, Paper 109 at 13 (P.T.A.B. Apr. 13, 2022); *Intel Corp. v. Parkervision, Inc.*, IPR2020-01265, Paper 44 at 55-56, 66 n.22, 71-75, 77 (P.T.A.B. Jan. 21, 2022)); *see also Dexcom Inc. v. Waveform Techs, Inc.*, IPR2016-01680, Paper 46 at 30-31 (P.T.A.B. Feb. 28, 2018) ("Federal Circuit case law indicates that a motion to exclude is a proper vehicle for enforcing our rule and trial practice guide regarding the scope of evidence that may be submitted with a reply brief.") (citing, *inter alia*, *Intelligent Bio-Systems, Inc. v. Illumina Cambridge, Ltd.*, 821 F.3d 1359 (Fed. Cir. 2016)).

Petitioner's assertion that PO failed to provide the requisite notice misses the forest for the trees. PO identified Petitioner's improper, Ground-expanding Reply argument early and often: First in direct correspondence with Petitioner, then in its June 3, 2022, communication with the Board requesting authorization to file a

motion to strike, and again, per the Board's instructions, in its Sur-reply.[2] *See* Paper 73 at 18. This record does not support Petitioner's suggestion that it was denied timely notice — Petitioner was specifically notified of these issues ***before*** the due date for PO's evidentiary objections, and duly responded to these arguments in its Opposition. *See Laboratoire Francais*, IPR2017-00028, Paper 109 at 12 (striking new reply arguments on PO's motion to exclude where petitioner had the opportunity to respond in opposition). Finally, Petitioner's contention that it was deprived of an opportunity to "correct[] in the form of supplemental evidence" makes no sense. Paper 84 at 2. The filing of supplemental evidence would not cure Petitioner's improper expansion of its Grounds.

II. Petitioner's Ground-Expanding Reply Argument Should Be Excluded

Petitioner's Opposition takes a broad (and incorrect) view of what constitutes "responsive" argument on Reply. In Petitioner's view, if a theory advanced in the Petition is rebutted in the POR, Petitioner may then raise a new theory "in response," which PO can address in sur-reply. Paper 84 at 5-6. But "[s]hifting arguments in

[2] PO did not file a separate table identifying arguments exceeding the scope of Reply because the Board's June 7 Order provided that such a table should be filed only as an alternative to identifying and addressing such arguments in Sur-Reply, which PO did.

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