

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 IPR2021-00881¹

Patent 9,254,338 B2

PETITIONER'S MOTION TO SEAL

37 C.F.R. §§ 42.14 AND 42.54

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

Petitioner Mylan Pharmaceuticals Inc. (“Petitioner” or “Mylan”) moves to seal portions of Petitioner’s Reply to Patent Owners’ Response (“Petitioner’s Reply”) and portions of Exhibits 1137, 1108, 1111, and 1151. These exhibits and documents were filed concurrently with Petitioner’s Reply. Patent Owner indicated that it did not oppose this Motion.

I. DOCUMENTS TO BE SEALED AND REASONS FOR SEALING.

A. Good Cause Exists for Sealing Confidential Information.

The Board may seal documents for good cause. *See* 37 C.F.R. § 42.54(a); *Garmin v. Cuozzo*, IPR2012-00001, Paper 36, 8-9 (2013). “The rules aim to strike a balance between the public’s interest in maintaining a complete and understandable file history and the parties’ interest in protecting truly sensitive information.” Office Patent Trial Practice Guide, 77 Fed. Reg. 48756, 48760 (2012). The public’s interest in having access to confidential business information that is only indirectly related to patentability is “minimal.” *Garmin v. Cuozzo*, IPR2012-00001, Paper 36, 8-9 (2013) (granting a motion to seal an agreement relating to the “commercializ[ation]” of the patent-at-issue).

The information that Petitioner seeks to seal has been designated PROTECTIVE ORDER MATERIAL by Patent Owner and Petitioner is obligated to maintain the confidentiality of such information. *See* Paper 34, Addendum A, Default Protective Order at 4. Further, it is Petitioner’s understanding that the

information Petitioner seeks to seal constitutes or reflects either Regeneron's confidential research and development information, Regeneron's confidential commercial and financial information, third-party confidential research and development information, or third-party confidential information. *See* Paper 42, Patent Owner's Motion to Seal. To Petitioner's knowledge, the information sought to be sealed has not been published or otherwise made public. According to Patent Owner, public disclosure of this confidential information would competitively harm Regeneron's business prospects and put it at a competitive disadvantage relative to other similarly positioned companies in the same industry. *Id.* at 3-5. Therefore, it is Petitioner's understanding good cause exists to seal portions of Petitioner's Reply and portions of Exhibits 1137, 1108, 1111, and 1151.

B. Petitioner's Reply.

Petitioner seeks to seal the portions of Petitioner's Reply that discuss Patent Owner's confidential information, designated as PROTECTIVE ORDER MATERIAL, in the Exhibits that Petitioner currently seeks to seal. For the same reasons discussed below, it is Petitioner's understanding there is good cause to seal the portions of the Reply that include confidential information appearing in at least Exhibits 1137, 1108, 1111, and 1151.

C. Exhibit 1137 (Hofmann Reply Declaration).

Exhibit 1137 is a declaration from Petitioner's expert witness, Ivan T. Hofmann. Portions of Exhibit 1137 describe and include Regeneron's confidential PROTECTIVE ORDER MATERIAL, which Petitioner is obligated to file under seal. Petitioner relies on such confidential information to rebut Regeneron's arguments concerning obviousness of the claims of the '338 Patent. Portions of Exhibit 1137 describe exhibits filed by Regeneron under seal. *See, e.g.*, Ex.1137, ¶70 (discussing Ex.2176, filed under seal).

Petitioner understands that Exhibit 2176, if publicly disclosed, would cause competitive harm to Patent Owner. *See* Paper 42 at 6. Therefore, it is Petitioner's understanding good cause exists to seal portions of Exhibit 1137.

D. Exhibits 1108, 1111, and 1151 (IPR Deposition Transcripts).

Exhibits 1108, 1111, 1151 are cross-examination deposition transcripts of Patent Owner's witnesses taken in this IPR proceeding. Petitioner seeks to seal portions of Exhibit 1108 (Klibanov Dep. Tr.), Exhibit 1111 (Del Priore Dep. Tr.), and Exhibit 1151 (Manning Dep. Tr.). Each of Exhibits 1108, 1111, and 1151 describe and include Regeneron's confidential PROTECTIVE ORDER MATERIAL, which Petitioner is obligated to file under seal. *See e.g.* Ex.1108 at 50-54 (discussing confidential sections of Ex.2049 (Expert Declaration of Dr. Alexander M. Klibanov, Ph.D.)); Ex.1111 at 59-60 (discussing confidential

sections of Ex.2048 (Expert Declaration of Dr. Lucian V. Del Priore, M.D., Ph.D.); Ex.1151 at 18-19 (discussing confidential Ex.2138 (Regeneron, “Physician ATU: Wave 2,” 2/2013, at 3)).

Petitioner understands that Exhibits 2049, 2048 and 2138, if publicly disclosed, would cause competitive harm to Patent Owner. *See* Paper 42 at 7-9. Therefore, it is Petitioner’s understanding good cause exists to seal portions of Exhibits 1108, 1111, and 1151.

* * *

Petitioner respectfully requests that the Board grant its motion to seal portions of Petitioner’s Reply, and portions of Exhibits 1137, 1108, 1111, and 1151, and there exists good cause for them to be maintained under seal.

II. PROTECTIVE ORDER

Pursuant to 37 CFR §§ 42.54 and 42.55(a), Patent Owner filed a motion for entry of the Board’s default protective order. *See* Paper 34. Petitioner did not oppose Patent Owner’s motion.

III. CERTIFICATION

Pursuant to 37 CFR § 42.54, Petitioner certifies that it has conferred with Patent Owner regarding this motion to seal. Patent Owner has indicated that it will not oppose Petitioner’s motion.

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