

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 IPR2021-00880¹
Patent 9,669,069 B2

PETITIONER'S MOTION TO SEAL

37 C.F.R. §§ 42.14 AND 42.54

¹ IPR2022-00257 and IPR2022-00301 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 1114, 1108, and 1111. 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 37, 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 1114, 1108, and 1111.

B. Petitioner's Reply.

Petitioner seeks to seal the portions of Petitioner's Reply that discuss Patent Owner's confidential information, in Exhibits 2096 and 2259. Petitioner understands that Exhibit 2096, if publicly disclosed, would cause competitive harm to Regeneron, *see* Paper 37 at 4, and Exhibit 2259, if publicly disclosed, would cause competitive harm to ASRS, *see* IPR2021-00881, Paper 42 at 7. Therefore, it is Petitioner's understanding good cause exists to seal portions of Petitioner's Reply.

C. Exhibit 1114 (Albini Reply Declaration).

Exhibit 1114 is a declaration from Petitioner's expert witness, Dr. Thomas A. Albini. Portions of Exhibit 1114 describe and include Regeneron's or third party confidential PROTECTIVE ORDER MATERIAL, which Petitioner is obligated to file under seal. Petitioner relies on such confidential information to rebut Regeneron's arguments concerning anticipation and obviousness of the claims of the '338 Patent. Portions of Exhibit 1114 describe exhibits filed by Regeneron under seal in related IPR2021-00881. *See, e.g.*, Ex.1114, ¶39 (discussing Ex.2259, filed under seal in related IPR2021-00881).

Petitioner understands that Exhibit 2259, if publicly disclosed, would cause competitive harm to ASRS. *See* IPR2021-00881, Paper 42 at 7. Therefore, it is Petitioner's understanding good cause exists to seal portions of Exhibit 1114.

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

Exhibits 1108 and 1111 are cross-examination deposition transcripts of Patent Owner's witnesses taken in this IPR proceeding. Petitioner seeks to seal portions of Exhibit 1108 (Alexander M. Klibanov Dep. Tr.) and Exhibit 1111 (Lucian Del Priore Dep. Tr.). Each of Exhibits 1108 and 1111 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.)).

Petitioner understands that Exhibits 2048 and 2049, if publicly disclosed, would cause competitive harm to Regeneron. *See* Paper 37 at 4-5. Therefore, it is Petitioner's understanding good cause exists to seal portions of Exhibits 1108 and 1111.

* * *

Petitioner respectfully requests that the Board grant its motion to seal portions of Petitioner's Reply, and portions of Exhibits 1114, 1108, and 1111, 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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