

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

REGENERON PHARMACEUTICALS, INC.,
Petitioner,

v.

NOVARTIS PHARMA AG,
NOVARTIS TECHNOLOGY LLC,
NOVARTIS PHARMACEUTICALS CORPORATION,
Patent Owner.

Case No. IPR2021-00816
U.S. Patent No. 9,220,631

PETITIONER'S MOTION TO SEAL
37 C.F.R. §§ 42.14 AND 42.54

I. PRECISE RELIEF REQUESTED

Petitioner Regeneron Pharmaceuticals, Inc. (“Petitioner” or “Regeneron”) moves to seal portions of Petitioner’s Reply to Patent Owners’ Response (“Petitioner’s Reply”), portions of Petitioner’s Opposition to Patent Owner’s Contingent Motion to Amend (“MTA Opposition”), portions of Exhibits 1100-1102, 1105-1107, 1109, 1172, 1207-1208, 1210 that rely on confidential business information, pursuant to 37 C.F.R. §§ 42.14 and 42.54. Petitioner also moves to seal the entirety of Exhibits 1112-1114, 1116-1128, 1130-1162, 1167-1168, 1185, 1203, 1205-1206, 1211, 1213, 1215-1226, 1248-1249, and 1254-1256.

II. REASONS FOR THE REQUESTED RELIEF AND STATEMENT OF FACTS

A. Good Cause Exists for Sealing Confidential Information

The Board will seal documents for good cause. *See* 37 C.F.R. § 42.54(a); *see also* *Argentum Pharms. LLC v. Alcon Research, Ltd.*, Paper 27, 2 (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 Regeneron seeks to seal is either Regeneron’s confidential research and development information, Regeneron’s confidential commercial and financial information, Novartis’s confidential research and development information, or third party confidential information, as explained in more detail below. To the undersigned’s knowledge, the information sought to be sealed has not been published or otherwise made public. Public disclosure of Regeneron’s, Novartis’s or third party confidential information would competitively harm Regeneron’s, Novartis’s, and/or third parties’ business prospects and put these companies at a competitive disadvantage relative to other similarly positioned companies in the same industry. Therefore, good cause exists to seal portions of Petitioner’s Reply, portions of Petitioner’s MTA Opposition, portions of Exhibits 1100-1102, 1105-1107, 1109, 1172, 1207-1208, 1210 and the entirety of Exhibits 1112-1114, 1116-1128, 1130-1162, 1167-1168, 1185, 1203, 1205-1206, 1211, 1213, 1215-1226, 1248-1249, and 1254-1256.

B. Petitioner’s Reply and Opposition to MTA

Regeneron seeks to seal the portions of Petitioner’s Reply and Opposition to MTA that discuss confidential information in the Exhibits that Regeneron currently seeks to seal. For the same reasons that these exhibits should be sealed as discussed

below, there is good cause to seal the portions of the Reply and Opposition to MTA that include confidential information appearing in at least Exhibits 1100-1102, 1105, 1107, 1112-1114, 1116-1128, 1130-1162, 1167-1168, 1172, 1185, 1203, 1205-1208, 1211, 1213, 1215-1220, 1222-1226, 1248-1249, 1254-1256.

C. Exhibit 1100 (Agalloco Declaration)

Exhibit 1100 is a declaration from Petitioner's expert witness, James Agalloco. Portions of Exhibit 1100 describe and include Genentech's and Novartis's confidential development and research information. Regeneron relies on such confidential information to rebut Novartis's arguments concerning obviousness of the claims of the '631 Patent. Portions of Exhibit 1100 describe exhibits filed by Novartis under seal. *See e.g.* Ex. 1100, ¶ 50 (discussing Exhibit 2063, filed under seal). Portions of Exhibit 1100 also describe exhibits designated by third party Genentech as Confidential in co-pending litigation. *See e.g.*, Ex. 1100, ¶ 58 (discussing Exhibit 2106).

Novartis has asserted that similar confidential and proprietary research and development information of Novartis and Genentech, if publicly disclosed, would substantially harm Novartis's and Genentech's competitive positions in the pre-filled syringe industry. *See* Paper 38 at 9-13. For example, Novartis has asserted that documents with similar information, if not sealed, "would provide a competitive advantage to the third party's competitors to its detriment" and "would

harm Novartis because insight into its research and development processes would provide a competitive advantage to Novartis's competitors to Novartis's detriment." Paper 38 at 10, 12. Therefore, good cause exists to seal portions of Exhibit 1100.

D. Exhibit 1101 (Sawyer Declaration)

Exhibit 1101 is a declaration from Petitioner's expert witness, Dr. Gregory Sawyer. Portions of Exhibit 1101 describe and include Novartis's and third party Vetter's confidential research and development information. Regeneron relies on such information to support its argument regarding the invalidity of Novartis's proposed substitute claims. Portions of Exhibit 1101 describe exhibits filed by Novartis under seal. *See e.g.* Ex. 1101, ¶¶ 72-73 (discussing Ex. 2143, filed under seal). Portions of Exhibit 1101 also describe exhibits designated by third party Vetter as Confidential in co-pending litigation. *See e.g.*, Ex. 1101, ¶ 72.

Novartis has asserted that similar confidential and proprietary research and development information of Novartis and its third party business partners, if publicly disclosed, would substantially harm Novartis's and its third party business partner's competitive positions in the pre-filled syringe industry. For example, Novartis has asserted that documents with similar information, if not sealed, "would harm Novartis and its third party business partners because Novartis's competitors would gain insight into Novartis's business approaches and

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