

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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REGENERON PHARMACEUTICALS, INC.,  
Petitioner,

v.

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

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IPR2021-00816  
Patent 9,220,631 B2

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Before ERICA A. FRANKLIN, ROBERT L. KINDER, and  
JAMIE T. WISZ, *Administrative Patent Judges*.

KINDER, *Administrative Patent Judge*.

ORDER  
Granting Petitioner's Motion to Seal  
*37 C.F.R. §§ 42.14 and 42.54*

### *I. Introduction*

Petitioner Regeneron Pharmaceuticals, Inc. (“Petitioner” or “Regeneron”) filed a Motion to Seal portions of Petitioner’s Reply to Patent Owner’s 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<sup>1</sup>–1208, and 1210 that rely on confidential business information. Paper 71, 1 (“Pet. Mot.”). 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. *Id.*

For the reasons set forth below, Petitioner’s Motion to Seal is *granted*.

### *II. Motion to Seal Legal Standard*

“There is a strong public policy for making all information filed in a quasi-judicial administrative proceeding open to the public.” *Garmin Int’l v. Cuozzo Speed Techs., LLC*, IPR2012–00001, slip op. at 1–2 (PTAB Mar. 14, 2013) (Paper 34). The record for an *inter partes* review shall be made available to the public, except as otherwise ordered, and a document filed with a motion to seal shall be treated as sealed until the motion is decided. 35 U.S.C. § 326(a)(1); 37 C.F.R. § 42.14. The standard for granting a motion to seal is “good cause.” 37 C.F.R. § 42.54; *see also Argentum Pharms. LLC v. Alcon Res., Ltd.*, IPR2017-01053, Paper 27 at 3–4 (PTAB Jan. 19, 2018) (Informative) (describing the “good cause” standard). The moving party bears the burden of showing that the relief requested should be granted. 37 C.F.R. § 42.20(c). That includes showing that the information

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<sup>1</sup> Exhibit 1207 was filed only as “Board and Parties Only” with no corresponding redacted version.

is truly confidential, and that such confidentiality outweighs the strong public interest in having an open record. *See Argentum*, Paper 27 at 3–4 (“[A] movant to seal must demonstrate adequately that (1) the information sought to be sealed is truly confidential, (2) a concrete harm would result upon public disclosure, (3) there exists a genuine need to rely in the trial on the specific information sought to be sealed, and (4), on balance, an interest in maintaining confidentiality outweighs the strong public interest in having an open record.”).

### *III. Petitioner’s Motion to Seal*

In its Motion to Seal, Petitioner contends that the documents it seeks to seal contain truly confidential information. Pet. Mot. 2 (“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.”). Petitioner also attests a concrete harm would result for Regeneron, Novartis, or third parties upon public disclosure of the information. *Id.* at 2 (stating that “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”).

We find Petitioner’s showing persuasive in establishing good cause to seal the identified documents.

#### *1. 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. Pet. Mot. 2–3. Petitioner relies on reasons provided for certain exhibits, alleging “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.” *Id.* at 3.

For the reasons set forth more below, we determine that Petitioner establishes good cause for redacting the information it seeks to keep confidential in the Petitioner’s Reply and Opposition to MTA. The information redacted is truly confidential, would result in harm if disclosed, is pertinent to the ongoing trial, and maintaining confidentiality outweighs the strong public interest in having an open record. As such, Petitioner has established good cause for sealing Petitioner’s Reply and Opposition to MTA.

2. *Exhibit 1100 (Agalloco Declaration)*

Regeneron seeks to seal portions of Exhibit 1100, which is a declaration from Petitioner’s expert witness, James Agalloco. Petitioner asserts that portions of Exhibit 1100 describe and include Genentech’s and Novartis’s confidential development and research information and that the information is necessary to address issues related to the alleged obviousness of the claims of the ’631 patent. Pet. Mot. 3. Further, portions of Exhibit 1100 describe exhibits filed by Novartis under seal as well as exhibits designated by third party Genentech as Confidential in co-pending litigation. *Id.* Petitioner further contends that “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 prefilled syringe industry." *Id.* (citing Paper 38, 9–13).

Based on this evidence and argument, we are persuaded that the redacted information does not appear to unreasonably impede the public's understanding of the record. We are sufficiently persuaded that Petitioner's showing establishes good cause for redacting the information it seeks to keep confidential in Exhibit 1100.

3. *Exhibit 1101 (Sawyer Declaration)*

Regeneron seeks to seal portions of Exhibit 1101, which is a declaration from Petitioner's expert witness, Dr. Gregory Sawyer. Pet. Mot. 4. Petitioner asserts that portions of Exhibit 1101 describe and include Novartis's and third-party Vetter's confidential research and development information as well as exhibits filed by Novartis under seal. *Id.* Regeneron relies on such information to support its argument regarding alleged invalidity of Novartis's proposed substitute claims. *Id.* Petitioner further contends that 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 prefilled syringe industry. *Id.* (citing Paper 38, 4, 13).

Based on this evidence and argument, we are persuaded that the redacted information does not appear to unreasonably impede the public's understanding of the record. We are sufficiently persuaded that Petitioner's showing establishes good cause for redacting the information it seeks to keep confidential in Exhibit 1101.

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