

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.

IPR2021-00816
Patent 9,220,631 B2

Before ERICA A. FRANKLIN, ROBERT L. KINDER, and
KRISTI L. R. SAWERT, *Administrative Patent Judges*.

KINDER, *Administrative Patent Judge*.

ORDER
Granting Patent Owner's Second Motion to Seal
37 C.F.R. §§ 42.14 and 42.54

Introduction

Novartis Pharma AG, Novartis Technology LLC, and Novartis Pharmaceuticals Corporation (collectively, “Novartis” or “Patent Owner”) filed a Second Motion to Seal Exhibits 2002, 2063, 2064, and 2066–2088. Paper 18, 1 (“Sec. Mot.”). Along with the Second Motion, Novartis filed redacted public versions of Exhibits 2063–2064 and 2066–2088.¹ We denied an earlier unopposed motion to seal but granted leave to file the current amended motion before us. *See* Paper 15, 10 (holding Patent Owner’s Motion to Seal (Paper 10) is denied without prejudice). For the reasons set forth below, Patent Owner’s Second Motion is *granted*.

Motion to Seal

“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 is truly confidential, and that such confidentiality outweighs the strong

¹ Novartis filed a redacted public version of Exhibit 2002 with its Patent Owner Preliminary Response.

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.”).

Novartis seeks to seal Exhibits 2002, 2063, 2064, and 2066–2088, which purportedly “contain Novartis’s confidential research and development information, confidential information of third parties, and employee personal information.” Sec. Mot. 3. Novartis states that “the information sought to be sealed has not been published or otherwise made public,” and such “disclosure of Novartis’s confidential information would competitively harm Novartis’s business prospects and put Novartis at a competitive disadvantage.” *Id.* at 2. Novartis relies on the accompanying declaration of Martina Athanas, which also details the requirements established by Articles 162 and 273 of the Swiss Criminal Code (“SCC”) that prohibit the unauthorized disclosure or communication of certain manufacturing and employee information. Ex. 2097; Sec. Mot. 4. We find Patent Owner’s showing persuasive and further address each set of exhibits below.

Exhibit 2002 (Declaration of Marie Picci)

Exhibit 2002 is a declaration of named inventor Marie Picci. Sec. Mot. 3. As noted above, Novartis filed a corresponding redacted public version of Exhibit 2002. The Second Motion avers that the redacted information pertains to “two categories of confidential information in

Exhibit 2002 that Novartis seeks to seal: (1) Novartis’s proprietary research and development information, and (2) confidential information of third parties.” *Id.* Novartis explains how this information is pertinent to key issues in this proceeding such as conception and reduction to practice in order to predate alleged prior art references. *Id.*

The Second Motion explains how the first category of confidential information pertains to Novartis’s research and development work related to the subject matter of the ’631 patent. Sec. Mot. 3. Novartis explains how the information includes specific quantitative and qualitative details regarding the development of the subject matter, such as dosage accuracy testing, syringe components under investigation, break-loose and slide force testing, particle testing, siliconization process, terminal sterilization process, and syringe packaging. *Id.* at 3–4.

The second category of confidential information pertains to portions of Exhibit 2002 that contain third party confidential information that Novartis is legally obligated to protect from public disclosure because Novartis Pharma AG is a company organized under and governed by the laws of Switzerland. *Id.* at 4. Relying on the Declaration of Martina Athanas (Ex. 2097), Novartis details how and why certain information must be maintained as confidential to comply with Swiss law. *Id.* For example, under Articles 162 and 273, Novartis is prohibited from disclosing such confidential information related to a third party unless the third party consents to that disclosure or the disclosure is made during legal assistance proceedings under the applicable Hague evidence convention. *Id.* Novartis’ declarant, who aided in the Swiss compliance review and redaction of the documents presented in Exhibits 2002, 2063, 2064, and

2066–2088, testifies that the companies that provided consent for Novartis to disclose their information in these proceedings did so only under an agreement that Novartis would disclose this information in such a way that would protect the information from public disclosure. Ex. 2097 ¶¶ 3–5, 34. We find this testimony persuasive.

We determine that Novartis has established good cause for redacting the information it seeks to keep confidential in Exhibit 2002. Novartis has proven that the information is truly confidential, pertinent to the ongoing trial, and that such confidentiality outweighs the strong public interest in having an open record.

Exhibits 2063 and 2064

Exhibit 2063 is an internal Novartis PowerPoint presentation, and Exhibit 2064 is a technical report authored by a named inventor. Sec. Mot. 6. The Second Motion avers that “Novartis seeks to seal three categories of information: (1) Novartis’s proprietary development information, (2) business information of third parties, and (3) personal information of Novartis and third party employees.” For similar reasons as noted above, Novartis relies on these documents in support of its argument that it conceived and reduced to practice the subject matter claimed in the ’631 patent prior to the publication of certain alleged prior art. *Id.*

Novartis explains how Exhibits 2063 and 2064 contain details pertaining to Novartis’s research and development work related to the subject matter of the ’631 patent, and thus how the information is confidential research and development information. *Id.* at 7. Novartis provides pinpoint cites and shows that the “information includes the technical data generated from experiments on terminal sterilization and

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.