

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 Owners

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Case IPR2021-00816  
Patent 9,220,631

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**PATENT OWNERS' SECOND MOTION TO SEAL**

Patent Owners Novartis Pharma AG, Novartis Technology LLC, and Novartis Pharmaceuticals Corporation (collectively, “Novartis”) respectfully renew their request that the Board seal Exhibits 2002, 2063–2064, and 2066–2088, which contain Novartis’s confidential research and development information, confidential information of third parties, and employee personal information. On October 28, 2021, the Board granted Novartis’s motion for entry of a modified protective order, but denied Novartis’s first motion to seal. *See* IPR2021-00816, Paper No. 15. In its denial, the Board invited Novartis to file a second motion to seal with additional information. *See id.* at 7. Novartis addresses these issues in this renewed motion.

In determining whether to grant a Motion to Seal, the Board must find “good cause” to seal the information in question and “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.” 37 C.F.R. § 42.54(a); Consolidated Trial Practice Guide November 2019 at 19. As described in the *Consolidated Trial Practice Guide*, the Board identifies confidential information in a manner “consistent with Federal Rule of Civil Procedure 26(c)(1)(G), which provides for protective orders for trade secret or other confidential research, development, or commercial information.” *Id.*

The information that Novartis seeks to seal in this motion is either confidential research and development related to the subject matter of U.S. Patent

No. 9,220,631 (“the ’631 patent”) or is subject to contractual or statutory obligations of confidentiality to third party companies or individuals, 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 Novartis’s confidential information would competitively harm Novartis’s business prospects and put Novartis at a competitive disadvantage relative to other similarly positioned companies in the same industry. In addition, we are advised by Swiss counsel that public disclosure of the third party confidential information or personal information of employees could subject Novartis to civil and criminal penalties under the laws of Switzerland. As such, good cause exists to seal the confidential versions of Exhibits 2002, 2063–2064, and 2066–2088.

Novartis publicly filed a redacted version of Exhibit 2002 with its Patent Owner Preliminary Response (“POPR”). With this motion, Novartis is publicly filing redacted versions of Exhibits 2063–2064, and 2066–2088.<sup>1</sup> These redactions are narrowly tailored to protect the confidential information of Novartis and third parties, and the personal information of employees, from public disclosure.

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<sup>1</sup> Novartis previously requested that Exhibits 2063–2064, and 2066–2088 be sealed in their entirety, but is currently submitting redacted public versions.

**Exhibit 2002 (Picci Declaration)**

Exhibit 2002 is the Declaration of Marie Picci, a named inventor on the '631 patent. Novartis relies on Exhibit 2002 to support its argument that neither Chacornac (Ex. 1014)<sup>2</sup> nor Wolgemuth (Ex. 1072)<sup>3</sup> is prior art to the '631 patent because Novartis conceived of the invention claimed in the '631 patent prior to the publication of Chacornac and Wolgemuth, and diligently worked to reduce the invention to practice. *See, e.g.*, Ex. 2002.005–.007, .009–.013; POPR at 42, 48.

There are 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.

*First*, portions of Exhibit 2002 contain information pertaining to Novartis's research and development work related to the subject matter of the '631 patent, and are therefore "confidential research [and] development . . . information" pursuant to FRCP 26(c)(1)(G). This work includes specific quantitative and qualitative details regarding the development of the subject matter claimed in the '631 patent, such as dosage accuracy testing, syringe components under investigation, break-

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<sup>2</sup> Chacornac (Ex. 1014) is a patent application filed on October 17, 2011 and published on April 19, 2012.

<sup>3</sup> Wolgemuth (Ex. 1072) is a reference dated October 2011.

loose and slide force testing, particle testing, siliconization process, terminal sterilization process, and syringe packaging. *See, e.g.*, Ex. 2002.006–.008, .0017–.0032. Public disclosure of this information would harm Novartis because insight into its research and development processes would provide a competitive advantage to Novartis’s competitors to Novartis’s detriment.

*Second*, portions of Exhibit 2002 that Novartis seeks to seal contain third party confidential information that Novartis is legally obligated to protect from public disclosure. Novartis Pharma AG is a company organized under and governed by the laws of Switzerland. As set forth in the accompanying declaration of Martina Athanas, Articles 162 and 273 of the Swiss Criminal Code (“SCC”) prohibit the unauthorized disclosure or communication of manufacturing or business secrets to third parties, including foreign authorities, the opposing party or its counsel. Exhibit 2097, Declaration of Martina Athanas, ¶¶ 4, 8, 10. These provisions are designed to protect manufacturing and business secrets of entities and individuals against unauthorized disclosure by persons bound to confidentiality by contract or by law. *Id.* ¶¶ 8–14. Any information qualifies as manufacturing and business secrets under the SCC provided that the information impacts or relates to the economic success of a company. *Id.* ¶ 13. Swiss law protects all information relating to a company’s manufacturing and production process and any other elements of economic life over which the owner of a secret is presumed to

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