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' THIRD MOTION TO SEAL AND MOTION FOR A MODIFIED DEFAULT PROTECTIVE ORDER

Patent Owners Novartis Pharma AG, Novartis Technology LLC, and Novartis Pharmaceuticals Corporation (collectively, "Novartis") respectfully request that the Board seal portions of the Patent Owners' Response ("POR"), portions of Novartis's Motion to Amend ("MTA"), and Exhibits 2099–2115, 2119–2121, 2123–2124, 2126, 2128–2134, 2136–2148, 2150, 2155–2159, 2166–2172, 2194, 2201, 2203–2206, 2208, 2224, and 2254, which contain Novartis's confidential commercial and research and development information, confidential information of third parties, and personal employee information. Novartis concurrently requests entry of a Modified Default Standing Protective Order (Ex. 2323), to provide additional protections for confidential information of a third party. Exhibit 2324 shows the proposed modifications to the order that the Board previously entered in this case. Petitioner does not oppose entry of this Modified Protective Order, set forth in Exhibit 2323.

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." Consolidated Trial Practice Guide November 2019 at 19. 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 is either Novartis's confidential research and development related to the subject matter of U.S. Patent No. 9,220,631 ("the '631 patent"), Novartis's confidential commercial information, third party confidential information, or information that 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 or third party confidential information would competitively harm Novartis's and/or the third parties' business prospects and put these companies 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 the POR, portions of Novartis's Motion to Amend, and Exhibits 2099–2115, 2119–2121, 2123–2124, 2126–2128, 2129–2134, 2136–2148, 2150, 2155–2159, 2166–2172, 2194, 2201, 2203–2206, 2208, 2224, and 2254. With this motion, Novartis is publicly filing redacted versions of Exhibits

2119–2121, 2123–2124, 2126–2128, 2129–2134, 2136–2148, 2150, 2155–2159, 2166–2172, 2201, 2203–2206, 2208, 2224, and 2254. These redactions are narrowly tailored to protect the confidential information therein from public disclosure.

Exhibits 2120, 2126, 2128–2131, 2136–2145, 2150, 2244, and 2254 (Novartis's Technical Documents)

Exhibits 2120, 2126, 2128–2131, 2136–2145, 2150, 2244, and 2254 are Novartis presentations discussing its research and development of the '631 patent and project timelines, reports prepared for submission to regulatory authorities, and emails regarding creating a product that would meet standards set by the European Medicines Agency. Novartis relies on these documents to support its arguments regarding secondary considerations of non-obviousness.

As in Novartis's Second Motion to Seal, Novartis seeks to seal three categories of information in these documents: (1) Novartis's proprietary development information, (2) business information of third parties, and (3) personal information of Novartis and third party employees.

First, Exhibits 2120, 2126, 2128–2131, 2136–2145, 2150, 2244, and 2254 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 numerical data measuring the effect of certain sterilization processes on the stability of the drug product, discussions on dosing accuracy and particulate matter, and diagrams of stopper and plunger designs. 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 Exhibits 2120, 2128–2129, 2130–2131, 2136–2139, 2141–2145, 2150, and 2254 that Novartis seeks to seal certain third party confidential information that Novartis is legally obligated to protect from public disclosure. As previously explained in Novartis's Second Motion to Seal, 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. *See* Paper No. 18 at 4–5 (stating that 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 have an interest in confidentiality").

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

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