

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' FOURTH MOTION TO SEAL**

Pursuant to 37 C.F.R. §§ 42.14, 42.22, and 42.54, Patent Owners Novartis Pharma AG, Novartis Technology LLC, and Novartis Pharmaceuticals Corporation (collectively, “Novartis”) respectfully request that the Board seal Exhibits 2337 and 2338, filed herewith, which contain Novartis’s confidential research and development information of Patent Owner, confidential research and development information of third parties, and employee personal information.

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 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 that Novartis seeks to seal is non-public and proprietary. 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 Exhibits 2337, and 2338.

**Exhibit 2337**

Exhibit 2337 is the deposition transcript of Regeneron's expert witness, James Agallaco, taken in the related International Trade Commission ("ITC") investigation regarding the '631 patent. *See Certain Pre-Filled Syringes for Intravitreal Injection and Components Thereof*, Inv. No. 337-TA-1207. Novartis relies on this document to rebut Regeneron's arguments concerning the claims of the '631 Patent.

Exhibit 2337 contains information on Novartis's business relationships with third parties as well as third party confidential business information. This document contains details on collaboration efforts on pre-filled syringe design and manufacture (*See e.g.*, 2337.0018) and contractual agreements between Novartis and third party business partners. *Id.*

This document was part of the record developed in the ITC action, and in that action, these documents were subject to a protective order requiring that these

documents only be accessible by outside counsel. The parties to this IPR proceeding have agreed to modify the protective order in this action to extend the same level of protection for these documents as was provided in the ITC action. Exhibit 2323.

Therefore, good cause exists to seal exhibit 2337 due to the presence of information regarding Novartis and its third party business partners because Novartis's competitors would gain insight into Novartis's business approaches and commercial interests when collaborating with third parties, thereby placing Novartis at a competitive disadvantage.

### **Exhibits 2338**

Exhibit 2338 is Novartis document produced in the related ITC case. Novartis relies on these documents to rebut Regeneron's arguments concerning the claims of the '631 Patent.

Exhibit 2338 contains Novartis internal communications pertaining to research and development activities related to the subject matter of the '631 patent, and are therefore, "confidential research [and] development...information" pursuant to Fed. R. Civ. P. 26(c)(1)(G). Exhibit 2337 contains proprietary information regarding details on Novartis's research strategy, such as the evaluation of physiochemical properties of the drug products and discussions on project feedback. *See e.g.*, 2338.001–.003. Exhibit 2337 also contains personal

information of Novartis and third party employees, including the identities of Novartis and third party employees and their roles and responsibilities. As discussed above, Novartis is legally obligated to prevent the public disclosure of employee information, and public disclosure of this information may expose Novartis to criminal sanctions and civil liability.

This documents was part of the record developed in the ITC action, and in that action, these documents were subject to a protective order requiring that these documents only be accessible by outside counsel. The parties to this IPR proceeding have agreed to modify the protective order in this action to extend the same level of protection for these documents as was provided in the ITC action. Exhibit 2323.

Therefore, good cause exists to seal exhibit 2338 due to the presence of Novartis's confidential information and confidential information from a third party, the disclosure of which would put Novartis and the third party at a competitive disadvantage. There is also good cause to seal the personal information of individuals employed by Novartis and third parties based on obligations under Swiss privacy laws.

Accordingly, Novartis respectfully requests that the Board grant Patent Owners' Fourth Motion to Seal.

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