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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U.S. Patent No. 9,220,631

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**PETITIONER'S NOTICE RANKING PETITIONS**

Petitioner concurrently filed two petitions challenging all claims of U.S. Patent No. 9,220,631 ("the '631 Patent"). As instructed in the Patent Trial and Appeal Board Consolidated Trial Practice Guide (Nov. 2019) ("CTPG"), Petitioner submits this Notice to provide (1) a ranking of the petitions in the order in which it wishes the Board to consider the merits; and (2) a succinct explanation of the differences between the petitions, why the issues addressed by the differences are material, and why the Board should exercise its discretion to institute an additional petition if it identifies one petition that satisfies Petitioner's burden under 35 U.S.C. § 314(a). CTPG at 60.

Although Petitioner believes that both Petitions are meritorious and justified, Petitioner requests the Board to consider the petitions according to the following ranking:

| Rank | Petition | Claims | Principal References |
|---|---|---|---|
| 1 | IPR2020-01317 | 1-26 | Sigg[1] and Boulange[2] |
| 2 | IPR2020-01318 | 1-26 | Lam[3] and Reuter[4] |

[1] PCT Patent Publication No. WO 2011/006877 to Sigg *et al*. (Ex. 1007)

[2] PCT Patent Publication No. WO 2009/030976 to Boulange *et al*. (Ex. 1008)

[3] PCT Patent Publication No. WO 2008/077155 to Lam *et al.* (Ex. 1029)

[4] Bruno Reuter & Claudia Petersen, *Syringe Siliconization*, 4 TECHNOPHARM 2, 238 (2012). (Ex. 1010)

The claims of the '631 Patent are directed to a terminally sterilized pre-filled glass syringe containing a VEGF-antagonist that includes low levels of silicone oil (e.g., less than 100 µg) and a stopper break loose force less than 11 N. Petition #1 (Sigg + Boulange) and Petition #2 (Lam + Reuter) present different combinations of terminal sterilization and siliconization prior art: Sigg and Lam disclose different methods of terminal sterilization, while Boulange and Reuter disclose siliconized pre-filled glass syringes having the claimed levels of silicone oil and stopper break loose force. As explained below, there are several material differences between the petitions and prior art that warrant the Board's separate consideration of each petition.

First, there is an issue regarding the priority date of the '631 Patent that merits the consideration of two petitions. CTPG at 59 ("the Board recognizes that there may be circumstances in which more than one petition may be necessary, including, for example, … when there is a dispute about priority date requiring arguments under multiple prior art references."). Although the '631 Patent was filed on January 25, 2013, the '631 Patent claims priority to a foreign application (EP12174860) filed on July 3, 2012.[5] Petition #1, relies on publications—Sigg and Boulange—that qualify as prior art under pre-AIA § 102(b) even if the '631 Patent

[5] There is a typo on the face of the '631 Patent, which lists the earliest foreign application priority date as July 30, 2012.

is entitled to its earliest claimed priority date. Patent Owner cannot swear behind Sigg and Boulange. In contrast, Petition #2 argues that the '631 Patent is not entitled to a July 3, 2012 priority date because EP12174860 fails to disclose the break loose forces required by every challenged claim. For this reason, Reuter, which was publicly available no later than August 14, 2012, is prior art to the '631 Patent under pre-AIA § 102(a). Even if the claims of the '631 Patent are not entitled to a July 3, 2012 priority date, Patent Owner Novartis may still attempt to swear behind Reuter. A single petition provided inadequate space to challenge the priority date of the '631 Patent, while also including grounds based on both Sigg/Boulange and Lam/Reuter.

Second, there are differences between the principal references asserted in Petition #1 and Petition #2 that warrant consideration of both petitions. Sigg and Lam disclose different processes for terminal sterilization of a pre-filled syringe—ethylene oxide (EtO) v. hydrogen peroxide ($H_2O_2$). Petitioner cannot predict whether Patent Owner may argue that this distinction is relevant to the obviousness combinations proposed in the petitions. Accordingly, Petitioner should be permitted to include grounds based on both Sigg and Lam. In addition, with respect to dependent claims 18 and 19 of the '631 Patent, Lam discloses explicit data regarding the amount of EtO residue remaining (Ex. 1029 at 13:10-16:3),

whereas Sigg discloses "degrad[ing] all potentially remaining hydrogen peroxide residue" (Ex. 1007 at 3:22-24).

Third, there are differences between the secondary references asserted in Petition #1 and Petition #2 that warrant consideration of both petitions. While Boulange and Reuter both disclose siliconizing a pre-filled glass syringe with low levels of silicone oil, only Reuter explicitly discloses the use of DC 365 silicone oil emulsion with a silicone oil having a viscosity of 350 cP as required by dependent claims 4, 10, and 23 of the '631 Patent. In Petition #1, the ground addressing dependent claims 4, 10 and 23 introduces an additional reference (Fries). For this reason, Petition #1 requires five grounds to address all of the challenged claims, while Petition #2 requires only four grounds.

Fourth, consideration of both petitions is warranted due to the large number of claims in the '631 Patent asserted by Patent Owner. CTPG at 59 ("the Board recognizes that there may be circumstances in which more than one petition may be necessary, including, for example, when the Patent Owner has asserted a large number of claims in litigation …"). In an ITC complaint filed on June 19, 2020, Patent Owner alleged infringement of claims 1-6 and 11-26, and a domestic industry based on claims 1-10 and 14-26. Patent Owner has not yet identified asserted claims for the NDNY action. Given that all twenty-six claims are at issue in the co-pending litigation and the number of grounds required to address all

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