

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 Owners

Case IPR2020-01317
Patent 9,220,631

**PATENT OWNERS' RESPONSE TO PETITIONER'S
NOTICE RANKING PETITIONS**

Petitioner filed two, largely duplicative, petitions challenging U.S. Patent No. 9,220,631 (“the ’631 Patent”). IPR2020-01317, Paper 3 (“-01317 Petition”); IPR2020-01318, Paper 3 (“-01318 Petition”). As explained in Patent Owner’s Preliminary Responses, the Board should decline to institute both petitions. If the Board decides to institute review of the ’631 Patent, however, it should only institute one petition.

In most cases, one petition is sufficient to challenge the claims of a patent. Consolidated Trial Practice Guide November 2019 (“TPG”) at 59 (“[M]ultiple petitions by a petitioner are not necessary in the vast majority of cases.”). Addressing two petitions at the same time places an unnecessary burden on the Board and Patent Owner. *Id.* Petitioner argues that both of these petitions should be instituted because they fall within the scope of the two scenarios contemplated in the TPG where a second petition might be warranted—a potential dispute regarding priority date, and Patent Owner’s assertion of a large number of claims. Petitioner, however, only states that these issues may be *present*, but does not provide any explanation of *why* these circumstances warrant a second petition here.

First, the mere presence of a potential priority dispute does not justify multiple petitions, and in fact, the need for multiple petitions in these cases “should be rare.” TPG at 59; *Square, Inc. v. 4361423 Canada Inc.*, IPR2019-01626, Paper 14 at 10 (March 30, 2020) (“[T]he November 2019 TPG does not contemplate that

whenever there is a priority dispute, Petitioner is justified in filing two petitions against the same patent.”). Here, Petitioner’s second petition is completely unnecessary and a problem of Petitioner’s own making.

Petitioner ranked IPR2020-01317 (Sigg and Boulange) *first* and IPR2020-01318 (Lam and Reuter) *second*. Paper 2 at 1. Petitioner suggests its second petition is warranted because there is a possible priority dispute implicating the applicability of Reuter (asserted as 102(a) prior art). *Id.* at 2-3. But that gets it backwards—it is Petitioner’s *second* petition that has a possible priority question, not Petitioner’s *first* petition. Notably, Petitioner identifies no material differences between Boulange (asserted as 102(b) art) and Reuter except that “Reuter explicitly discloses the use of DC 365 silicone oil emulsion.” *Id.* at 4. This alleged distinction is applicable to just three dependent claims, and Petitioner separately alleges “was a known, commercially available silicone oil emulsion” in its first petition. *See* -01317 Petition at 59-61. Petitioner does not identify any other perceived strengths in the disclosure of Reuter compared to the disclosure in Boulange that would necessitate a second petition. Simply choosing to raise a set of duplicative arguments should not entitle Petitioner to two petitions. Nor does it justify burdening the Patent Owner and the Board. *See Dropbox, Inc. v. WhitServe LLC*, IPR2019-01018, Paper 13 at 8-9 (Nov. 1, 2019) (rejecting a second petition where petitioner presented another petition with alternative arguments that could

not be antedated).

Second, Petitioner's only other justification for the second petition is that a single petition did not provide enough space to present its alternative arguments. Paper 2 at 3. But Petitioner does not provide any explanation of why its arguments present the rare circumstance that justifies a second review. For example, Petitioner does not address only a subset of claims in the first petition and a different subset in the second petition. Nor does Petitioner allege that claim construction issues make some asserted references more (or less) relevant. Moreover, Petitioner was able to challenge all 26 claims in each of the petitions, eliminating any risk of prejudice to Petitioner and demonstrating that the number of claims did not make a challenge in a single petition impossible. *See Square* at 10 (rejecting multiple petitions were "Petitioner was able to assert multiple grounds against all eighteen challenged claims in a single petition"); *Dropbox*, IPR2019-01018, Paper 13 at 6 ("Th[e] duplication of challenges undermines Petitioner's argument that the number . . . of the claims requires two petitions."). Additionally, the number of claims is not a deciding factor, as the Board has denied multiple petitions where Petitioners have challenged more than 26 claims. *Comcast Cable Commc'ns, LLC, v. Rovi Guides, Inc.*, IPR2019-01377, Paper 9 at 8-9 (Feb. 10, 2020) (denying institution of two of three petitions challenging 30 claims); *Nalox-1 Pharms., LLC, v. Opiant Pharms., Inc.*, IPR2019-00686, Paper 11 at 6-7 (Aug. 27,

2019) (denying two of three petitions challenging 29 claims); *Nalox-1 Pharms., LLC, v. Opiant Pharms., Inc.*, IPR2019-00689, Paper 11, 6-7 (Sept. 9, 2019) (denying two of three petitions challenging all 45 claims in patent); *Nalox-1 Pharms., LLC, v. Opiant Pharms., Inc.*, IPR2019-00695, Paper 10, 6 (Oct. 1, 2019) (denying two of three petitions challenging all 30 claims in patent).

Moreover, the fact that the asserted references may be different is not enough to merit a second petition. *See Volkswagen Grp. of Am., Inc. v. Mich. Motor Techs. LLC*, IPR2020-00161, Paper 8 at 10 (PTAB June 2, 2020) (“A petition that presents alternative arguments directed to the same claims is not sufficient to show, in accordance with the [TPG], that the differences between the petitions warrant institution of both proceedings.”). Nonetheless, the grounds raised here in each IPR are essentially the same: the combination of a reference allegedly disclosing terminal sterilization of a pre-filled syringe with another reference allegedly disclosing siliconization of a pre-filled syringe. For example, the only difference Petitioner identifies between Sigg (Petitioner’s lead reference in the -01317 Petition) and Lam (Petitioner’s lead reference in the -01318 Petition) is the different specific processes for terminal sterilization. Paper 2 at 3. However, none of the claims of the ’631 patent is limited to either one of these processes, and this difference does not impact Patent Owners’ position that these references would not have rendered the challenged claims unpatentable.

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