

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NALOX-1 PHARMACEUTICALS, LLC,
Petitioner,

v.

ADAPT PHARMA LIMITED, and
OPIANT PHARMACEUTICALS, INC.,
Patent Owner.

Case Nos.
IPR2019-00697, IPR2019-00698, and IPR2019-00699
Patent No. 9,775,838 B2

Before: ERICA A. FRANKLIN, ZHENYU YANG, and
JACQUELINE T. HARLOW, *Administrative Patent Judges*.

FRANKLIN, *Administrative Patent Judge*.

Conduct of the Proceedings
37 C.F.R. § 42.5

IPR2019-00697
IPR2019-00698
IPR2019-00699
Patent No. 9,775,838 B2

On February 19, 2019, in each of the three above-captioned proceedings, Petitioner filed a Petition requesting an *inter partes* review of claims 1–46 of U.S. Patent No. 9,775,838 B2.¹ In its Preliminary Responses, Patent Owner contends the Petitions in IPR2019-00698 and IPR2019-00699 are “secondary, redundant petitions” because they “merely add[] grounds that make the same arguments with more complicated combinations of more references” than those set forth in IPR2019-00697. *See, e.g.*, IPR2019-00698, Paper 9, 1–2. According to Patent Owner, “not only are large swaths of text word-for-word identical,” but each Petition “relies extensively on the Wyse reference that is the principal reference in Case IPR2019-00697.” *Id.* at 2. Patent Owner argues that we should exercise discretion to deny institution of IPR2019-00698 and IPR2019-00699 on this basis. *Id.*

The Director has discretion to deny a petition under 35 U.S.C. § 314(a). *See Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2140 (“[T]he agency’s decision to deny a petition is a matter committed to the Patent Office’s discretion.”). The Board takes into account various considerations when exercising discretion on behalf of the Director. *See General Plastic Indus. Co. v. Canon Kabushiki Kaisha*, Case IPR2016-

¹ In all, Petitioner has challenged 5 patents with 15 separate petitions filed at or about the same time. IPR2019-00697, Paper 9, 1; *see also* IPR2019-00697, Paper 6, 1–2 (listing petitions for *inter partes* review filed by Petitioner against patents held by Patent Owner). According to Patent Owner, all of these patents relate to the same product, “NARCAN[®] Nasal Spray 4 mg.” IPR2019-00697, Paper 9, 1.

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01357 (PTAB Sept. 6, 2017) (Paper 19) (Section II.B.4.i. designated as precedential) (stating factors considered in Board’s exercise of discretion under 35 U.S.C. § 314(a)). Although the facts of *General Plastic* concern serial or “follow-on” petitions, the August 2018 Update to the Office Trial Practice Guide notes

[t]here may be other reasons besides the “follow-on” petition context where the “effect . . . on the economy, the integrity of the patent system, the efficient administration of the Office, and the ability of the Office to timely complete proceedings,” favors denying a petition even though some claims meet the threshold standards for institution.

Office Trial Practice Guide August 2018 Update² referenced at 83 Fed. Reg. 39,989 (“August 2018 TPG Update”) (Aug. 13, 2018), at 10 (quoting 35 U.S.C. § 316(b)). With particular regard to “parallel petitions,” i.e., “[t]wo or more petitions filed against the same patent at or about the same time,” the July 2019 Update to the Office Trial Practice Guide explains that such petitions “may place a substantial and unnecessary burden on the Board and the patent owner and could raise fairness, timing, and efficiency concerns.” Office Trial Practice Guide July 2019 Update³ referenced at 84 Fed. Reg. 33,925 (“July 2019 TPG Update”) (July 16, 2019), at 26 (citing 35 U.S.C. § 316(b)).

Maintaining multiple, concurrent proceedings per patent presents a significant burden for the Board, because, among other things, the Board

² Available at <https://go.usa.gov/xU7GP>.

³ Available at <https://www.uspto.gov/sites/default/files/documents/trial-practice-guide-update3.pdf>.

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endeavors to assign all such cases to the same panel. *See* SOP 1 (Rev. 15), III.G.3. Additionally, when there are other related patents challenged by multiple petitions at the same time, as is the case here, this can undermine the Office’s ability to complete proceedings in a timely manner and may place an unfair burden on Patent Owner. *See* August 2018 TPG Update at 10; *cf. General Plastic*, slip op. at 16 (requiring the Board to consider ability to meet statutory deadlines as an institution factor); 37 C.F.R. § 42.1(b) (“[The rules] shall be construed to secure the just, speedy, and inexpensive resolution of every proceeding.”).

We agree with Patent Owner that the number of Petitions challenging the same patent here may place a substantial and unnecessary burden on the Board and Patent Owner, particularly if we determine the Petitions rely on substantially overlapping grounds and theories. Accordingly, the panel issues this Order under 37 C.F.R. § 42.5 to give the parties an opportunity to focus the Board’s limited resources on genuine issues in dispute.

Within 7 days of this Order, Petitioner shall provide a Notice not to exceed 3 pages identifying (1) a ranking of the three Petitions in the order in which it wishes the panel to consider the merits, if the Board uses its discretion to institute any of the Petitions, and (2) a succinct explanation of the differences between the Petitions, why the differences are material, and why the Board should exercise its discretion to consider the additional Petitions if it identifies a Petition that satisfies Petitioner’s burden under 35 U.S.C. § 314(a). The Board encourages Petitioner to use a table to aid in identifying the similarities and differences between the Petitions.

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If it so chooses, Patent Owner may, within 7 days of the receipt of Petitioner's Notice, provide a Response not to exceed 3 pages, stating its position with respect to any of the differences identified by Petitioner. In particular, Patent Owner should explain whether the differences identified by Petitioner are material and in dispute. If stating that reasons are not material or in dispute, Patent Owner should clearly proffer any necessary stipulations. For example, Patent Owner may seek to avoid additional Petitions by proffering a stipulation that certain claim limitations or priority dates are not disputed.

Petitioner and Patent Owner are instructed to file the same paper in all proceedings and use this Order's case caption format. The panel will consider the parties' submissions in determining whether to exercise its discretion to institute *inter partes* review under 35 U.S.C. § 314(a).

It is

ORDERED that within 7 days of this Order, Petitioner shall file a Notice consistent with the foregoing instructions; and

FURTHER ORDERED that, within 7 days of Petitioner's Notice, if it chooses to, Patent Owner may file a Response consistent with the foregoing instructions.

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