

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 Owners.

Cases IPR2019-00697, IPR 2019-00698, and IPR 2019-00699
Patent 9,775,838

PATENT OWNERS' RESPONSE TO PETITIONER'S NOTICE

Petitioner's Notice confirms that the Wang and Davies Petitions are redundant of the Wyse Petition. Like Patent Owners, Petitioner ranks the Wyse Petition (IPR2019-00697) first, ahead of the Wang and Davies Petitions (-00698 and -00699).

Petitioner largely dodges the Board's request for an explanation of the differences among the Petitions. Petitioner's handful of examples of alleged differences largely boil down to reasons why Wang and Davies teach fewer claim limitations and are even weaker references than Wyse. As Patent Owners explained in their Preliminary Responses, all three Petitions have fatal deficiencies. In addition, the district court trial related to these Petitions is scheduled to start in two weeks. The Board should thus decline to institute any of these IPR proceedings. But if the Board institutes anything, it should institute only the Wyse Petition.

First, Petitioner asserts that the Wyse Petition presents different issues because Wyse may not be prior art if the claims that were ultimately granted in the '838 patent are entitled to the provisional application date of March 14, 2014. Notice at 1. For the purpose of these proceedings, however, Patent Owners will not dispute that Wyse, Davies, and Wang are all prior art. Thus, there is no need to institute a second petition as a precaution, and Petitioner's comment that different statutory provisions apply to whether Wyse, Davies and Wang are prior art is moot. Notice at 1-2.

Petitioner also argues that the Petitions are non-redundant because Petitioner has submitted a certified translation of Wang, rather than the machine translation that

was before the Examiner. Notice at 2. But Petitioner fails to point out any differences between the translations or how the way the various references were translated has any bearing on the references' substance. Petitioner's translation argument is just a convoluted way of stating the truism that the three Petitions do not cite exactly the same references. This does not change the point that the Petitioner's arguments are substantially the same for each of the references.

When Petitioner finally turns to purported differences among its obviousness arguments, it simply points to a few (unavailing) examples of purported differences, making no effort to catalog "the similarities and differences" as the Board directed. Order at 4. Petitioner does not deny the Petitions' similarities—and that, in many cases, they exhibit word-by-word sameness—on critical issues, including the volume of the nasal spray, the naloxone dose, the choice of excipients (including BZK and EDTA), etc. As a striking example, the Wang and Davies Petitions cite Wyse—not Wang or Davies—for the dose limitation of all claims, which is likely to be a central issue in any instituted proceedings. Wang Pet. at 18–19; Davies Pet. at 18–19.

Petitioner's chart, Notice at 3, reflects that there are *no issues* which Petitioner asserts are taught by Wang and Davies but not Wyse. In other words, according to Petitioner, Wang and Davies are inferior references to Wyse. According to Petitioner, the Wyse Petition relies on Wyse for the teaching of benzalkonium chloride ("BZK"), while the other Petitions do not. *See* Notice at 2–3. If true, this

would merely demonstrate the superiority of the Wyse Petition. But in fact, it is incorrect. *All three Petitions rely on HPE, not Wyse.* The Wyse Petition concedes that “Wyse discloses the preservative may be benzyl alcohol”—not BZK—and then proceeds to rely on HPE for the teaching of BZK, *id.* at 33–35, as do the other two Petitions, Wang Pet. at 32–33; Davies Pet. at 31–32. And the three Petitions contain the same discussion on Wyse’s teaching on BZK—or, more precisely, teaching away—*verbatim*. Wyse Pet. at 61–63; Wang Pet. at 62–64; Davies Pet. at 62–64.

Petitioner also argues that Wyse anticipates certain claim limitations relating to device, pH, disodium edetate, and plasma concentration, and that the other two primary references do not. But the question is not whether the disclosures of the references are different but rather whether “the Petitions rely on substantially overlapping grounds and theories.” Order at 4. Critically, for these limitations, all three Petitions similarly rely on Wyse. The Wang and Davies Petitions both cite to Wyse to demonstrate the alleged obviousness of device, pH, disodium edetate, *and* plasma concentration. *See* Wang Pet. at 20–21, 61–62; Davies Pet. at 20–21, 61–62. All Petitioner has established is that the disclosures of Wang and Davies are even further removed from the claimed invention than that of Wyse, and so Petitioner must bring in additional references to allege obviousness in the Wang and Davies Petitions. That does not constitute a “rare” instance in which two—let alone three—petitions may be needed. July 2019 TPG Update at 26.

Date: August 12, 2019

Respectfully submitted,

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