UNITED STATES PATENT AND TRADEMARK OFFICE

_____

BEFORE THE PATENT TRIAL AND APPEAL BOARD

_____

NALOX-1 PHARMACEUTICALS, LLC,
Petitioner,

v.

OPIANT PHARMACEUTICALS, INC.
Patent Owner.

_____

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

_____

PETITIONER'S NOTICE
(As Authorized by the Board's Order Dated August 1, 2019)

Petitioner Nalox-1 Pharmaceuticals, a pharmaceutical company, is currently developing, and plans to seek FDA approval to market a much needed generic version of Narcan® naloxone nasal spray far in advance of the 2035 patent expiration. The '838 patent is one of several related Orange Book patents listed for Narcan® that Petitioner has challenged to remove the barriers to an approved generic naloxone nasal spray. The '838 patent claims are invalid, primarily in light of the teachings of Wyse, Davies, and Wang. Due to different statutory bases for invalidity, as well as substantive differences in these three primary references, Petitioner filed three separate, non-redundant, IPR Petitions. The Board should consider the Petitions in the following order, and for at least the following reasons, the Board should institute review for all three Petitions:

Rank	Petition	Primary Reference
1	IPR2019-00697	Wyse
2	IPR2019-00699	Davies
3	IPR2019-00698	Wang

A. **Statutory Bases for Invalidity and Different Version of Wang Used in Petitions Render the Petitions Non-Redundant**

Petition 1 challenges the priority claim of the '838 patent and relies on Wyse, which is prior art because the '838 patent is not entitled to a priority date of March 14, 2014. The other Petitions do not rely on challenging the priority claim.

Petition 1 relies on Wyse, which is prior art under § 102(a)(2). Petitions 2 and 3, on the other hand, rely on primary references Davies and Wang, each of which is

prior art under § 102(a)(1). Patent Owner may seek to remove Wyse as prior art under an exception under § 102(b)(2), but will be unable to do so for Davies and Wang under the same exception, as Davies and Wang are prior art under § 102(a)(1) and can only be removed as prior art if an exception under a separate statutory section, § 102(b)(1), applies. Instituting each Petition will ensure that Patent Owner cannot eliminate all instituted Petitions, should it present evidence sufficient to qualify as an exception for only one category of prior art.

In addition, Petitions 2 and 3 rely on a human translation of Wang, certified to be true and accurate, while, during prosecution, Patent Owner provided to the Office only a machine translation. Patent Owner may argue about the materiality of such differences, and may otherwise seek to disqualify or discredit Wang as prior art. For these reasons, the Petitions are not redundant.

B. Differences of Disclosure Between Primary References Renders the Petitions Non-Redundant

There are numerous differences in the disclosures of the three primary references, such that certain references anticipate certain claim limitations while others do not. Petition 1 relies on Wyse, which Patent Owner argues teaches away from the use of benzalkonium chloride (BAC). Petition 1 relies on Wyse as a primary reference and the Declaration of Dr. Donovan to support the position that a POSA would not have considered Wyse to teach away from the use of BAC. Petitions 2 and 3 do not rely Wyse for the teaching of BAC, but instead for its other teachings.

In addition, Wyse and Davies each anticipates the "pre-primed device" limitation (claims 1, 41), while Wang does not. Wyse and Wang each anticipate the "pH between about 3.5 and about 5.5" limitation (claim 32), while Davies does not. And Wyse anticipates the "about 0.1% (w/v) disodium edetate" (claim 3) and the plasma concentration limitations (claims 25-29, 41-46), while Davies and Wang do not. Different legal standards apply depending on whether a claim limitation is anticipated by a single reference, or obvious in view of multiple references. Therefore, the Petitions are not redundant.

The following highlights these differences, as well as additional information the Board may find useful in determining the disposition of the Petitions.

	Wyse	Davies	Wang
Statutory category of primary reference	§102(a)(2)	§102(a)(1)	§102(a)(1)
Was primary reference cited	Y	Y	Machine translation
Relies on Wyse for teaching of BAC	Y	N	N
Anticipates "pre-primed device" limitation (claims 1, 41)	Y	Y	N
Anticipates "pH between about 3.5 and about 5.5" (claim 32)	Y	N	Y
Anticipates "about 0.1% (w/v) disodium edetate" (claim 3)	Y	N	N
Anticipates plasma concentration limitations (claims 25-29, 41-46)	Y	N	N

The Petitions do not rely on substantially overlapping grounds or theories, and the Petitioner respectfully requests that the Board institute each Petition.

Dated: August 5, 2019

    /s/ Yelee Y. Kim
Dr. Yelee Y. Kim
Reg. No. 60,088
ARENT FOX LLP
1717 K Street NW
Washington D.C. 20006
Telephone: (202) 857-6000
Fax: (202) 857-6395
yelee.kim@arentfox.com

Attorney for Petitioner

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.

fastcase
Smarter legal research.