UNITED STATES PATENT AND TRADEMARK OFFICE

—————————

BEFORE THE PATENT TRIAL AND APPEAL BOARD

—————————

AMNEAL PHARMACEUTICALS LLC AND
AMNEAL PHARMACEUTICALS OF NEW YORK, LLC,
Petitioners,

v.

ALMIRALL, LLC
Patent Owner.

—————————

Case IPR2018-00608
Patent No. 9,161,926 B2

—————————

**OPPOSITION TO PETITIONERS'
MOTION TO EXCLUDE EVIDENCE**

Patent Owner Almirall, LLC ("Almirall") responds to each of the arguments raised in Petitioners' Motion to Exclude Evidence (Paper 34). Petitioners' motion to should be denied for at least the following reasons:

I. THE BOARD SHOULD NOT EXCLUDE THE CONTESTED PORTIONS OF DR. KLIBANOV'S DECLARATION (EX. 2003)

Petitioners seek to exclude certain paragraphs of the Declaration of Almirall's expert Dr. Klibanov (Ex. 2003) as irrelevant and unfairly prejudicial because Almirall did not cite these paragraphs in its papers. *See* Paper 34 at 3–5. Petitioners apparently performed a text search of Almirall's papers, and if a paragraph was not expressly cited therein, Petitioners included it in its motion to exclude as "irrelevant and/or prejudicial," irrespective of the substance of those paragraphs. That is not the law. A cursory review of the record, moreover, reflects the allegedly uncited paragraphs are in fact relevant, undermining Petitioners' premises in any event.

Petitioners' overarching, if tacit, contention that something not directly cited in a Patent Owner Response or Sur-Reply is *per se* irrelevant and/or prejudicial is legally incorrect. Evidence is relevant if it "has *any* tendency to make a fact more or less probable than it would be without the evidence." Fed. R. Evid. 401 (emphasis added). This threshold for admissibility is quite low. *Laird Techs., Inc. v. GrafTech Int'l Holdings, Inc.*, IPR2014-00025, Paper 45 at 44 (Mar. 25, 2015);

OddzOn Prods., Inc. v. Just Toys, Inc., 122 F.3d 1396, 1407 (Fed. Cir. 1997).

Unremarkably flowing from its competence to evaluate the *weight* of record

evidence is the Board's pronouncement that, "[r]ather than excluding evidence that

is allegedly confusing, misleading, untimely, and/or irrelevant, we will simply not

rely on it or give it little weight, as appropriate, in our analysis." *SK Hynix Inc. v.*

Netlist, Inc., IPR2017-00562, Paper 36 at 49 (July 5, 2018) (denying motion to

exclude paragraphs of expert declarations and exhibits not cited in briefing). And,

in the *inter partes* review context, "the better course is to have a complete record

of the evidence to facilitate public access as well as appellate review." *Id.*

The paragraphs Petitioners seek to exclude are in any case relevant:

- Paragraphs 1–20: pertain to (i) Dr. Klibanov's background and

  qualifications as an expert in this proceeding; (ii) the materials he considered

  in forming his opinions; (iii) an overview of his opinions in this proceeding;

  and (iv) the legal principles he assumed and relied upon in rendering his

  expert opinions.

- Paragraphs 21–40: recite the claims of the '926 patent, review its

  prosecution history, and describe Dr. Klibanov's understanding regarding

  the effective filing date.

- Paragraphs 43, 61, 62, 64, 66–68 & 71-77: conceern Dr. Klibanov's

  understanding of the background of the invention.

- Paragraphs 78–80, 88–90, 92–98 & 100: set forth Dr. Klibanov's understanding of the prior art references—Garrett, Nadau-Fourcade, and Bonacucina—asserted by Petitioners in their two Grounds.

- Paragraphs 104–112, 116–122 & 125–136: relate to Dr. Klibanov's understanding of additional prior art references cited to by Petitioners and their experts, though not comprising either of their Grounds.

- Paragraphs 137–143, 146–148, 152–158, 164–167, 169–171, 173, 175–181, 183–192, 194–196 & 200: provide transitions, context, and analyses for surrounding paragraphs

- Paragraphs 202–217: respond to the portion of Dr. Michniak-Kohn's Declaration (Ex. 1002), offered by Petitioners, regarding objective indicia of non-obviousness.

- Paragraph 218: provides a conclusion.

- Paragraphs 161, 162, 163 & 168: are expressly cited in Patent Owner's Response. *See* Paper 23 at 28, 44, & 45.

Petitioners, not surprisingly, fail to explain how these paragraphs are unfairly prejudicial to Petitioners. The Board accordingly should deny Petitioners' motion to exclude certain portions of Exhibit 2003.

II.   THE BOARD SHOULD NOT EXCLUDE THE CONTESTED PORTIONS OF DR. HARPER'S DECLARATION (EX. 2022)

Petitioners likewise seek to exclude certain paragraphs of the Declaration of Almirall's clinician-expert, Dr. Harper (Ex. 2022), as irrelevant and unfairly prejudicial because Almirall did not cite these paragraphs in its papers. *See* Paper 34 at 3–5. Petitioners' arguments are no more availing in respect of Dr. Harper's Declaration. The relevance of the challenged paragraphs of Exhibit 2022 similarly cannot credibly be questioned:

- Paragraphs 1–22, 32 & 36–37: pertain to (i) Dr. Harper's background and qualifications as an expert in this proceeding; (ii) the materials she considered in forming her opinions; (iii) an overview of her opinions in this proceeding; and (iv) the legal principles she assumed and relied upon in rendering her expert opinions.

- Paragraphs 23–31: recite the claims of the '926 patent.

- Paragraph 35: reflects the indisputable agreement between Dr. Harper and her Petitioners' counterpart, Dr. Gilmore, as to the appropriate qualifications of a clinical person of ordinary skill in the art.

- Paragraphs 38–39, 65 & 78–80: provide context regarding the surrounding paragraphs that set forth the background and state of the art relating to the invention.

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.