

Filed: April 28, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC. and
AMNEAL PHARMACEUTICALS LLC

Petitioners,

v.

YEDA RESEARCH & DEVELOPMENT CO. LTD.

Patent Owner.

Case No. IPR2015-00643 (8,232,250 B2)
Case No. IPR2015-00644 (8,399,413 B2)
Case No. IPR2015-00830 (8,969,302 B2)^{1,2}

PETITIONERS' REPLY IN SUPPORT OF ITS MOTION TO EXCLUDE

¹ Case Nos. IPR2015-01976, IPR2015-01980 and IPR2015-01981 have been joined with these proceedings.

² A word-for-word identical Reply is being filed in each proceeding.

Petitioners brought this Motion because Patent Owner failed to file evidence upon which it relies. The Board and Petitioners thus cannot assess the accuracy or reliability of this evidence, so it must be excluded.

I. The IMS Related Exhibits and Declaration Testimony Are Inadmissible

The Board previously refused to admit Patent Owner’s IMS data when it denied Patent Owner’s motion for leave to file the IMS data that it omitted from its Response. Paper 48 (IPR2015-00643) (“Supp. Filing Order”) at 4-6. Patent Owner now seeks to admit documents purporting to be “summary exhibits” based on the inadmissible IMS data. Summary exhibits are admissible only when the underlying data is admitted or, at the very least, made available for copying and inspection. Fed. R. Evid. 1006. But the IMS data is not admitted, and Patent Owner never served it on Petitioners in this proceeding. That the underlying IMS data has not been made of record is of particular concern here—in this administrative proceeding, the Board only has the administrative record to consider, and will not see Dr. Grabowski testify. Patent Owner’s purported “summary exhibits” based on the IMS data (Exhibits 2108-2114 and 2120-2122)—and the corresponding paragraphs of Dr. Grabowski’s Declaration relying on these exhibits—are thus inadmissible under Federal Rule of Evidence 1006.

Patent Owner principally relies on the Board’s decision in *Phigenix, Inc. v. Immunogen, Inc.*, IPR2014-00676, Paper 39, at 28-29 (P.T.A.B. Oct. 27, 2015).

Opposition at 6-7, 10. But Patent Owner omits that in *Phigenix* the patent owner actually *filed* the IMS data. Exhibits 2347 and 2348 in *Phigenix* are the IMS data from which the economics expert prepared the summary exhibits. *Phigenix* accordingly did not address the issue here: whether Rule 1006 summaries are admissible where the underlying data is not of record and was not made available.

Patent Owner's remaining arguments are red herrings. Patent Owner argues the IMS data is too voluminous, Opposition at 6, but, of course, that is not the only requirement for admissibility under Rule 1006. Patent Owner next asserts that "[s]ummaries are often featured in expert reports, and exhibits prepared as summary evidence to accompany an expert report are almost never excluded under Rule 1006." *Id.* at 7 (internal quotations omitted). Summary exhibits may be common, but they must be based on data that can be verified as accurate. Here, neither Petitioners nor the Board are able to scrutinize the IMS data based on the administrative record. Patent Owner then complains that it produced the IMS data to Petitioners in the district court litigation. However, as Petitioners noted and the Board credited in relation to Patent Owner's Motion to File Supplemental Information, Mylan's lead counsel is not subject to the protective order in the district court litigation. Supp. Filing Order at 4-5. Production in the district court litigation also does not allow the Board to assess the exhibits' reliability. Patent Owner finally contends that IMS data is a common source of information on

pharmaceutical sales, but this assertion is irrelevant because the Board has ruled this IMS data inadmissible here.³

II. The Mid-Year Tracker Survey And Related Declaration Testimony Are Inadmissible

Similarly, Patent Owner's failure to file the complete Mid-Year Tracker survey renders its excerpted portions inadmissible. "If a party introduces all or part of a writing or recorded statement, an adverse party may require the introduction, at that time, of any other part—or any other writing or recorded statement—that in fairness ought to be considered at the same time." Fed. R. Evid. 106. The Board already denied Patent Owner leave to submit the complete Mid-Year Tracker. Supp. Filing Order at 5-6. Clearly, the full Mid-Year Tracker survey is required—without it, the Board and Patent Owner cannot critically assess its results or Dr. Grabowski's reliance upon them. Motion at 8 n.10. The Board should therefore exclude the Mid-Year Tracker survey excerpts (Exhibits 2115-2119) and related portions of Dr. Grabowski's Declaration.

Patent Owner tries to shift the burden of filing its evidence to Petitioners, arguing that Petitioners must state why the Mid-Year Tracker is unreliable and that Petitioners must themselves introduce other portions of the Mid-Year Tracker. Opposition at 11-12. But these arguments are absurd—the Mid-Year Tracker has

³ Dr. Grabowski's opinions relying on the inadmissible summary exhibits should be excluded for the same reasons described *infra* at 4-5.

not been filed or served in this proceeding, so they *cannot* refute it or admit other excerpts. Patent Owner's contentions and case cites all assume a district court litigation structure, in which Patent Owner produces the full Mid-Year Tracker in discovery and later seeks to admit only portions at trial. In the context of this administrative proceeding, however, there was no discovery period, so Petitioners have never seen the full Mid-Year Tracker survey. Petitioners and Dr. Hay thus cannot judge the reliability of Dr. Grabowski's opinions concerning the Mid-Year Tracker excerpts, and even if they could, the Board could not resolve any disagreement between the experts based on an incomplete paper record. The Mid-Year Tracker survey excerpts (Exhibits 2115-2119) and related portions of Dr. Grabowski's Declaration must be excluded.

III. Declaration Testimony Based On Undisclosed Evidence Is Inadmissible

Finally, other portions of Dr. Grabowski's Declaration cite evidence not of record. Rather than take Dr. Grabowski's word for what this evidence says, the Board should exclude Dr. Grabowski's opinions that rely on undisclosed evidence (¶¶ 15, 19-23, 37, and 50-56) under Federal Rules of Evidence 702 and 703.

Patent Owner asserts that not all bases for an expert's opinion must be admissible, but there are three problems with this argument. First, Rule 702 requires expert testimony to be "based on sufficient facts or data," and Dr. Grabowski cites no sources other than unfiled evidence for the opinions Petitioners

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.