APOTEX INC., APOTEX CORP.,
ARGENTUM PHARMACEUTICALS LLC,
ACTAVIS ELIZABETH LLC, TEVA PHARMACEUTICALS USA, INC.,
SUN PHARMACEUTICAL INDUSTRIES, LTD.,
SUN PHARMACEUTICAL INDUSTRIES, INC., and
SUN PHARMA GLOBAL FZE,
Petitioners,

v.

NOVARTIS AG.,
Patent Owner.

Case IPR2017-00854[1]
Patent US 9,187,405 B2

Before LORA M. GREEN, CHRISTOPHER M. KAISER,
and ROBERT A. POLLOCK, *Administrative Patent Judges.*

POLLOCK, *Administrative Patent Judge*.

ORDER
Granting-in-part Petitioner's Request for Additional Discovery
37 C.F.R. § 42.51(b)(2)
37 C.F.R. § 42.5

In our Order of January 11, 2018, we granted lead Petitioner Apotex's request for discovery under 37 C.F.R. § 42.51(b)(2) of (1) minutes of a February 2,

---

[1] Cases IPR2017-01550, IPR2017-01946, and IPR2017-01929 have been joined with this proceeding.

2005 face-to-face meeting between FDA and Novartis ("the FDA minutes"); (2) Novartis's briefing book for a March 26, 2007 End-of-Phase II meeting ("the briefing book"); and (3) an unredacted version of Exhibit 2063. Paper 34. In accord with our Order, the Apotex submitting briefing directed to the discovery of those documents (Paper 35 ("Mot.")); Patent Owner Novartis filed a simultaneous brief opposing Apotex's motion (Paper 39 ("Opp.")).

Apotex's brief, however, further argued for the production of a fourth document, the Phase III clinical trial protocol mentioned in Exhibit 2065 ("the protocol"). In the conference call of January 24, 2018, Novartis sought to strike the entirety of Apotex's briefing on the grounds that we had not authorized briefing with respect to the protocol, whereas Apotex argued that the protocol was reasonably within the scope of our Order. Upon weighing the equities, we authorized Novartis to submit additional briefing directed to Apotex's request for the protocol. Paper 41.

Novartis submitted its supplemental briefing on January 29. Paper 45 ("Sup. Br."). The parties filed their briefs under seal. *See* Paper 36 (Petitioner's motion to seal); Paper 37 (Patent Owner's motion to seal); Papers 38, 45 (redacted versions of Patent Owner's motions); redacted versions of Exhibits 1042–1045 and 2088. In light of the time necessary for briefing and any resultant discovery, we issued an Order extending each of DUE DATES 2 through 6. Paper 46.

RELEVANT STANDARDS

"The test for a party seeking additional discovery in an *inter partes* review is a strict one." *Symantec Corp. v. Finjan, Inc.*, Case IPR2015-01545, slip op. at 4 (PTAB Dec. 11, 2015) (Paper 9). "The moving party must show that such additional discovery is in the interests of justice." 37 C.F.R. § 42.51(b)(2)(i).

Among the factors important to this analysis is whether Petitioner can show more than "[t]he mere possibility of finding something useful, and mere allegation that something useful will be found." *See Garmin Int'l, Inc. v. Cuozzo Speed Techs. LLC*, Case IPR2012–00001, slip op. at 6 (PTAB Mar. 5, 2013) (Paper 26) (precedential). "The mere possibility of finding something useful, and mere allegation that something useful will be found, are insufficient to demonstrate that the requested discovery is necessary in the interest of justice." *Id.* A party should already be in possession of evidence tending to show beyond speculation that in fact something useful will be uncovered. *Id.* We also consider whether the requested discovery seeks the other party's litigation positions or the basis for those positions; seeks information that reasonably can be generated without the discovery requests; is easily understandable; and whether the requests are overly burdensome to answer ("Requests should be sensible and responsibly tailored according to a genuine need."). *Id.* at 6–7.

ANALYSIS

In the Patent Owner Response (Paper 27, "PO Resp."), Novartis contends that it "included a 0.5 mg daily dose in the Phase III trials [redacted] PO Resp. 25–26 (citing Ex. 2025 ¶¶ 5, 39–42). According to Dr. Lublin, the study, therefore, included a "futility analysis" procedure [redacted] Ex. 2025 ¶¶ 6, 44–47. Apotex now argues that the requested "documents are relevant because they contain or refer to communications between Patent Owner and the FDA addressing the justification for administering the 0.5 mg dose" and "[t]he only way to prove or disprove

Novartis's argument is to see the actual documents." Mot. 2.

1. The Phase III clinical trial protocol

Patent Owner's expert, Dr. Lublin, "participated in an advisory board of physicians that helped Novartis to design the Phase III trials." Ex. 2025 ¶ 43. [redacted]

By March 2007, Dr. Lublin or his assistant had provided a copy of the trial protocol to the Mount Sinai IRB. Ex. 1042, 185:14—24, 187:2–188–4; [redacted]

As we understand the testimony, section 11, or some like portion of the Phase III clinical trial protocol, contains Novartis's justification to the FDA for administering the 0.5 mg dose. Because Novartis has placed its reasons for including that dose at issue, we consider Apotex's discovery request reasonable. In particular, such discovery would provide means for testing Novartis's position here against statements it made to the FDA in submitting the protocol and is, thereby, "useful" to Petitioner's case. Moreover, in pointing to the statements of Dr. Lublin and Ms. Farrell, Apotex demonstrates more than a "mere allegation that something useful will be found" in the protocol, as required under *Garmin* Factor 1.

We balance this strong showing under Garmin Factor 1 against Novartis's arguments that production of the protocol would be unduly burdensome for the

reasons set forth in the Second Declaration of Peter J. Waibel, Esq. Sup. Br. 5, Ex. 2088. [redacted] it would be unreasonable in terms of time and effort to determine the exact version provided to Mount Sinai in March 2007. Ex. 2088 ¶¶ 6–13. Such investigations are unnecessary because we focus here not on what information the Mount Sinai IRB relied on in objecting to the 0.5 mg study arm, but on what justification for that dose Novartis provided to the FDA.[2] [redacted] We, therefore, infer that Novartis maintains a database of those amendments, such that it can readily identify which version[s] of the protocol were provided to the FDA.

Upon weighing the equities, we find the thrust of Apotex's request in the interest of justice. Accordingly, Novartis shall produce a copy of each unique version of the section of the Phase III clinical trial protocol provided to the FDA that contains Novartis's justification for administering the 0.5 mg dose.

2. Novartis's briefing book

Dr. Lublin relies on an excerpt of the Novartis briefing book quoted in Exhibit 2064, [redacted] Ex. 2025 ¶ 46. Dr. Lublin testified that he did not rely on any other portion of the briefing book in preparing his declarations. Ex. 1042, 157:25–158:7. And though the remaining portions of the FDA minutes *may* bear on

[2] Patent Owner's argument that "FDA is not a person of ordinary skill" is inapposite because we focus on Novartis's representations *to* the FDA, and not what the FDA understood from those representations. *See* Sup. Br. 4.

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.