Paper No. ___
Filed: January 22, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

NOVARTIS A.G.,
Patent Owner.

IPR2017-00854[1]
Patent No. 9,187,405

PETITIONER'S MOTION FOR DISCOVERY

---

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

I. RELIEF REQUESTED

Pursuant to 37 C.F.R. §§42.51(b), 42.52(a)(2) and Paper 34, Petitioner requests an order requiring Novartis to produce (i) minutes of its February 2, 2005 meeting with FDA ("FDA Minutes"), (ii) Novartis's briefing book for the March 26, 2007 End-of-Phase II meeting ("Briefing Book"), (iii) the phase III protocol referenced in Exhibit 2065 ("Protocol"), and (iv) an unredacted copy of EX2063.

Novartis relies in its Patent Owner's Response ("POR") upon excerpts from the FDA Minutes and Briefing Book to argue that the 0.5 mg daily dose of fingolimod was administered to RRMS patients in the phase III trials because it was expected to lack "any efficacy." POR at 25-27, 40. Petitioner is entitled to see the entire documents, not just the excerpts Novartis selected for inclusion. Otherwise, Patent Owner will deny Petitioner its right to submit other portions of the documents "that in fairness ought to be considered." F.R.E. 106.

Petitioner initially objected to Novartis's reliance in its POR and declarations on excerpts of the documents quoted in Exhibits 2063-2066. Paper 31 at 10. The same day that Novartis served its supplemental evidence, Petitioner again asked Novartis to produce complete copies of the FDA minutes and Briefing Book. EX1044. After an unfruitful meet and confer, Petitioner promptly requested Board assistance. EX1045 at 2. Petitioner then began depositions of Novartis's witnesses. During one of those depositions, Dr. Lublin testified that the clinical

trial protocol referenced in EX2065 describes Novartis's justification for including the 0.5 mg dose. EX1042 at 158:15-166:24. Petitioner requested production of the Protocol, but Novartis never complied. EX1042 at 245:23-246:3.

Petitioner followed up with another email to Trials regarding its teleconference request and noted that it was also requesting the Protocol. EX1045 at 1. After the teleconference, the Board issued an order stating "Petitioner Apotex may file a motion seeking additional discovery." Paper 34 at 4.

As explained in detail below, all four 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. The only way to prove or disprove Novartis's argument is to see the actual documents. Requiring production of the documents is thus in the interests of justice and is necessary to afford Petitioner a fair cross-examination of Novartis's witnesses. 37 C.F.R. §§ 42.51(b)(1)(i), (iii), (2)(i)-(ii). Petitioner's Reply is due February 2, 2018. Petitioner thus requests Novartis produce the documents promptly.

II. DETAILS ABOUT REQUESTED DOCUMENTS

A. "FDA Minutes" Document

Dr. Lublin relies on [redacted]

[redacted]

EX2025 at ¶55. Dr. Lublin repeatedly testified that the [redacted]

EX1042 at 165:16-24; EX2025 at ¶¶4-5 ("FDA accordingly pressed to understand fingolimod's minimum effective dose."), ¶39 ("FDA was dissatisfied with the Phase II trial's failure to identify a minimum effective dose. FDA accordingly pushed Novartis to include a lower dose in the Phase III trial."), ¶44 ("We debated whether and how to include the lower dose FDA wanted."), ¶¶57-58 ("[redacted]"). [redacted]

Novartis relied upon Dr. Lublin's testimony to establish [redacted]" POR 40 (discussing EX2064); POR at 25-27 (citing EX2025, ¶¶5, 7, 39-42, 50-58). Novartis has directly put at issue [redacted]

[redacted]. POR at 27 ("[I]f 0.5 mg daily had been obvious in June 2006, [redacted] and Novartis would have bypassed that dose to include an even lower dose in the Phase III Trials. (Lublin Dec., Ex. 2025 ¶¶ 8, 64-65)."

B. "Briefing Book" Document

In support of its argument that it included the 0.5 mg dose in the phase III trials [redacted]. POR at 25-26 (citing EX2025, ¶¶6, 45-47); POR at 40. Dr. Lublin specifically testified that "[redacted]." EX2025 at ¶46. Exhibit 2064 states that this description was excerpted from "[redacted]." EX2064 at 1. During his deposition, Dr. Lublin admitted [redacted]

C. "Clinical Trial Protocol" Document

During his deposition, Dr. Lublin identified the Protocol as containing the justification [redacted]. EX1042 at 184:13-185:24; EX2065 at 3-4 ("[redacted]

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.