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Paper 11
Entered: January 11, 2018

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
Conduct of the Proceeding
Discovery under 37 C.F.R. § 41.51(b)(1)
Ordering Briefing on Discovery under
37 C.F.R. § 41.52(b)(2)

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

At the request of lead Petitioner, Apotex, a conference call in the above proceedings was held on January 10, 2018, among counsel for the respective Petitioners, Patent Owner, and Judges Pollock, Green, and Kaiser to discuss Apotex's request for routine or additional discovery of (1) minutes of a February 2, 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.

A. Routine Discovery

Under 37 C.F.R. § 41.51(b)(1)(i), "[u]nless previously served or otherwise by agreement of the parties, any exhibit cited in a paper or in testimony must be served with the citing paper or testimony." A brief excerpt of the FDA minutes is quoted in Exhibit 2066, which is a letter from Novartis to a Dr. Miller of Mount Sinai School of Medicine ("the Miller letter). In Exhibit 2025 (Dr. Lublin's second declaration), Patent Owner's expert relies on the excerpt quoted in Exhibit 2066. Ex. 2025, ¶ 55; *see also* Paper 26, 26–27 (referencing same). As we understand the record, Novartis and Dr. Lublin rely on the Miller letter with respect to the excerpt of the FDA minutes, but not on any other portion of the FDA minutes. Accordingly, the FDA minutes are not "cited in a paper or in testimony."

The briefing book is similarly not "cited in a paper or in testimony." Rather, an excerpt of that document is quoted in Exhibit 2064, a letter Novartis sent to the FDA regarding a March 26, 2007 End-of Phase II meeting ("the Katz letter"). As with the FDA minutes, Dr. Lublin relies on the Katz letter rather than the entirety of the briefing book. Ex. 2025 ¶ 46; *see also* Paper 26, 26 (referencing same).

Dr. Lublin relies on Exhibit 2063 as evidence of communications in the Spring of 2007 between Novartis and Dr. Lublin's assistant, Colleen Farrell, on

behalf of the Mount Sinai IRB. Ex. 2025 ¶¶ 51, 56; *see also* Paper 26, 26–27 (referencing same). Shortly after the January 10, 2018 conference call in this case, Patent Owner filed, at our request, a December 5, 2017 Declaration of Peter J. Waibel, attesting that "the redacted portion of [Exhibit 2063] constitutes internal conversation at Novartis only and does not include additional communication with any personnel at Mount Sinai School of Medicine." Ex. 2078, ¶ 11. Because Dr. Lublin does not rely on the redacted portion of Exhibit 2036—nor have we any reason to believe that he even saw the unredacted document—the redacted portion of the exhibit is also not "cited in a paper or in testimony."

Also, under 37 C.F.R. § 41.51(b)(1)(iii), and absent a claim of privilege, "[u]nless previously served, a party must serve relevant information that is inconsistent with a position advanced by the party during the proceeding concurrent with the filing of the documents or things that contains the inconsistency." As the Board explained in *Garmin*, "[r]outine discovery under 37 C.F.R. § 41.51(b)(1)(iii) is narrowly directed to specific information known to the responding party to be inconsistent with a position advanced by that party in the proceeding, and not broadly directed to any subject area in general within which the requesting party hopes to discover such inconsistent information. *Garmin Int'l, Inc. v. Cuozzo Speed Techs. LLC*, Case No. IPR2012-00001, slip op. at 4 (PTAB March 5, 2013) (Paper 26) (precedential).

In the present case, Petitioner has not articulated any evidence or reasoning indicating that the requested documents relevant information that is inconsistent with a Novartis's positions. As we have no reason to doubt the integrity of Novartis or it counsel, we decline to order production of these documents under 37 C.F.R. § 41.51(b)(1). *See* 37 C.F.R. § 41.11.

B. Additional Discovery

In the alternative, Apotex seeks the requested documents as additional discovery under 37 C.F.R. § 42.51(b)(2). "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 interest 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, at *6.*

After considering the parties' arguments, we are persuaded that Petitioner has made a sufficient showing to warrant briefing on the matter. Briefing shall be conducted as set forth in following Order.

ORDER

It is

ORDERED that Petitioner Apotex may file a motion seeking additional discovery and Patent Owner may file an opposition to Petitioner's motion;

FURTHER ORDERED that both papers are due 10 days from the date of this Order and shall not exceed 10 pages in length.

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