Paper No. ___
Filed: April 30, 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 INDUSTRIES, 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

PETITIONERS' REPLY IN SUPPORT OF MOTION TO EXCLUDE

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

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Petitioners file this Reply in response to Paper 89 filed on April 24, 2018.

I. EXHIBITS 2057& 2070.

Novartis contends Mr. Schnell authenticated EX2057 as "a report" he "prepared." Opp., 2. But he testified that he only prepared "part of the document" and never saw the EAE portion and had no role in finalizing it. EX1050 at 32:9-34:7, 42:11-15, 56:8-57:17. He testified he never saw the final until preparing his declaration (*id.*, 32:12-36:6, 42:11-15), and he still had never read most of it (*id.*, 57:18-60:4), so his testimony that he "remembers" EX2057 "going with" EX2070 is pure guesswork. Novartis failed to authenticate EX2057 prior to 2017 when its employees retrieved it. Novartis curiously argues Mr. Schnell's lack of personal knowledge proves Peter Hiestand had personal knowledge. Opp., 4. But he offered no declaration and Novartis's argument is mere speculation.

Novartis concedes no exception justifies admission by arguing the report is offered not for the truth, but merely as a record of beliefs about RRMS efficacy expressed in June 2009. Opp., 3-4. But no such belief is expressed. In fact, RRMS is not mentioned, nor is any dosing RRMS recommendation, as opposed to confirming FTY720 can "ameliorate EAE in the Lewis rat" and that it may be "effective even if a dose of the drug is missed." EX2057 at 21-22.

Novartis's assertion that it relies on EX2057 for only non-hearsay purposes is also plainly incorrect. Novartis repeatedly relies on EX2057 as establishing the

truth of actual test results to support the efficacy of once-weekly administration of 0.3 mg/kg fingolimod. POR, 22-24; EX2024, ¶¶101-107; EX2022, ¶¶101-108.

Novartis's argument (Opp., 5) that expert testimony based on inadmissible evidence theoretically may be admitted proves nothing. *See Monsanto Co. v. David*, 516 F.3d 1009, 1015-16 (Fed. Cir. 2008) (expert testimony admissible where its sponsor established expert could reasonably rely on a scientific report "prepared by his team" and that the report was "of a type reasonably relied upon by experts in the particular field in forming opinions."). None of Novartis's experts testified that experts in their fields routinely rely upon the type of report in EX2057, even though they provided such testimony for other exhibits. EX2076, ¶¶3, 5, 7; EX2077, ¶¶3, 5. Neither Dr. Jusko nor Dr. Steinman cite either the Waibel or Schnell declarations or explain why one should rely on EX2057. Counsel's representations are insufficient. EX1042 at 170:11-25, 178:6-179:6. Novartis also failed to establish that either Dr. Jusko or Dr. Steinman's discussion of EX2057 is admissible under F.R.E. 703. Dr. Benet identified fatal flaws in Novartis's reliance on EX2057 to establish efficacy of the 0.5 mg. EX1047, ¶¶102-105. Novartis has now abandoned that analysis, arguing EX2057 should not be relied upon for the truth. Opp., 3. Its experts' reliance on the hearsay assertions in EX2057 are not entitled to admission under F.R.E. 702-703.

II. EXHIBITS 2063-2066.

Novartis argues (Opp., 6) that Petitioners "strain" to exclude Exhibits 2063-2066 because they allegedly demonstrate that one IRB panel out of thousands was skeptical. Petitioners seek exclusion because Novartis's reliance on it is unlawful. Novartis submits for the truth of the matter hearsay statements purporting to summarize further hearsay statements, the latter attributed to unidentified persons sitting on an IRB panel or at the FDA. EX2063 at 2-3 ("They had the following comment:"); EX2065 at 5 ("The comment reads:"), 4 ("comments still involving"; "as per FDA's request"), 3 ("it wasn't enough."), 1 ("IRB has said"); 2 ("FDA's request"); EX2066 ("FDA's request"; description and purported quote from FDA minutes). The Waibel declaration authenticates only the time stamp for the final email in the chain, not the statements attributed to IRB or FDA therein.

Novartis argues the hearsay statements are "state of mind" evidence. Opp., 8-9. But it fails to establish Ms. Farrell or the IRB panel members were persons of ordinary skill. Further, the truth of her assertions that these statements came from an IRB panel are required to prove Novartis's argument that the panel espoused these views. This is not a case where an industry publication established that the statements were made. *Weatherford*, IPR2016-01509, Paper 65 at 15-16.

Novartis argues EX2065 is admissible under F.R.E. 803(3), (5) and 807. Opp., 7-9. The "state of mind" of Ms. Farrell, Mr. Watson, or Mr. Prodafikas is not at issue. Novartis may not rely on a record of the "memory or belief" of its non-

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