Paper No. ___
Filed: April 17, 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

PETITIONERS' MOTION TO EXCLUDE
37 C.F.R. §42.64

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

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I. INTRODUCTION

Pursuant to 37 C.F.R. §§ 42.62 and 42.64(c), Petitioners respectfully move to exclude Exhibits 2057, 2063-2066, 2070, and portions of Exhibits 2022, 2024, 2025, 2096-2098. The Federal Rules of Evidence apply. 37 C.F.R. § 42.62; *LKQ Corp. v. Clearlamp, LLC*, IPR2013-00020, Paper 17, at 3 (Mar. 5, 2013). This Motion addresses issues listed in Petitioner's Objections to Evidence (Paper Nos.14, 31, 71) and information subsequently obtained through the depositions of Novartis's witnesses. *See, e.g.*, EX1042, EX1050, EX1061-EX1064.

II. ARGUMENT

A. Exhibits 2057& 2070 and any reliance thereon.

Novartis served Exhibits 2057 and 2070 with its Patent Owner Response ("POR") (Paper 27). Novartis's exhibit list describes EX2057 as a May 12, 2009 Novartis report and EX2070 as a "signature sheet." Dr. Jusko discusses EX2057 in ¶¶101-07 of his second declaration (EX2024) but never cites EX2070. Dr. Steinman discusses EX2057 in his First Declaration (EX2022, ¶¶101-08) and incorporates his prior testimony into his Third Declaration (EX2096, ¶53). but never cites EX2070. Novartis relies on EX2057 and EX2070 and the cited paragraphs of Exhibits 2022 and 2024 in Paper 27 at 22-25. Petitioners timely objected to Exhibits 2057 and 2070 and reliance thereon. Paper 31 at 8-10. Exhibits 2057 and 2070 and the above-referenced paragraphs of EX2022, EX2024,

and EX2096 should be excluded under F.R.E. 602, 801-803, 805, and 901.

Novartis relies on statements in the report for the truth of the matters asserted, namely that Peter Hiestand did, in fact, perform the EAE experiments and observed the results recited in EX2057. POR at 22-25. Novartis relies on these statements to prove that administering 0.3 mg/kg of fingolimod once per week to Lewis rats with EAE did, in fact "suppress the progression of subsequent relapses, and also reduced the relapse's symptoms," to support the claims of the '405 patent. *Id.* Because Novartis relies on the underlying assertions in the report, Novartis must establish admissibility of the underlying assertions. F.R.E. 801, 802, 805, 901; *Neste Oil OYJ v. REG Synthetic Fuels, LLC*, IPR2013-00578, Paper 52 at 6-8 (excluding meeting minutes authenticated by author because each hearsay-within-hearsay required its own exception to the hearsay rule); *US Endodontics, LLC v. Gold Standard Instr., LLC.*, PGR2015-00019, Paper 54 at 40-41-42 (excluding sworn declaration from another proceeding as hearsay).

Novartis submitted a declaration from an in-house attorney, Peter Waibel, to identify Exhibit 2057 as having been produced from a collection of documents previously submitted to FDA. EX2078, ¶10. But Mr. Waibel does not address or purport to have personal knowledge of how the report itself came to be created or how the experiments discussed therein were conducted. In short, Mr. Waibel's testimony merely establishes that Novartis placed a document into its records

system at some undisclosed point in time and thereafter maintained that copy in its records. This is insufficient to satisfy F.R.E. 602, 801-803, 805, or 901.

Christian Schnell's declaration (EX2026) fails to remedy these deficiencies. Mr. Schnell purports to authenticate Exhibit 2057 as a Novartis report "we prepared in 2009." EX2022, ¶¶1-4. He states that Exhibit 2070 was filed in the same system as EX2057, that it is common for the final signature pages to be filed separately from the main report, and that "this is the signature page that I remember going with this report." *Id.* However, Mr. Schnell admitted during his deposition that he did not see Peter Hiestand sign the final report, that "I have not seen the signed page by Peter Hiestand and the TR head," that he did not personally enter the final report or signature page into the Novartis computer system, that he never looked at the final report in the Novartis system until he was preparing his declaration, and that he "had no role" in filing either Exhibit 2057 or 2070 in the Novartis system. EX1050 at 32:12-36:6, 42:11-15. Mr. Schnell's fails to establish admissibility of EX2057 or EX2070.

Peter Hiestand, not Christian Schnell, is the purported, unsworn and unauthenticated declarant of the hearsay assertions in EX2057. Mr. Schnell testified that Peter Hiestand was in charge of designing the protocol for the EAE experiments, that Mr. Schnell prepared only the "neoangiogenesis casing part of the document, not the EAE-related part," and that Mr. Schnell did not review the

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