Paper No. ___
Filed: April 24, 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' OPPOSITION TO NOVARTIS'S 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

Petitioners oppose Novartis's Motion to Exclude (Paper 80). Novartis fails to establish entitlement to the requested relief. 37 C.F.R. § 42.20(c). "A party wishing to challenge the admissibility of evidence must object timely to the evidence at the point it is offered[.]" Office Patent Trial Practice Guide, 77 Fed. Reg. 48756, 48767 (Aug. 14, 2012). A motion to exclude evidence must identify where each objection originally was made, and must explain why the evidence is not admissible, "but may not be used to challenge the sufficiency of the evidence to prove a particular fact." *Id.* Novartis chose to disregard the Board's rules regarding the timing and identification of objections. This failure alone justifies denial of the Motion. Novartis's Motion is also a thinly-veiled challenge to the sufficiency of the evidence, and fails on the merits. It should be denied.

II. ARGUMENT

A. Exhibits 1002 and 1003.

Novartis moves to exclude "all, or at least the pharmacology opinions in, the declaration of Dr. Barbara Giesser and related CV" under F.R.E. 702. Mot., 1. Yet, Novartis never identifies portions of EX1002 or EX1003 with particularity that it believes should be excluded or where it objected to such portions.

Novartis's Motion should also be denied because it a thinly-veneered challenge to the sufficiency of the evidence. Novartis repeats its baseless and

spurious allegation against Dr. Giesser's review of the prior art. Mot., 2-4. Novartis's assertions are simply untrue. Dr. Giesser is a Professor of Clinical Neurology at UCLA who has spent the past 30 years treating RRMS patients. EX1002, ¶¶ 1-4; EX1003. She provided credible, reliable, independent, and relevant testimony based on her many years of experience in the field.

Novartis argues that Dr. Giesser admitted during her deposition that counsel allegedly limited her analysis to a selection of references they permitted her to see. Mot., 3-4. This is not correct. Although Dr. Giesser testified that her "work" with fingolimod related to treating patients and that she had not done "any laboratory testing" for this case (EX2039 at 11:14-12:14), Novartis falsely argues that Dr. Giesser failed to search the prior art. Novartis began by asking whether Dr. Giesser's literature search identified references "other than" those she identified in her declaration, which she answered affirmatively by identifying a reference she did not cite in her declaration. EX2039 at 49:12-50:6. Novartis then asked, aside from what Dr. Giesser already mentioned, whether she performed other searches. Novartis reads limitations into Dr. Giesser's analysis that are not present.

Novartis also erroneously argues that Dr. Giesser failed to review the references she discusses in her declaration. Mot., 3-4.. Dr. Giesser testified unequivocally that she "read the exhibits mentioned in the declaration on which I've rendered an opinion." EX2039 at 95:23-96:1; *id.* at 97:8-13 ("if it's mentioned

in the declaration, I would have read it. I just don't remember it off the top of my head."), 97:22-98:2 ("I would have read enough of the paper to be able to form an opinion."), 105:17-106:3 ("I do not believe that I would have quoted a reference or formed an opinion about something that I haven't read.").

Novartis insinuates that, because Dr. Giesser testified that she received copies of the exhibits from counsel, these references must have been previously unknown to her. Mot., 3-5. But Dr. Giesser never testified that she was previously unaware of the references she relied upon or that her analysis was restricted to documents counsel approved. Indeed, at least some of the documents she received from counsel are documents she uses regularly in her medical practice. EX2039 at 102:24-105:16. Dr. Steinman, Novartis's witness, also confirmed that he received the vast majority of the documents he relied upon from counsel. EX1061 at 76:4-78:15. He also testified that he did not read all of them and that it would have been impossible to do so. *Id.* at 92:19-93:5, 94:8-23 ("I don't think there's a single document that I read every word"). Novartis's accusations are a red herring.

Novartis faults Dr. Giesser for not discussing the Webb reference in a reply declaration because Novartis considers Webb a "key" reference "on the Patent's face." Mot., 3-5. Novartis's emphasis on Webb greatly exaggerates its relevance. Dr. Giesser discussed the subsequent and more informative Kataoka reference (EX1029) in her declaration. EX1002, ¶¶52, 64, 136, 140. Dr. Steinman testified

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