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 AG,

Patent Owner.

Case IPR2017-00854[1]

U.S. Patent No. 9,187,405

PATENT OWNER NOVARTIS'S 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 have largely ignored Novartis's motion to exclude, and instead used their brief as a platform to address merits arguments. The Board should disregard this naked end-run around the Board's order prohibiting any further merits briefing from Petitioners (Paper 66), and grant Novartis's motion to exclude.

A. Dr. Giesser's Testimony Is Inadmissible

1. Dr. Giesser Did Not Do Her Own Review of the Art

Petitioners still do not dispute that putative expert opinions about obviousness based only on counsel's handpicked references are *per se* hindsight and thus unlawful. (*See* cases cited in Paper 26 at 42–43; Paper 80 at 4–5.) Nor do they dispute that hindsight-driven opinions are inadmissible under Rule 702. (Paper 80 at 3–5.) Dr. Giesser's opinion accordingly should be excluded under FRE 702.[2]

In her deposition, Dr. Giesser testified that, other than looking up one longer version of a study counsel had already provided, she conducted no independent research for her declaration: "Q. Other than that, have you performed any searches for literature? A. No. Q. Okay. How did you get the references that are cited in your declaration? A. *References were supplied by counsel*." (Ex. 2039 50:4-9

[2] Petitioners complain (at 1) that Novartis did not cite this objection in the motion to exclude, though Petitioners claim no prejudice from that fact or that the objection is untimely. Nor could they. Novartis objected under Rule 702 in Paper 13 at 1–2.

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(emphasis added).) Nor did Dr. Giesser provide a reply declaration to address what she missed initially. Her opinion is thus *per se* hindsight and unlawful.

The most Petitioners say in response is that Dr. Giesser already knew about some of the references counsel supplied. (Paper 94 at 3.) That is irrelevant. She indisputably was not aware of the full scope of the prior art, and conducted no independent research to bring herself up to speed. And even when Novartis submitted references she did not consider, Petitioners submitted no reply declaration to address those references and try to fix her omissions. That ends the analysis.

Petitioners bizarrely try to change the subject by discussing their deposition of Dr. Jerold Chun, a co-author of the Webb reference (Ex. 2014). Apart from being a *non-sequitur* and improper subject matter for a motion about Dr. Giesser, Petitioners' brief grossly mischaracterizes Dr. Chun's testimony. He never once said that Novartis's points about Webb are incorrect, as Petitioners claim (Paper 94 at 5). To the contrary, he affirmed that he and his co-authors concluded that 70% lymphocyte suppression was needed for clinical efficacy that is "replicable," "consistent," and "predominant" (Ex. 1063 at 185:10–20)—just as he said in his declaration (Ex. 2098 ¶¶ 38–40). Novartis has never moved to exclude this testimony. Why would it? The testimony helps Novartis. Dr. Chun indeed specifically refused to agree that lesser suppression would be just as likely to be effective; he said the opposite. (Ex. 1063 at 275:3–276:21.)

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In other words, Dr. Chun stood by his refutation of Petitioners' effort to rewrite Webb. Petitioners' effort to distract from Dr. Giesser's testimony with mischaracterizations about Dr. Chun just bespeaks their desperation.

2. Dr. Giesser Is Not A Pharmacologist

In addition to challenging her methodology, Novartis challenged Dr. Giesser's lack of any expertise in pharmacology. (Paper 80 at 2–3, 6.) As Petitioners do not dispute, "Dr. Giesser's 'pharmacologic testimony was beset with error.'" (Opp. at 7.) But Petitioners pretend, without any citation to the record, that Dr. Benet somehow resuscitated Dr. Giesser. (*Id.*) He did not. In fact, even after pharmacologist Dr. Jusko pointed out the errors in Dr. Giesser's pharmacology analysis, and even after Dr. Benet acknowledged those criticisms in his declaration, he did not contest them or come to Dr. Giesser's defense. (Ex. 2024 ¶¶ 118–23; Ex. 1047 ¶¶ 31–37.) Dr. Giesser simply is not qualified as a pharmacologist, and thus is unable to support the Petition from the perspective of a full person of skill.

B. Exhibits 1032, 1035, 1037, 1041, and 1051 Are Irrelevant

Novartis showed that Petitioners' exhibits about the '283 IPR (Ex. 1032, 1035, 1037, 1041) are irrelevant here. (Paper 80 at 7–8.)[3] Petitioners barely respond, asserting that the references could be relevant for "preclusion or estoppel"

[3] Novartis objected to these exhibits as irrelevant in Papers 13 at 9–12, and 55 at 4.

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