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 AG'S AUTHORIZED SUR-REPLY

Mail Stop Patent Board
Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

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

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INTRODUCTION

Inventors Hiestand and Schnell discovered that far lower doses of fingolimod could help RRMS patients than were previously thought possible. The '405 Patent claims these methods for using 0.5 mg daily to reduce relapses, treat the disease, and slow its progression. Unique EAE rodent model experiments gave the inventors the insight to see past the art teaching that a dose this low would not work. Later, clinical trials overcame experts' skepticism and ultimately proved the dose effective.

The Petition here relied on testimony from only a single expert, MS physician Dr. Barbara Giesser. (Ex. 1002.) But discovery showed Dr. Giesser conducted no independent literature review to support her obviousness arguments, instead relying solely on references supplied by counsel. Courts categorically reject such lawyer-driven analyses as *per se* hindsight, and thus unlawful. (Paper 26 at 42-44.) Dr. Giesser also lacks the qualifications and experience needed to provide the full view of a person of skill, which the Institution Decision defined to include a pharmacologist. Dr. Giesser manifestly is not a pharmacologist. (*Id.* at 44-46.)

Petitioners dispute none of this in their Reply. (Paper 49.) Either the lack of testimony from a pharmacologist or the undisputed lawyer-driven nature of Dr. Giesser's review would, by themselves, defeat the Petition for failing to make out a *prima facie* case. Petitioners now seek to back-fill with new testimony from Dr. Leslie Z. Benet, a pharmacologist. (Ex. 1047.) It is too late. The Board should deny

the Petition based on its failure to make a *prima facie* showing. But even if the Board were to consider Dr. Benet's views, they cannot save the Petition.

Petitioners and Dr. Benet begin by trying to recast the Board's claim constructions contrary to what the Institution Decision says. They then argue the prior art says something other than what it says; offer opinions on MS and EAE models beyond Dr. Benet's expertise; improperly propound new invalidity theories beyond the Petition's scope; and otherwise create a smokescreen around the Petition's inadequacies. The Board should deny all three Grounds.

ARGUMENT

Dr. Benet is an eminent pharmacologist, but the wrong witness for this case. On cross-examination, he admitted his experience with the disease MS, the EAE animal model system, or the drug fingolimod is limited or non-existent—each key aspects of this case. (Ex. 2100 at 43:9-46:2; Ex. 2096 at ¶¶ 6-7.) Respectfully submitted herewith are declarations from experts to address Dr. Benet's testimony: Exhibits 2096 (3d Steinman), 2095 (4th Jusko), 2097 (4th Lublin), and 2098 (Chun).

I. The Patent's Claims Require Efficacy and Daily Administration.

A. The Preambles. The Patent claims methods "for" achieving different effects from giving 0.5 mg "daily" to a "subject in need": (i) "preventing, reducing, or alleviating" relapses (claims 1 and 2); (ii) "treating" RRMS (claims 3 and 4); and (iii) "slowing progression" of RRMS (claims 5 and 6). (Ex. 1001 at 12:49-13:9.)

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