UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS VIII, LLC,
Petitioner,

v.

THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA,
Patent Owner

Case: IPR2015-01835
Patent 8,618,135 B2

PATENT OWNER'S CORRECTED MOTION TO AMEND UNDER 37 C.F.R. § 42.121

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I. INTRODUCTION

Inventor Dr. Daniel Rader designed and conducted the first clinical trial demonstrating that serious adverse side effects of lomitapide could be mitigated with forced titration, even at higher doses. He thus paved the way for clinical use of lomitapide as an adjunct therapy in patients suffering from HoFH, a severe genetic disease. Shortly after completing the clinical trial, Dr. Rader filed a provisional patent application describing his invention. Nevertheless, in its institution decision, the Board found that Petitioner had "reasonably shown" that Dr. Rader's '135 patent could not claim priority to that provisional application because the claimed "mg" dose ranges of the '135 patent "are not obtained" from the "mg/kg" doses disclosed in the provisional and the claimed piperidine N-oxide derivative of the compound is not apparent from the provisional.

Although Patent Owner maintains its position that the '135 patent claims are entitled to the March 5, 2004 priority date, in the event that the Board accepts the Petitioner's obviousness arguments and deems the issued claims unpatentable, Patent Owner now contingently moves to substitute the canceled claim(s) with corresponding proposed amended claims 11-18. The amended claims clearly resolve both alleged deficiencies raised by Petitioner—first, by claiming dose ranges on a mg/kg basis; second, by eliminating the piperidine N-oxide derivative from the scope of the claim. *See* Appendix A.

The resulting substitute claims meet the requirements of 35 U.S.C. § 316(d)(3) insofar as they narrow the claims by, *inter alia*, shrinking the range of doses that may be administered in the claimed three-step method. In addition, the amended claims have express support in both the original disclosure of the '135 patent and the provisional application.

With priority thus established, two of the references relied upon to contend that the claimed method is obvious—Pink Sheet (Ex. 1013) and Stein (Ex. 1014)—do not qualify as prior art. Neither was published more than a year prior to the filing of Dr. Rader's patent application, and both were published ***after*** Dr. Rader conceived of and reduced to practice his invention. The third reference relied upon by Petitioner—Chang (Ex. 1015)—does not describe any dose regimen for lomitapide (let alone the claimed forced titration method) and is thus not anticipatory. Patent Owner is not aware of any art or teaching that a person of ordinary skill in the art (POSA) would combine with Chang (or any other material art) to render the proposed amended claims obvious. Accordingly, Patent Owner has met its burden of proving patentability of the proposed amended claims.

II. THE PROPOSED AMENDMENTS NARROW THE ISSUED CLAIMS

The substitute claims retain the step-wise increasing dose regimen developed by Dr. Rader, but narrow the scope of the claims by: 1) narrowing the dose range and claiming it with reference to mg/kg/day dose amounts; and 2) claiming one

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