For the Petitioners
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Paper No. __

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS V LLC;
HAYMAN CREDES MASTER FUND, L.P.;
HAYMAN ORANGE FUND SPC – PORTFOLIO A;
HAYMAN CAPITAL MASTER FUND, L.P.;
HAYMAN CAPITAL MANAGEMENT FUND, L.P.;
HAYMAN OFFSHORE MANAGEMENT, INC.;
HAYMAN INVESTMENTS, LLC;
NXN PARTNERS, LLC;
IP NAVIGATION GROUP, LLC;
J KYLE BASS, and ERICH SPANGENBERG,
Petitioners,
v.
BIOGEN MA INC.,
Patent Owner.

Case IPR2015-01993
Patent 8,399,514 B2

PETITIONERS' REQUEST FOR REHEARING

I. INTRODUCTION

Petitioners respectfully request rehearing under 37 C.F.R. § 42.71(d) of the Patent Trial and Appeal Board's ("Board's") 21 March 2017 Final Written Decision (Paper 63) ("Decision") as to claims 1-20 of U.S. Patent No. 8,399,514 ("the '514 Patent" (Ex. 1001)).

The Decision found Petitioners failed to challenge Biogen's testimony that the magnitude of clinical efficacy at 480 mg/day would have been unexpected. Unfortunately, the Decision overlooked the fact that Petitioners ***did*** challenge that testimony. Considering the Board's other findings laying out a very strong *prima facie* case of obviousness as presented by Petitioners, had the Decision not overlooked Petitioners' challenge to that testimony, the Board would have found claims 1-20 unpatentable.

II. STATEMENT OF PRECISE RELIEF REQUESTED

Petitioners respectfully request that the Board reconsider its Decision and hold that Petitioners have shown claims 1-20 of the '514 Patent are unpatentable.

III. THE REQUESTED RELIEF SHOULD BE GRANTED

A. The Board Overlooked Petitioners' Challenge to Biogen's Testimony on the Expected Magnitude of Results

According to the Decision, Petitioners did not point to evidence, or provide a reason, to doubt Biogen's expert testimony that the magnitude of clinical efficacy at 480 mg/day would have been unexpected (Paper 63 at 25):

> Petitioner's Reply does not effectively address Biogen's unexpected results argument and evidence. Petitioner responds only with a single sentence: "As demonstrated above, success was expected, not unexpected." Pet. Reply, Paper 46, p. 24. Biogen's argument, however, is not merely that it would have been unexpected that some lower doses would have been an effective therapeutic treatment. Rather, Biogen's position is that the magnitude of the clinical efficacy at the specifically claimed dose of about 480 mg/day would have been unexpected. Biogen Res., Paper 38, pp. 43-49. Petitioner has not directed us to evidence, or provided a reason, for us to doubt the unrebutted testimony of Biogen's highly qualified and credible experts. Biogen's expert testimony on this point stands unchallenged.

However, Petitioners ***did*** direct the Board to evidence and ***did*** provide a reason to doubt that testimony. Petitioners pointed to evidence that the magnitude of clinical efficacy would have been expected to be essentially equal to or similar to that of the prior art.

Petitioners challenged Biogen's "unexpected results" testimony by presenting the testimony of Dr. Samuel Pleasure. Dr. Pleasure is a renowned Professor of Neurology, an attending physician at the University of California-San Francisco Multiple Sclerosis Center, and a standing member of a National Multiple Sclerosis Society Scientific Review Panel. **Ex. 1045** ¶¶ 4-15; **Ex. 1046**. While spending more than five pages detailing the credentials of Biogen's experts, the Decision does not once mention Dr. Pleasure, his credentials, his opinions, or even his name.

Biogen's experts relied on the simplistic notion that the claimed daily dosage total of 480 mg/day was closer to an ineffective total (360 mg/day) than an effective one (720 mg/day) in *Kappos 2006*. From that, they concluded it was "stunning and unexpected" to find a dosage of 480 mg/day almost as effective as one of 720 mg/day. Paper 63 at 25.

However, Dr. Pleasure explained specifically that POSA would have known more about *Kappos 2006* than simply the daily dosage totals. POSA also would have known the amount of drug given at one time (the "point dose"), including especially that the 360 mg/day regimen used three 120 mg point doses, and that the successful 720 mg/day regimen used three 240 mg point doses. In other words, it was the 240 mg point dose that was successful in *Kappos 2006*. **Ex. 1045** at ¶¶ 62-65 and 67-72. Dr. Pleasure testified "the finding of a point dose of 240 mg DMF

was the key finding of Kappos 2006 rather than the frequency of treatment." **Ex. 1045** at ¶ 70.

Dr. Pleasure further testified there were known examples in the MS field of modifying an established dosage regimen by using successful point doses but reducing the frequency with which the point dose was administered. For example, he testified Copaxone had an approved dosage regimen of administering a certain point dose once per day. Subsequent influential studies showed that cutting the frequency in half "provided ***essentially equally effective*** therapy for MS." Ex. 1045 ¶ 69 (emphasis added) (cited in Petitioners' Reply, Paper 46, at 20-21).

Petitioners relied on Dr. Pleasure's testimony to rebut Biogen's experts and support Petitioners' position that POSA expected the successful 240 mg point dose to be essentially equally effective whether given three times a day (TID) for a total of 720 mg as in *Kappos 2006* or twice a day (BID) for a total of 480 mg as claimed. Paper 46 at 3-4, 15-17, and 20-24. In challenging Biogen's testimony on unexpected results, Petitioners stated: "[g]iven the known point dose concentration of 240 mg DMF administered TID on the immune system (Kappos 2006), POSA would have been motivated to administer 240 mg DMF BID with a reasonable expectation of seeing ***similar immunomodulatory effect over time***." Paper No. 46 at 22-23 (emphasis added). Thus, Petitioners challenged Biogen's expert testimony and showed it was ***not*** unexpected that 480 mg per day (a 240 mg point

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