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Paper 65
Entered: May 12, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

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, 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

Before RICHARD E. SCHAFER, SALLY GARDNER-LANE, and DEBORAH KATZ, *Administrative Patent Judges.*

SCHAFER, *Administrative Patent Judge.*

DECISION
Request for Rehearing
37 C.F.R. § 42.71(d)

The Coalition for Affordable Drugs, et al. (Petitioner) seeks reconsideration and reversal of our decision holding that it did not establish the unpatentability of claims 1-20 of Biogen Ma (Biogen) Patent 8,399,514. We have considered Petitioner's request, but decline to make any change to our opinion or decision.

Relying on the testimony of Biogen witnesses Drs. Thisted, Brundage and Rudick (Exs. 2038, 2042 and 2044), and the reports on the results of the phase III trials for Tecfidera® (Exs. 2025 and 2026), our opinion held that Biogen had established that the efficacy of treatment of MS with 480 mg/day of dimethyl fumarate (DMF) would have been unexpected by those of ordinary skill in the art. Our opinion noted that "Petitioner's reply does not effectively address Biogen's unexpected results argument and evidence." Final Decision. Paper 63, p. 25.

Petitioner argues that it provided evidence to rebut and doubt the testimony of Biogen's witnesses. Pet. Req., Paper 64, pp. 2-3. Specifically, Petitioner directs us to the declaration testimony of Dr. Samuel Pleasure (Ex. 1045). Petitioner also directs us to its Reply (Paper 46) at pp. 20-21 where it referenced ¶ 69 of Dr. Pleasure's testimony.

Petitioner's Reply argued that a person having ordinary skill in the art

> would recognize Kappos 2006 is a phase II study designed to identify potential pharmacodynamically effective point doses for further study and be aware of examples in the MS field, e.g., Copaxane®, wherein less frequent dosing of the drug provided essentially equally effective therapeutic results, while lowering the frequency of side effects (see e.g., Ex. 1045 ¶69).

Reply, Paper 46, pp. 20-21.

We considered Dr. Pleasure's testimony in reaching our decision, but did not find it enlightening with respect to the unexpected results issue raised by Biogen. For the most part, Dr. Pleasure's testimony is directed to the motivation and the reasonable expectation of success of the person having ordinary skill in the art to

modify the 720 mg/day dosage taught in Kappos 2006. Pleasure Dec., Ex. 1045, ¶¶ 67-72. For example, Dr. Pleasure opined:

> A [person having ordinary skill in the art], knowing that GI side effects are a limiting problem with DMF and that an effective point dose of 240 mg had been established by Kappos, would have been motivated to test 240 mg daily and 240 mg twice daily in therapy trials as an obvious next step in establishing the safety and effectiveness of the drug as disclosed by ICH Guideline.

Pleasure Dec., Paper 1045, ¶ 69. Our opinion did not disagree with his testimony as to motivation and reasonable expectation of success. In the Final Decision, we stated:

> [W]e determine that one having ordinary skill in the art would have had ample reason to use routine experimentation, including appropriate clinical trials, to determine the optimum doses for MS treatment. Kappos 2006 teaches both the effectiveness of the 720 mg/day dose and that DMF is a result-effective variable:
>
> > [DMF] significantly reduces brain lesion activity, in a dose-dependent manner, as measured by MRI in patients with RRMS over 24 weeks of treatment.
>
> Ex. 1003A, p. 2 (emphasis added). Because of the reported side-effects from the treatment of with fumarates, (Joshi '999, Ex. 1030, 5:29-42; Press Release, Ex. 2057, p. 1), those working in the art would have had sufficient reason to investigate doses between 720 mg/day and 360 mg/day in hopes of identifying effective dose with fewer side-effects. Those working in the art would also have had a reasonable expectation of success in determining additional therapeutically effective doses. As noted by Dr. Brundage: "I would expect that 480 mg/day of DMF to show some increase in response compared to 360 mg/day based on the statement in Kappos 2006 that BG00012 (DMF) significantly reduced brain lesion activity in a dose dependent manner." Brundage Test., Ex. 2042, ¶ 39.

Final Decision, Paper 63, pp. 25-26.

With respect to the unexpected results issue, Dr. Pleasure testified only that:

> As explained above, one of ordinary skill in the art would not have found it unexpected that dosages of 240 mg DMF given BID and TID were similarly efficacious in treating MS.

Pleasure Dec., Ex. 1045, ¶ 75. Petitioner's sole argument on the issue was: "[a]s demonstrated above, success was expected, not unexpected." Pet. Reply, Paper 46, p. 24. Neither Petitioner's Reply, nor Dr. Pleasure's testimony addressed Biogen's specific arguments and evidence of unexpected results. Thus, Petitioner's argument and evidence failed to provide a basis for us to question the sufficiency of Biogen's evidence to show that the degree of efficacy of the 480 mg/day dose would have been unexpected to one having ordinary skill in the art. As we noted in our Final Decision, "[o]bjective indicia of non-obviousness 'may often establish that an invention appearing to have been obvious in light of the prior art was not.'" *Institut Pasteur & Universite Pierre et Marie Curie v. Focarino*, 738 F.3d 1337, 1346 (Fed. Cir. 2013).

Petitioner's request for rehearing is denied.

ORDER

Upon consideration of the Petition for Rehearing (Paper 64),

and for the reasons given, it is

ORDERED that the Request for Rehearing is *denied*.

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