Trials@uspto.gov
571-272-7822

Paper 63
Entered: March 21, 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.*

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I.

This is a Final Written Decision on the *inter parte* review of Patent 8,399,514. The '514 Patent is assigned to Biogen Ma, Inc. (Biogen). The Coalition for Affordable Drugs V LLC, et al., petitioned for the review seeking cancellation of Claims 1-20, all of the patent claims. Paper 1 (Pet.). In a Decision entered March 22, 2016, a Board panel held that there was a reasonable likelihood that the petitioner would prevail on the claims and grounds raised in the petition and initiated this proceeding. Paper 20 (Dec. Inst.), p. 27. Biogen subsequently filed a response to which Petitioner replied. Papers 38 and 46 (Biogen Res. and Pet. Reply, respectively). An oral argument was held on November 30, 2016. Paper 62.

We have jurisdiction pursuant to 35 U.S.C. § 6(c). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

For the reason detailed below, we determine that Petitioner has not satisfied its burden of establishing that the subject matter of Claims 1-20 would have been obvious and those claims, therefore, have not been shown to be unpatentable under 35 U.S.C. § 103(a). Specifically, we hold that a preponderance of the evidence shows that the magnitude of the clinical efficacy of treatment of MS patients with 480 mg/day of DMF would have been unexpected to one having ordinary skill in the art.[1]

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[1]Biogen was also authorized to file a motion to antedate one of the references (Kappos 2006) relied upon in the Petition. Paper 34. Biogen filed the motion (Paper 40). Petitioner filed an opposition (Paper 45) and Biogen replied (Paper 54). Biogen also argued that another reference (Joshi '999) was not eligible prior art under the provisions of 35 U.S.C. § 103(c). Biogen Res., Paper 38, pp. 17-24. Because post-filing date evidence demonstrates unexpected results, we did not reach the antedation and § 103(c) issues.

A.

Biogen's patent is also involved in pending Interference No. 106,023, captioned *Biogen Ma, Inc. v. Forward Pharma A/S*.

B.

The subject matter claimed in '514 patent is directed to methods of treating patients needing treatment for Multiple Sclerosis or MS. The heart of the treatment, and a requirement of every claim, is administering about 480 milligrams (mg) per day of certain fumarates. The fumarates are limited to dimethyl fumarate (DMF), monomethyl fumarate (MMF), or their combination. Biogen markets dimethyl fumarate under the tradename Tecfidera®. The drug is indicated for the treatment of patients with relapsing forms of MS (RRMS).

C.

The '514 patent has claims 1-20, with claims 1, 11, 15 and 20 being independent. We reproduce illustrative Claim 20, the broadest, below:

> 20. A method of treating a subject in need of treatment for multiple sclerosis comprising
>
> treating the subject in need thereof with a therapeutically effective amount of
>
> dimethyl fumarate,
>
> monomethyl fumarate, or
>
> a combination thereof,
>
> wherein the therapeutically effective amount of dimethyl fumarate, monomethyl fumarate, or a combination thereof is about 480 mg per day.

Ex. 1001, 30: 22-28. (paragraphing added). Each remaining independent claim requires *oral* administration of about 480 mg per day of the fumarates. Claim 11 specifies the treatment as "consisting essentially of" the oral administration of about 480 mg/day of the fumarates. Claim 1 requires oral administration of a composition "consisting essentially of" about 480 mg/day of the fumarates along with one or more excipients. Claim 15 specifies the oral administration of a

composition "consisting essentially of" 480 mg/day of DMF and one or more excipients. All remaining claims depend directly or indirectly from the independent claims. Ex. 1001, 28:58 - 30:27.

D.

The following references are relied upon in support of the Petition:

Name	Exhibit No.	Description	Date
Kappos 2006	1003A	*Efficacy of a Novel Oral Single-Agent Fumarate,BG00012, in Patients with Relapsing-Remitting Multiple Sclerosis: Results of a Phase 2 Study*, J. NEUROL (2006) 253 (SUPPL 2); II/1–II/170, page II27	May 2006
Clinical Trials	1022	*Double-Blind, Placebo-Controlled, Dose-Ranging Study to Determine the Effacacy and Safety of BG00012 in Subjects with Relapsing-Remitting Multiple Sclerosis*, CLINICALTRIALS.GOV ARCHIVE	Sept. 14, 2005
Joshi '999	1030	U.S. Patent 7,320,999 B2	Jan. 22, 2008 filed July 17, 2002
ICH	1004	*ICH Harmonised Tripartite Guideline*, DOSE-RESPONSE INFORMATION TO SUPPORT DRUG REGISTRATION E4	Mar. 10, 1994
Joshi '992	1036	U.S. Patent 6,436,992 B1	Aug. 20, 2002
Begleiter	1027	*Dietary Induction of NQOI Increases the Antitumour Activity of Mitomycin C in Human Colon Tumours in vivo*, 91 BRITISH J. CANCER 1624–1631	2004

Pet., Paper 1, pp. 7-8.

E.

The panel instituted inter parte review on the following grounds:

Ground	Statutory Basis	Prior Art	Claims
1	35 U.S.C. § 103(a)	Kappos 2006, Clinical Trials, Joshi '999, and ICH	1–6, 8–16, and 20
2	35 U.S.C. § 103(a)	Kappos 2006, Clinical Trials, Joshi '999, ICH, and Joshi '992	7
3	35 U.S.C. § 103(a)	Kappos 2006, Clinical Trials, Joshi '999, ICH, and Begleiter	17–19

Dec. Inst., Paper 20, pp. 27-28.

II.

A.

The parties disagree on the level of skill of the person ordinarily skilled in the art. Each proposes its own definition. Petitioner, relying on the testimony of Dr. Steven E. Linberg, argues that the person of ordinary skill would have an advanced degree such as an M.D., a D.O., a Pharm D. or a Ph.D. in a life science and would be experienced with clinical trial design and dose selection. Petition, Paper 1, pp. 16-17; Ex. 1005, ¶ 9. Biogen, relying on the testimony of Dr. Rudick, argues it would be someone with at least a medical degree, at least three years of training in neurology and at least three years of clinical experience treating MS. Biogen Opp., Paper 38, p. 4; Ex. ¶ 36.

We recognize that the type of description provided by the parties as to the characteristics of the person having ordinary skill in the art is fairly typical in *inter parte* proceedings. However, in our experience, such descriptions are usually of little practical help in deciding obviousness questions. The person having ordinary skill in the art is a hypothetical person that is presumed to be aware of all the relevant prior art. *Custom Accessories, Inc. v. Jeffrey-Allan Indust., Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986); *Kimberly-Clarke Corp. v. Johnson & Johnson*, 745 F.2d

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