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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

BIOGEN MA INC,
Patent Owner.

Case IPR2018-01403
Patent No. 8,399,514 B2

Before SHERIDAN K. SNEDDEN, JENNIFER MEYER CHAGNON, and JAMIE T. WISZ, *Administrative Patent Judges.*

SNEDDEN, *Administrative Patent Judge.*

JUDGMENT
Final Written Decision
Determining No Challenged Claims Unpatentable
35 U.S.C. § 318(a)

I. INTRODUCTION

This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. Mylan Pharmaceuticals Inc. ("Petitioner") bears the burden of proving unpatentability of the challenged claims, and that burden of persuasion never shifts to Biogen MA Inc. ("Patent Owner"). *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). The evidentiary standard is a preponderance of the evidence. *See* 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d).

For the reasons that follow, we determine that Petitioner has not shown, by a preponderance of the evidence, that challenged claims 1–20 of U.S. Patent No. 8,399,514 B2 (Ex. 1001, "the '514 patent") are unpatentable.

A. Procedural History

Petitioner filed a Petition requesting an *inter partes* review of claims 1–20 of the '514 patent. Paper 2 ("Pet."). Patent Owner filed a Preliminary Response. Paper 7. With prior authorization, Petitioner filed a Reply to Patent Owner's Preliminary Response (Paper 9) to address the Federal Circuit's decision in *FWP IP APS v. Biogen MA Inc.*, 749 F. App'x 969, 972 (Fed. Cir. 2018). Patent Owner filed a Sur-Reply. Paper 10.

Upon consideration of the Petition, Preliminary Response, and the parties' additional briefing, we instituted an *inter partes* review of claims 1–20 of the '514 patent on each ground of unpatentability set forth in the Petition, which are as follows:

Ground	Claims	Basis[1]	References
1	1–20	§ 103(a)	Biogen Press Release[2] and Schimrigk 2004[3]
2	1–20	§ 103(a)	Kappos 2006[4] and Schimrigk 2004
3	1–20	§ 103(a)	Kappos 2006 and WO '342[5]
4	1–20	§ 103(a)	Kappos 2006, Clinical Trials[6], Joshi '999[7], and ICH Guideline[8]

[1] The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011), amended 35 U.S.C. §§ 102 and 103. Because the '514 patent was filed before March 16, 2013 (the effective date of the relevant amendment), the pre-AIA version of § 103 applies.

[2] Ex. 1005, Biogen News Release, *Phase II Study of Oral Compound BG-12 Meets Primary Endpoint in Multiple Sclerosis* (Jan. 9, 2006) ("Biogen Press Release").

[3] Ex. 1006, S. Schimrigk et al., *A Prospective, Open-Label, Phase II Study of Oral Fumarate Therapy for the Treatment of Relapsing-Remitting Multiple Sclerosis*, 10 (Suppl. 2) MULTIPLE SCLEROSIS CLIN. & LAB. RES. S258, Abstract P642 (2004) ("Schimrigk 2004").

[4] Ex. 1007, L. Kappos et al., *Efficacy of a Novel Oral Single-Agent Fumarate, BG00012, in Patients with Relapsing-Remitting Multiple Sclerosis: Results of a Phase 2 Study*, 253 (Suppl. 2) J. NEUROL. II27, O108 (2006) ("Kappos 2006").

[5] Ex. 1008, International Publication No. WO 2006/0037342 A2 (published Apr. 13, 2006) ("WO '342").

[6] Ex. 1010, NCT00168701, CLINICALTRIALS.GOV, https://clinicaltrials.gov/archive/NCT00168701/2005_09_14 ("Clinical Trials").

[7] Ex. 1009, R. K. Joshi et al., U.S. Patent No. 7,320,999, issued Jan. 22, 2008 ("Joshi '999").

[8] Ex. 1011, ICH Harmonised Tripartite Guideline - *Dose-Response Information to Support Drug Registration E4* (Mar. 10, 1994) ("ICH Guideline").

Paper 12.

Subsequently, Patent Owner filed a Patent Owner Response (Paper 38; "PO Resp."), Petitioner filed a Reply (Paper 68; "Reply"), and Patent Owner filed a Sur-Reply (Paper 79; "Sur-Reply").

Petitioner relies upon the Declarations of Dr. John R. Corboy (Ex. 1002), Dr. Leslie Z. Benet (Ex. 1003), and Dr. Ian McKeague (Ex. 1004) to support its contentions. On Reply, Petitioner relies on the Declarations of Dr. Benjamin M. Greenberg (Ex. 1121).[9]

Patent Owner relies upon the Declaration of Dr. Richard C. Brundage (Ex. 2057), Dr. Martin Duddy (Ex. 2058), Dr. Ronald A. Thisted (Ex. 2060), and Dr. Daniel Wynn (Ex. 2061) to support its contentions.[10]

Oral argument was conducted on November 13, 2019. A transcript is entered as Paper 93 ("Tr.").

We address herein the arguments and evidence set forth in the Papers to the extent necessary to resolve the dispute between the parties.

B. Related Matters

The parties identify the following litigation between the parties involving the '514 patent: *Biogen International GmbH v. Mylan Pharmaceuticals Inc.*, C.A. No. 17-cv-116-IMK (N.D. W.Va.). Pet. 2;

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[9] Petitioner also relies on the Declaration of Joel W. Hay, Ph.D. (Ex. 1120) in support of its contentions rebutting portions of Patent Owner's objective indicia evidence that we do not rely upon for this Final Written Decision.

[10] Patent Owner also relies on the Declaration of John C. Jarosz (Ex. 2202) in support of its contentions relating to objective indicia evidence that we do not rely upon for this Final Written Decision.

Paper 11, 3. The parties also identify several other litigations involving the '514 patent. *See* Pet. 2–3; Paper 11, 3.

The '514 patent has also been involved in the following proceedings before the Patent Trial and Appeal Board ("Board"): *Coalition for Affordable Drugs V LLC v. Biogen MA Inc*., IPR2015-01993; *Coalition for Affordable Drugs V LLC v. Biogen MA Inc*., IPR2015-01136; and *Biogen MA Inc., v. Forward Pharma A/S*, Patent Interference 106,023.

C. The '514 patent

The subject matter claimed in the '514 patent is directed to methods of treating patients needing treatment for Multiple Sclerosis (MS). Ex. 1001, 27:59–30:27. The heart of the treatment, and a requirement of every claim, is administering about 480 milligrams (mg) per day of certain fumarates. *Id.* The fumarates are limited to dimethyl fumarate (DMF), monomethyl fumarate (MMF), or their combination. *Id.* Patent Owner markets dimethyl fumarate under the tradename Tecfidera®. *See* PO Resp. 1. Tecfidera® is indicated for the treatment of patients with MS, including relapsing forms of MS (RRMS). Ex. 2003, 7–8, 90.

D. Illustrative Claims

Independent claims 1, 11, 15, and 20, reproduced below, are illustrative of the challenged claims:

> 1. A method of treating a subject in need of treatment for multiple sclerosis comprising orally administering to the subject in need thereof a pharmaceutical composition consisting essentially of
>
> (a) a therapeutically effective amount of dimethyl fumarate, monomethyl fumarate, or a combination thereof, and

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