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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 JACQUELINE T. HARLOW, *Administrative Patent Judges.*

SNEDDEN, *Administrative Patent Judge.*

DECISION
Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Mylan Pharmaceuticals Inc. ("Petitioner" or "Mylan"), filed a Petition requesting an *inter partes* review of claims 1–20 of Patent No. 8,399,514 B2 (Ex. 1001, "the '514 patent"). Paper 2 ("Pet."). Biogen MA Inc. ("Patent Owner" or "Biogen") filed a Preliminary Response. Paper 7 ("Prelim. Resp.").

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.*, No. 2017-2109, 2018 WL 5292070 (Fed. Cir. Oct. 24, 2018). Patent Owner filed a Sur-Reply. Paper 10.

To institute an *inter partes* review, we must determine that the information presented in the Petition shows "a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). The Supreme Court has held that a decision to institute under 35 U.S.C. § 314 may not institute on less than all claims challenged in the petition. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018) ("*SAS*"). After considering the evidence and arguments presented in the Petition, we determine that Petitioner has demonstrated a reasonable likelihood of success in proving that at least claim 1 of the '514 patent is unpatentable. Accordingly, an *inter partes* review of all of the claims and all of the grounds presented in the Petition is hereby instituted.

In this Decision, we address all issues raised by the parties in the pre-trial briefing. Our factual findings and conclusions at this stage of the proceeding are based on the evidentiary record developed thus far. This is not a final decision as to the patentability of claims for which *inter partes*

review is instituted. Our final decision will be based on the record as fully developed during trial.

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

The '514 patent has also been involved in the following proceedings before the Patent Trial and Appeal Board ("PTAB" or "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.

B. The '514 patent

The subject matter claimed in the '514 patent is directed to methods of treating patients needing treatment for Multiple Sclerosis or 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.* Biogen markets dimethyl fumarate under the tradename Tecfidera®. Prelim. Resp. 1–2. The drug is indicated for the treatment of patients with MS, including relapsing forms of MS (RRMS). Ex. 2003, 7–8.

C. 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
>
> (b) one or more pharmaceutically acceptable excipients, wherein the therapeutically effective amount of dimethyl fumarate, monomethyl fumarate, or a combination thereof is about 480 mg per day.
>
> 11. A method of treating a subject in need of treatment for multiple sclerosis consisting essentially of orally administering to the subject about 480 mg per day of dimethyl fumarate, monomethyl fumarate, or a combination thereof.
>
> 15. A method of treating a subject in need of treatment for multiple sclerosis comprising orally administering to the subject pharmaceutical composition consisting essentially of
>
> (a) a therapeutically effective amount of dimethyl fumarate and
>
> (b) one or more pharmaceutically acceptable excipients, wherein the therapeutically effective amount of dimethyl fumarate is about 480 mg per day.
>
> 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.

D. Evidence Relied Upon

Petitioner relies upon the following prior art references:

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").

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").

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").

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

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

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

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

Petitioner also relies upon the Declarations of Dr. John R. Corboy (Ex. 1002), Dr. Leslie Z. Benet (Ex. 1003), and Dr. Ian McKeague (Ex. 1004 ("McKeague Decl.")) to support its contentions.

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