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Paper 17
Entered: September 12, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAWAI USA, INC. AND
SAWAI PHARMACEUTICAL CO., LTD.,
Petitioner,

v.

BIOGEN MA INC.,
Patent Owner.

Case IPR2019-00789
Patent No. 8,399,514

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(a)

Granting of Motion for Joinder
37 C.F.R. § 42.122(b)

I. INTRODUCTION

Sawai USA, Inc. and Sawai Pharmaceutical Co., Ltd. (collectively "Sawai" or "Petitioner") filed a Petition to institute an *inter partes* review of claims 1–20 ("the challenged claims") of U.S. Patent No. 8,399,514 B2 (the "'514 patent"). Paper 1 ("Pet."). Biogen MA Inc. ("Patent Owner") filed a Preliminary Response to the Petition. Paper 15 ("Prelim. Resp.").

Concurrently with its Petition, Petitioner filed a Motion for Joinder seeking to join Petitioner as a party to the following instituted proceeding: *Mylan Pharmaceuticals Inc. v. Biogen MA Inc.*, Case IPR2018-01403 (PTAB) ("the Mylan IPR"). Paper 2 ("Mot."). Patent Owner filed an Opposition to Petitioner's Motion for Joinder. Paper 9 ("Opp."). Petitioner filed a Reply to Patent Owner's Opposition. Paper 10 ("Reply"). Patent Owner filed a Sur-Reply to Petitioner's Reply. Paper 14 ("Sur-Reply").

For the reasons discussed below, we institute *inter partes* review of all challenged claims, and grant Petitioner's Motion for Joinder.

A. Related Matters

Petitioner identifies the following litigation between the parties involving the '514 patent: *Biogen Int'l GmbH v. Sawai USA, Inc.*, C.A. No. 17-cv-00875 (D. Del.). Pet. 2. The parties also identify several other litigations involving the '514 patent. *See* Pet. 2–3; Paper 7, 2.

In addition to the Mylan IPR, the '514 patent also has 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 No, 106,023. *See* Pet. 3; Paper 7, 2–3.

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.

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), Dr. Ian McKeague (Ex. 1004), and Jennifer Rock (Ex. 1055) to support its contentions. Pet. 5. In addition, Petitioner submits declarations of Robert Walter Baumhefner, M.D. (Ex. 1056), Jacquelyn Bainbridge, Pharm.D. (Ex. 1057), Ronald G. Marks, Ph.D. (Ex. 1058), and Jennifer Rock (Ex. 1059). Pet. 5. Petitioner explains that "Dr. Baumhefner's (Ex. 1056), Dr. Bainbridge's (Ex. 1057), and Dr. Marks' (Ex. 1058) declarations . . . [are] substantively identical to that of Dr. John R. Corboy's (Ex. 1002), Dr. Leslie Z. Benet's (Ex. 1003), and Dr. Ian McKeague's (Ex. 1004) expert declarations, respectively, in the Mylan IPR." Pet. 6 n.1. In its Motion for Joinder, Petitioner explains the purpose of the additional set of expert declarations submitted with the Petition as follows:

> In order to further simplify the proceeding, Sawai will rely on the same declarants as Mylan, Dr. John R. Corboy, Dr. Leslie Z. Benet, Ms. Rock, and Dr. Ian McKeague, should Mylan permit it. If Mylan allows Sawai to use the same declarants, then Sawai will withdraw the declarations of Dr. Baumhefner, Dr. Bainbridge, Ms. Rock, and Dr. Marks, and rely solely on the declarations and testimonies of Mylan's declarants: Dr. John R. Corboy, Dr. Leslie Z. Benet, Ms. Rock and Dr. Ian McKeague.

Mot. 4–5.

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