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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS VIII, LLC,
Petitioner,

v.

THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA,
Patent Owner.

Case IPR2015-01836
Patent 7,932,268 B2

Before GRACE KARAFFA OBERMANN and MICHAEL P. TIERNEY, *Vice Chief Administrative Patent Judges*, LORA M.GREEN, *Administrative Patent Judge*.

GREEN, *Administrative Patent Judge*.

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

I. INTRODUCTION

Coalition for Affordable Drugs VIII, LLC ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1–8 of U.S. Patent No. 7,932,268 B2 (Ex. 1001, "the '268 patent"). Paper 1 ("Pet."). The Trustees of the University of Pennsylvania ("Patent Owner") filed a Preliminary Response to the Petition. Paper 6 ("Prelim. Resp."). We determined that the information presented in the Petition and the Preliminary Response demonstrated that there was a reasonable likelihood that Petitioner would prevail in challenging claims 1–8 as unpatentable under 35 U.S.C. § 103(a). Pursuant to 35 U.S.C. § 314, the Board instituted trial on March 7, 2016, as to the challenged claims of the '268 patent. Paper 7 ("Institution Decision" or "Dec. Inst.").

Patent Owner filed a Response (Paper 16, "PO Resp."), as well as a Corrected Motion to Amend (Paper 24, "Mot. Amend"). Petitioner subsequently filed a redacted copy of its Reply (Paper 32), as well as an unredacted copy of the Reply as Board and parties only (Paper 31). ("Reply"). Petitioner filed also an Opposition to the Motion to Amend. Paper 33 ("Opp. Mot. Amend"). Patent Owner filed a Reply in Support of its Motion to Amend. Paper 36 ("Reply Mot. Amend").

In addition, Patent Owner filed a Motion to Exclude (Paper 40, "Mot. Exclude"), to which Petitioner filed an Opposition (Paper 46, "Opp. Mot. Exclude"), and Patent Owner filed a Reply (Paper 48, "Reply Mot. Exclude"). Patent Owner filed Observations on the Cross-Examination of Petitioner's Reply Witness (Paper 41), to which Petitioner filed a Response (Paper 47). Petitioner filed Observations on the Cross-Examination of Dr. Thomas A. Baille (Paper 43), to which Patent Owner filed a Response

(Paper 45). Oral hearing was held on December 1, 2016, and a transcript of that hearing has been entered into the record. Paper 56 ("Tr.").

We have jurisdiction under 35 U.S.C. § 6. Petitioner bears the burden of proving unpatentability of the challenged claims, and that burden never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). To prevail, Petitioner must establish facts supporting its challenge by a preponderance of the evidence. *See* 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

Based on the record before us, we conclude that Petitioner has failed to demonstrate by a preponderance of the evidence that claims 1–8 of the '268 patent are unpatentable. Moreover, we *dismiss* Patent Owner's Motion to Amend as moot, and *dismiss* Patent Owner's Motion to Exclude in part and *deny* Patent Owner's Motion to Exclude in part.

A. Related Proceedings

Petitioner concurrently filed a Petition for *Inter Partes* Review of U.S. Patent No. 8,618,135 B2 (IPR2015-01835), which is a member of the same family as the '268 patent. Pet. 3. The final written decision in IPR2015-01835 is being issued concurrently with this Decision.

B. The '268 Patent (Ex. 1001)

The '268 patent issued on April 26, 2011, with Daniel J. Rader as the listed inventor. Ex. 1001. It claims priority to Provisional application No. 60/550,915, filed on March 5, 2004. *Id.* The '268 patent relates to "methods of treating disorders associated with hypercholesterolemia and/or hyperlipidemia." *Id.* at 6:35–37.

The ’268 patent teaches that “[a] large number of genetic and acquired diseases can result in hyperlipidemia.” *Id.* at 1:60–61. Primary hyperlipidemias include “common hypercholesterolemia, familial combined hyperlipidemia, familial hypercholesterolemia, remnant hyperlipidemia, chylomicronemia syndrome and familial hypertriglyceridemia.” *Id.* at 1:65–2:2. For example, with homozygous familial hypercholesterolemia (“HoFH”), total plasma cholesterol levels are over 500 mg/dl, and left untreated, patients develop atherosclerosis by age 20 and often do not survive past age 30. *Id.* at 3:45–52. Such patients, however, are often unresponsive to conventional drug therapy. *Id.* at 3:55–57. According to the ’268 patent, “[a] number of treatments are currently available for lowering serum cholesterol and triglycerides.” *Id.* at 2:3–4. The ’268 patent notes, however, that “each has its own drawbacks and limitations in terms of efficacy, side-effects and qualifying patient populations.” *Id.* at 2:4–6. For example, statins may have side effects that include liver and kidney dysfunction. *Id.* at 2:30–39.

The ’268 patent teaches that abetalipoproteinemia is a rare genetic disease that is characterized by extremely low cholesterol and triglyceride levels and is caused by mutations in microsomal triglyceride transport protein (“MTP”). *Id.* at 5:1–7. Thus, the ’268 patent teaches that the “finding that MTP is the genetic cause of [abetalipoproteinemia] . . . led to the concept that pharmacologic inhibition of MTP might be a successful strategy for reducing atherogenic lipoproteins levels in humans.” *Id.* at 5:30–35. Bristol-Myers Squibb [“BMS”] developed a series of compounds, including BMS-201038 (i.e., lomitapide), which are potent inhibitors of MTP. *Id.* at 5:47–49.

According to the ’268 patent, however:

> Clinical development of BMS-201038 as a drug for large scale use in the treatment of hypercholesterolemia has been discontinued, because of significant and serious hepatotoxicities. For example, gastrointestinal side effects, elevation of serum transaminases and hepatic fat accumulation were observed, primarily at 25 mg/day or higher doses.

Id. at 6:20–25. The ’268 patent notes that “[c]ombinations using MTP inhibitors and other cholesterol or triglyceride drugs have been previously disclosed . . . but suffer the same drawbacks as described above for MTP inhibitors.” *Id.* at 8:30–34.

Thus, according to the ’268 patent, the “invention is based on the surprising discovery that one may treat an individual who has hyperlipidemia and/or hypercholesterolemia with an MTP inhibitor in a manner that results in the individual not experiencing side-effects normally associated with the inhibitor, or experiencing side-effects to a lesser degree.” *Id.* at 7:11–16.

The ’268 patent specifically teaches:

> In some embodiments, the MTP inhibitor is administered at escalating doses. In some embodiments, the escalating doses comprise at least a first dose level and a second dose level. In some embodiments, the escalating doses comprise at least a first dose level, a second dose level, and a third dose level. In some embodiments, the escalating doses further comprise a fourth dose level. In some embodiments, the escalating doses comprise a first dose level, a second dose level, a third dose level, a fourth dose level and a fifth dose level. In some embodiments, six, seven, eight, nine and ten dose levels are contemplated.

Id. at 11:60–12:3.

The ’268 patent teaches further:

> In some embodiments, the first dose level is from about 2 to about 13 mg/day. In some embodiments, the second dose level

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