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Paper No. 7
Entered: March 7, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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COALITION FOR AFFORDABLE DRUGS VIII, LLC,
Petitioner,

v.

THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA,
Patent Owner.

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Case IPR2015-01835
Patent 8,618,135 B2

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

GREEN, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
*37 C.F.R. § 42.108*

# I. INTRODUCTION

Coalition for Affordable Drugs VIII, LLC ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1–10 of U.S. Patent No. 8,618,135 B2 (Ex. 1001, "the '135 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 have jurisdiction under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." Upon considering the Petition and the Preliminary Response, we determine that Petitioner has shown a reasonable likelihood that it would prevail in showing the unpatentability of claims 1–10. Accordingly, we institute an *inter partes* review of those claims.

## *A. Related Proceedings*

Petitioner states that it "is concurrently filing a Petition for *Inter Partes* Review of U.S. Patent No. 7,932,268 [IPR2015-01836], which is a member of the same family as the '135 patent." Pet. 3.

## *B. The '135 Patent (Ex. 1001)*

The '135 patent issued on December 31, 2013, with Daniel J. Rader as the listed inventor. Ex. 1001. It claims priority to application No. 10/591,923, filed as application No. PCT/US2005/007435 on March 7, 2005, which issued as Patent No. 7,932,268, as well as to Provisional application No. 60/550,915, filed on March 5, 2004. *Id.* The '135 patent relates to "methods of treating a subject suffering from a disorder associated with hyperlipidemia and/or hypercholesterolemia." *Id.* at 6:38–40.

The ’135 patent teaches that “[a] large number of genetic and acquired diseases can result in hyperlipidemia.” *Id.* at 1:61–62. Primary hyperlipidemias include “common hypercholesterolemia, familial combined hyperlipidemia, familial hypercholesterolemia, remnant hyperlipidemia, chylomicronemia syndrome and familial hypertriglyceridemia.” *Id.* at 1:66–2:3. 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 3:46–53. Such patients, however, are often unresponsive to conventional drug therapy. *Id.* at 3:56–58.

According to the ’135 patent, “[a] number of treatments are currently available for lowering serum cholesterol and triglycerides,” noting, however, that “each has its own drawbacks and limitations in terms of efficacy, side-effects and qualifying patient population.” *Id.* at 2:4–7. For example, statins may have side effects that include liver and kidney dysfunction. *Id.* at 2:31–40.

The ’135 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 ’135 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 developed a series of compounds, including BMS-201038, which are potent inhibitors of MTP. *Id.* at 5:47–49.

According to the '135 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.

Thus, according to the '135 patent, the "invention is based on the surprising discovery that one may treat an individual who has with 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 '135 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.

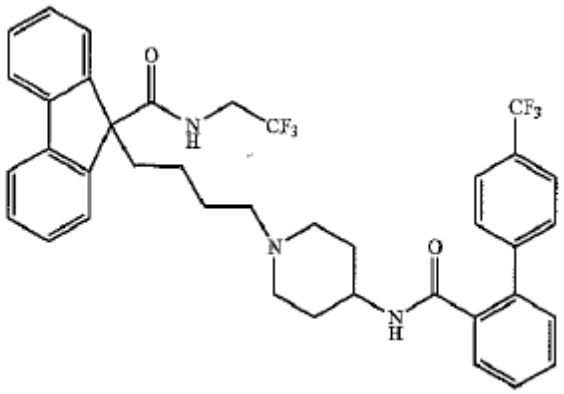
*Id.* at 11:60–12:3. The '135 patent teaches further:

> In some embodiments, the first dose level is from about 2 to about 13 mg/day. In some embodiments, the second dose level is from about 5 to about 30 mg/day. In some embodiments, the third dose level is from about 10 to about 50 mg/day. In some embodiments, the fourth dose level is from about 20 to about 60 mg/day. In some embodiments, the fifth dose level is from about 30 to about 75 mg/day.

*Id.* at 12:45–51. In addition, other lipid modifying compounds may be used with the MTP inhibitor. *Id.* at 11:34–41.

### *C. Illustrative Claim*

Petitioner challenges claims 1–10 of the '135 patent. Claims 1, 9, and 10 are independent. Claim 1 is illustrative of the challenged claims, and is reproduced below:

> 1. A method of treating a suffering from hyperlipidemia or hypercholesterolemia, the method comprising administering to the subject an effective amount of an MTP inhibitor, wherein said administration comprises at least three, step-wise, increasing dose levels of the MTP inhibitor wherein a first dose level is from about 2 to about 13 mg/day, a second dose level is from about 5 to about 30 mg/day, and a third dose level is from about 10 to about 50 mg/day, and wherein the MTP inhibitor is represented by:
>
> 
>
> or a pharmaceutically acceptable salt thereof or the piperidine N-oxide thereof, and wherein each dose level is administered to the subject for about 1 to about 5 weeks.

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