

IN THE 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.

TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA,

Patent Owner, based on Electronic Records of PTO

U.S. Patent 8,618,135 to Rader

Filing Date: March 11, 2011

Issue Date: December 31, 2013

TITLE: METHODS FOR TREATING DISORDERS OR DISEASES ASSOCIATED  
WITH HYPERLIPIDEMIA AND HYPERCHOLESTEROLEMIA WHILE MINIMIZING  
SIDE EFFECTS

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*Inter Partes* Review No.: IPR2015-01835

**PETITIONER'S OPPOSITION TO PATENT OWNER'S  
MOTION TO EXCLUDE EVIDENCE**

Petitioner, Coalition For Affordable Drugs VIII, LLC opposes Patent Owner The Trustees of the University of Pennsylvania motion to exclude Exhibits 1024, 1025, and 1050-1056 submitted by Petitioner.

**A. Exhibits 1024 and 1025**

Patent Owner argues that Exhibits 1024 and 1025 has not been authenticated. In particular, Patent Owner argues that “Petitioner has failed to provide *any* witness testimony whatsoever regarding the websites from where it allegedly obtained Exhibits 1024 and 1025, let alone any testimony from a witness with personal knowledge that the printouts themselves are authentic.”

Patent Owner fails to address the fact that Petitioner submitted the Declaration of Jeffrey Marx, an attorney and member in good standing of the Bars of the State of Illinois (2005) and the State of Wisconsin (2005). Exh. 1034. In that declaration, Mr. Marx authenticated both Exhibits 1024 and 1025. Contrary to Patent Owner’s assertions (“it appears that Petitioner would contend that Exhibits 1024 and 1025 are webpage printouts. But the Petition makes no attempt to establish the province of these exhibits”), Mr. Marx provided in his declaration the website address at which both of these documents could be found. In its motion, Patent Owner completely ignores the contents of Mr. Marx’s declaration.

Patent Owner seemingly argues that the information within the documents has not been authenticated. In this regard, Patent Owner argued, “Petitioner cites these exhibits on page 4 of the Petition, to support its allegation regarding the purported price of JUXTAPID.” Patent Owner, however, never contested the values cited in Petitioner’s exhibits or provided the actual prices cited in these documents in any of the numerous papers and exhibits filed by the Patent Owner. And considering Patent Owner is undoubtedly the best source of such information, it should hardly be heard to complain about the lack of authenticity of information it controls.

**B. Exhibits 1050-1055**

Exhibits 1050-1055 are the FDA labels for a number of drugs for the treatment of hypercholesterolemia. Patent Owner objected that the exhibits were not authenticated. Petitioner responded by submitting the Declaration of Christopher Casieri (Exhibit 1060) swearing to the authenticity of the labels and identifying the exact address on the FDA website at which each label could be located.

Patent Owner seemingly concedes these facts but maintains that the labels have not been authenticated. In this regard, Patent Owner merely states that offered proofs “are insufficient to authenticate the labels”. Patent Owner fails to identify what specifically about the Declaration of Christopher Casieri is

insufficient to authenticity of the documents. While not necessary for authentication, the Declaration provides the specific address where the label is available.

Patent Owner then argues that the labels are not relevant to prove the state of the art as of March 7, 2005. The dates of availability of these drugs however are not contested facts. Statins have been around long before 2005. See for example testimony of Dr. Richard Gregg:

Q Do you know, at the time that BMS discontinued development on lomitapide, were statins commercially available?

A Yes.

Q Do you know how long statins had been around at that time?

A Approximately 10 years. (Ex., Gregg at 35:18-24)

See also, Patent Owner's Exhibit 2019 reporting the so called "CURVES study" in 1998 comparing five statins. As for ezetimibe, Patent Owner's expert cites to several pre-2005 articles describing the ezetimibe alone and in combination with statins. See Ex. 2179 (Earl, J., et al., Ezetimibe, *Nature Reviews*, Vol. 2, 2003, 97); Ex. 2175 (Catapano, A.L., Ezetimibe: a selective inhibitor of cholesterol absorption, *European Heart Journal Supplements* (2001) 3 (Supplement E), E6-E10); Ex. 2182 (Gagne, C., et al., Efficacy and Safety of Ezetimibe Coadministered With Atorvastatin or Simvastatin in Patients with Homozygous Familial Hypercholesterolemia, *Circulation*, 2002; 105:2469-2475).

Accordingly, the labels are both authenticated and relevant.

**C. Exhibit 1056 (Kimball Deposition Transcript)**

Patent Owner filed Exhibit 2304 on August 10, 2016, which is reportedly the same as Exhibit 1056, for no obvious reason. Exhibits 2304 and 1056 are transcripts of the deposition of Petitioner's expert. The party taking a deposition typically files the transcript with the Board. In this instance, the Petitioner's Reply cites to the transcript as Exhibit 1056. Patent Owner does not cite to either exhibit. In response to the Patent Owner's rejection, Petitioner suggested Patent Owner should delete Exhibit 2304, which they apparently refused.

Date: November 10, 2016

Respectfully Submitted,



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Christopher Casieri

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