IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

Inter Partes Review No.: IPR2015-01835

PETITIONER'S OBSERVATIONS ON CROSS-EXAMINATION OF DR. THOMAS A. BAILLIE

Petitioner, COALITION FOR AFFORDABLE DRUGS VIII LLC hereby files observations on the testimony given by Patent Owner's Declarant Dr. Thomas A. Baillie (Exhibit 1060) at a deposition held on October 25, 2016.

(1) Testimony from Dr. Baillie Indicating That He Could Not Identify The Critical Features of the Claims Relating That Allegedly Resulted In Unexpected Results. At the following transcript locations, when asked about the importance of certain features of the claimed dosing protocal, Dr. Baillie could not provide a definitive answer:

> Q. **Is this third dosing level in the claimed regimen critical to promoting biological adaptation for lomitapid**e?
>
> MR. MITROKOSTAS: Objection to the form.
>
> A. **I don't know if it's critical or not critical.** I assumed it was derived from clinical experimentation, **but that's my assumption**. (Exh. 1060, p. 22:5-11(emphasis added))
>
> * * *
>
> Q. Yes.
>
> Is the two-fold sequential dose increase that is required by the substitute claims important to the underlying concept of using a step-wise forced titration dosing regimen to promote biological adaptation?

A. So the -- the question here relates to "two-fold." I think that's what is implied in your question. **And that factor of two-fold is not necessarily applicable to all types of forced-dose titrations. The fact it could be less, conceivably, it could be somewhat more.** In the case of lomitapide, it was found by Dr. Rader's clinical studies that that was an appropriate dose escalation factor. (Exh. 1060, p. 13:15-14:5 (emphasis added))

* * *

Q. So does this change your opinion as to whether the two-fold sequential dose increase is important to the underlying concept of using a step-wise forced titration dosing regimen to promote biological adaptation in lomitapide?

A. It suggests to me that the two-fold number is not absolute, that the two-fold number is one that clearly was effective in accomplishing the goals of the study, but the number of two is not an absolute number. **It could have been two and a half or perhaps three or perhaps one and a half,** but two-fold worked as demonstrated by Dr. Rader's clinical studies**. So I don't think it's absolute**. (Exh. 1060, p. 27:4-16 (emphasis added))

The testimony is relevant as to whether the recited dosing regimen is anything more than routine.

(2) Testimony from Dr. Baillie Indicating That He Could Not Exclude An Extremely Low Fat Diet As The Cause Of The Alleged Amelioration Of Side Effects. At the following transcript locations, when asked about the differences between the diet of the subjects in the earlier BMS trials as compared to the later U. Penn trials, Dr. Baillie could not provide a definitive answer:

> **Q. So my question was, do you know if the BMS clinical trials with lomitapide required the same low-fat diet as that of Dr. Rader's clinical trials for lomitapide?**
>
> **A. I don't know if they required the same low-fat diet.** (Exhibit 1060, p. 30:2-7 (emphasis added))
>
> * * *
>
> Q. It says, "All subjects entered for a seven-day dietary lead-in with an AHA Step I diet which was maintained throughout the study."
>
> Is this the low-fat diet that you're referring to in your declaration with regard to BMS's clinical trials?
>
> A. Yes. This AHA Step I diet would be a low-fat diet.
>
> **Q. Do you know how much fat is permitted in an AHA Step I diet in terms of total calories?**

A. No, I don't actually know that number. But I believe it's very low. I think it's something in the order of 5 to 10 percent of daily caloric intake. That number may not be correct but it's certainly very low.

Q. And why do you believe that it's 5 to 10 percent?

A. Simply because I recall reading that in one of these documents and I can't really cite which specific one at this point.

Q. One of the documents that's --

A. That was in the list of documents that I considered in writing the declaration. Perhaps it was in one of the publications that came from Dr. Rader's clinical trials, but I'm not sure that's the source.

Q. **But the trial here that's identified in Penn Exhibit 2078 is not one of Dr. Rader's trials, correct?**

A. That is correct, yes, so it may not have been from one of his trials. I'm sorry, I can't recall exactly where I read that.

Q. Okay. But you didn't look up on your own how much fat is permitted in an AHA Step I diet, did you?

A. I did not, no.

Q. If I told you a **Step I diet permits 30 percent of total calories from fats**, would that surprise you?

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