

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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LOWER DRUG PRICES FOR CONSUMERS, LLC

PETITIONER

V.

FOREST LABORATORIES HOLDINGS LIMITED

PATENT OWNER

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CASE NO.: IPR2016-00379

PATENT NO. 6,545,040

FILED: JANUARY 24, 1992

ISSUED: 4/8/2003

INVENTORS: XHONNEUX AND VAN LOMMEN

TITLE: METHOD OF LOWERING THE BLOOD PRESSURE

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**REQUEST FOR REHEARING OF DECISION  
DENYING INSTITUTION OF *INTER PARTES REVIEW* [PAPER NO. 14]  
PURSUANT TO 37 C.F.R. §42.71(d)**

The Board’s Decision Denying Institution of *Inter Partes* Review [Paper No. 14] – which defers entirely the USPTO’s previous allowance of the ’040 Patent without any consideration of the substance of the arguments raised in the Petition - is an abdication of the Board’s responsibility under the America Invents Act (“AIA”) to reexamine the agency’s earlier patent examination in order to invalidate bad patents that should never have issued. As the Supreme Court recently explained:

[T]he purpose of the [IPR] proceeding is not quite the same as the purpose of district court litigation. The proceeding involves what used to be called a reexamination . . . . The name and accompanying procedures suggest that the proceeding offers *a second look at an earlier administrative grant of a patent*. Although Congress changed the name from “reexamination” to “review,” nothing convinces us that, in doing so, Congress wanted to change its basic purposes, namely, *to reexamine an earlier agency decision*. Thus, in addition to helping resolve concrete patent-related disputes among parties, *inter partes* review helps protect the public’s “*paramount interest in seeing that patent monopolies . . . are kept within their legitimate scope*.”

*Cuozzo Speed Techs., LLC v. Lee*, 136 S.Ct. 2131, \_\_\_ (2016) (emphasis added).

With this IPR Petition, Petitioner submitted evidence that was not previously before the USPTO during examination. In particular, Petitioner submitted expert testimony from Dr. Ronald W. Millard, Ph.D explaining that it would have been

obvious and ordinary for a POSITA at the time to use well-known and routine laboratory protocols to discover the alleged “unexpected benefits” that the USPTO previously relied upon to allow the ’040 Patent claims. *See* Ex. 1052 at ¶¶67-69, 87, 93, 100. In its Decision Denying Institution, the Board mistakenly stated that USPTO “assumed this to be true . . .” during prosecution. *See* Decision, Paper No. 14 at 11-12. This is incorrect. The USPTO during prosecution never considered whether discovery of the alleged “unexpected benefits” – after the filing of the patent application - was itself ordinary and routine, and thus not sufficient to overcome the strong *prima facie* case that the ’040 Patent claims are obvious and unpatentable. *See* Ex. 1002 at 199-200; 248. Similarly, none of the declarations submitted by Patent Owner in support of the alleged unexpected benefits addressed whether the discovery of these unexpected benefits was ordinary and routine. *See* Ex. 1002 at 39-45; 219-230.

Rehearing of the Board’s Decision Denying Institution is appropriate because the Board misapprehended the nature and implication of this new evidence submitted by Petitioner. *See* 37 C.F.R. §42.71(d). This evidence and its implications were previously discussed in the IPR Petition. *See* Paper No. 6 at pp. 11-13. The Board was mistaken to state that “the Petition is silent” in addressing the “deficiencies in the examiner’s position with respect to the evidence of unexpected results . . . .” Decision, Paper No. 14 at 12. The Petition specifically

addressed the deficiencies in the unexpected results evidence. *See* Paper No. 6 at pp. 55-56. Moreover, the Board was incorrect to determine that “the same or substantially the same prior art or arguments previously were presented to the Office” as is required before exercising the Board’s discretion to deny institution under 35 U.S.C. §325(d).

The *prima facie* case that the ’040 Patent claims are obvious is particularly strong. The Board’s Decision Denying Institution itself recites the critical undisputed facts: (1) the Van Lommen reference teaches the claimed compounds, including all position isomers inherent in the claimed compound; and (2) a person of ordinary skill at the time of the invention would have viewed optical isomer separation as a routine procedure leading to production of the claimed compounds. *See* Paper No. 14 at pp. 6-8.

The Decision Denying Institution, however, provides no explanation as to why the alleged “unexpected benefits” evidence, even if taken at face value, is sufficient to overcome the strong *prima facie* showing of obviousness. The Decision instead merely defers to the USPTO’s previous reliance on the alleged unexpected results during the original *ex parte* patent examination. *See* Paper No. 14 at pp. 9-12. But, as stated above, the Petition presents new evidence that was not considered by the USPTO during prosecution – evidence showing that the discovery of the unexpected benefits was routine and ordinary. Moreover, as

argued in the Petition, the evidence of unexpected benefits has no nexus to the challenged patent claims – none of which contain claim elements regarding potentiating effects of the claimed compound. *See* Paper No. 6 at pp. 55-56.

The Board’s deference to the evidence of alleged unexpected results, and to the USPTO’s previous reliance upon such evidence, is strongly at odds with the way the PTAB treats such evidence in other cases. For example, the Board has held:

Patent Owner does not argue here that the previously-presented evidence of secondary considerations rebuts or outweighs the evidence presented by Petitioner supporting the unpatentability of [the challenged claims]. Moreover, the existence of previously-presented evidence of secondary considerations ***does not act as a bar to the institution of a trial or an additional burden which the Petitioner must overcome*** in demonstrating a reasonable likelihood that it would prevail in demonstrating the unpatentability of [the challenged claims].

*Redline Detection, LLC v. Star Envirotech, Inc.*, Case IPR2013-00106, Paper 17 at 30 (July 1, 2013) (emphasis added).

It is well known that the PTAB will not consider evidence of secondary considerations such as unexpected results unless there is an established nexus between the secondary considerations and elements of the challenged patent claims. *See, e.g., Coalition for Affordable Drugs II LLC v. NPS Pharmaceuticals, Inc.*, Case IPR2015-00990, Paper 28 at 9 (Oct. 23 2015) (“All types of objective

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