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Paper 15
Entered: January 11, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TARO PHARMACEUTICALS U.S.A., INC.,
Petitioner,

v.

APOTEX TECHNOLOGIES, INC.,
Patent Owner.

Case IPR2017-01446
Patent 7,049,328 B2

Before LORA M. GREEN, JEFFREY N. FREDMAN, and ZHENYU YANG, *Administrative Patent Judges.*

FREDMAN, *Administrative Patent Judge*.

DECISION
Request for Rehearing
37 C.F.R. § 42.71

Patent Owner, Apotex Technologies, Inc., filed a request for rehearing (Paper 11, "Req.") of the Decision on Institution (Paper 7, "Dec.") instituting *inter partes* review of claims 1, 2, 4–17, and 19 of U.S. Patent No. 7,049,328 B2 (Ex. 1001, "the '328 patent"). In its request, Patent Owner contends the Decision misapprehended the law regarding inherency. Req. 2–13. The request for rehearing is *denied*.

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ANALYSIS

When rehearing a decision on institution, the Board will review the decision for an abuse of discretion. 37 C.F.R. § 42.71(c). The applicable standard for a request for rehearing is set forth in 37 C.F.R. § 42.71(d), which provides in relevant part:

> A party dissatisfied with a decision may file a request for rehearing, without prior authorization from the Board. The burden of showing a decision should be modified lies with the party challenging the decision. The request must specifically identify all matters the party believes the Board misapprehended or overlooked, and the place where each matter was previously addressed in a motion, an opposition, or a reply.

Patent Owner "submits that the evidence of record fails to show that any of Hoffbrand 1998, Olivieri Abstract 1995, and Olivieri 1995 'unavoidably teaches' the treatment of patients who *have* an iron overload condition of the heart or iron-induced cardiac disease." Req. 2.

Hoffbrand 1998

Patent Owner specifically contends:

> Hoffbrand 1998 never discloses that any patient has an iron overload condition of the heart or iron-induced cardiac disease on the basis of liver iron content. Instead, Hoffbrand 1998 states—as quoted by the Board—that the 10 patients had liver iron content "'that has been associated with cardiac disease.'"

Req. 4. Appellants contend "although the Federal Circuit has made clear that inherency cannot be established based on 'probabilities or possibilities,' the Board based its conclusion on an 'association' between liver iron content and cardiac disease. An 'association,' however, does not meet the strict requirement of inevitability." *Id*. at 5.

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We agree with Patent Owner on the legal standard for inherency. As we acknowledged in our Decision, "[i]nherency . . . may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *MEHL/Biophile Int'l. Corp. v. Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999)." Dec. 14.

However, we remain persuaded at this stage of the proceeding on the current factual record based on Hoffbrand 1998 and the Mehta Declaration, that Petitioner established a "reasonable likelihood" that Hoffbrand 1998 necessarily disclosed treatment of patients with "an iron overload condition of the heart" with a therapeutically effective amount of deferiprone. *See* Dec. 16–20; 35 U.S.C. § 314(a).

Patent Owner does not identify a definition of the phrase "iron overload condition of the heart" in the '328 patent Specification that distinguishes the claimed patient population from Hoffbrand's disclosure of "10 patients [that] had a liver iron content above 15.0 mg/g dry weight, ie, falling within the range that has been associated with cardiac disease." Ex. 1007, 297. The reasonable understanding of Hoffbrand's teaching of this association between liver iron content and cardiac disease is that all ten patients with the elevated iron levels also necessarily fell into the spectrum of having "an iron overload condition of the heart."

Indeed, Patent Owner's Declarants do not rebut Hoffbrand's teaching that liver iron content above 15.0 mg/g identifies patients with cardiac disease, and, therefore, with "an iron overload condition of the heart." Dr. Coates simply notes that Hoffbrand 1998 reports five treated "patients suffered fatal complications. . . . Four of the five reported fatalities resulted from congestive heart failure." Ex. 2001 ¶ 37. *Cf*. Pennell Decl. Ex. 2003

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¶ 37. That statement supports the position that Hoffbrand 1998 treated patients who inherently had an ultimately fatal "iron overload condition of the heart" with 75 mg of deferiprone, acknowledged by claim 15 of the '328 patent as a therapeutically effective amount. Ex. 1007, 295; Ex. 1001, 28:33–37.

We recognize that Dr. Pennell stated that "a patient with a liver iron content above 15 mg/g dry weight is at risk of developing cardiac disease not that such liver iron content definitely establishes cardiac disease." Ex. 2003 ¶¶ 50–51, citing Exhibits 2007, 2015, and 2016. The Exhibits cited by Dr. Pennell do not identify evidence showing a single patient with a liver iron content that exceeds 15.0 mg/g but failed to display an "iron overload condition of the heart." *See* Ex. 2003 ¶ 51. Exhibit 2007 states "while whole liver iron levels >15 mg/g dry weight . . . have been shown to predict patients at highest risk of cardiac death, it is not known how these variables relate to cardiac iron deposition." Ex. 2007, 1. No specific patient data is provided in Exhibit 2007 comparing liver iron levels of particular patients with "iron overload." *See id.* Similarly, Exhibits 2015 and 2016 also do not identify any patients with elevated liver iron content >15 mg/g dry weight with normal cardiac iron levels.

Therefore, the evidence currently of record in Hoffbrand 1998, identifying ten patients as having liver iron levels associated with cardiac disease, provides factual support for finding a reasonable likelihood that these patients necessarily have an "iron overload condition of the heart." *See* Ex. 1007, 297.

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Olivieri Abstract 1995

Patent Owner contends "Olivieri Abstract 1995 never equates abnormal TRT values with 'an iron overload condition of the heart' or 'iron-induced cardiac disease.'" Req. 6. Patent Owner contends:

> the Board nonetheless instituted trial on the basis of inherent anticipation thereby committing legal error in at least three respects. *First*, although the Federal Circuit has made clear that inherency cannot be established based on "probabilities or possibilities," the Board improperly based its conclusion on the notion that abnormal TRT values indicate high cardiac iron, which in turn indicates cardiac disease.

Id. at 7. Patent Owner contends: "*Second*, the Board committed legal error when it based its assumptions on unsubstantiated testimony from Dr. Mehta." *Id*. at 8. Patent Owner contends "Dr. Mehta's statement that 'lower TRT values indicate cardiac disease due to iron overload.' (*see* Ex. 1002 at ¶ 75) is not based on any underlying fact or data, but instead is mere conjecture." *Id*. at 8.

Patent Owner contends also:

> *Third*, the Board appeared to improperly shift the burden of proof . . . The proper focus is not whether the Patent Owner, and its Declarants, provided evidence rebutting that Olivieri Abstract 1995 taught patients having an iron overload condition of the heart (which, to be clear Patent Owner did (*see* Preliminary Response at 43–44)), but whether Petitioner came forth with evidence sufficient to demonstrate this limitation was disclosed in Olivieri Abstract 1995.

Req. 9.

We address these arguments *seriatim*. Regarding the first argument, we found "Olivieri Abstract 1995 inherently anticipates even under a requirement 'that the claimed method have been actually performed.'

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