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Paper 7
Entered: November 28, 2017

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

I. INTRODUCTION

A. Background

Taro Pharmaceuticals U.S.A., Inc. ("Petitioner") filed a Petition (Paper 2, "Pet.") requesting an *inter partes* review of claims 1–17 and 19 (the "challenged claims") of U.S. Patent No. 7,049,328 B2 (Ex. 1001, "the '328 patent"). *See* 35 U.S.C. §§ 311–319. Apotex Technologies, Inc. ("Patent Owner") filed a Preliminary Response. Paper 6 ("Prelim. Resp.").

Institution of an *inter partes* review is authorized by statute when "the information presented in the petition . . . and any response . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314; *see* 37 C.F.R. §§ 42.4, 42.108. For the reasons set forth below, we conclude that Petitioner has established a reasonable likelihood that it would prevail in showing the unpatentability of at least one of the challenged claims of the '328 patent. Therefore, we institute an *inter partes* review for claims 1, 2, and 4–17 and 19 of the '328 patent. [1]

B. Related Proceedings

Petitioner indicates that the '328 patent was asserted in *ApoPharma Inc. v. Taro Pharmaceutical Industries, Ltd.*, No. 2:16-cv-00528 (E.D.Tx.) Pet. 2.

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[1] We note that "Apotex has filed a Statutory Disclaimer under 35 U.S.C. § 253(a) in compliance with 37 C.F.R. § 1.321(a) with the United States Patent and Trademark Office for the '328 patent to statutorily disclaim claim 3." Prelim Resp. 8. Therefore, because claim 3 is disclaimed, we dismiss the Petition for *inter partes* review as to claim 3 pursuant to 37 C.F.R. § 42.107(e).

C. The '328 Patent (Ex. 1001)

The '328 patent addresses patients who require "regular transfusions of red blood cells" that can result in "widespread iron overload in the patient." Ex. 1001, 1:27–30. "Iron overload is dangerous since the excessive iron can cause toxic degenerative changes in the heart, liver and endocrine organs." *Id.* at 1:30–32.

The '328 patent teaches: "Iron chelators are drugs that enhance the iron excretion. Iron overload is most often treated by the use of the iron chelator desferrioxamine." *Id.* at 1:52–54. "Recently another iron chelator, deferiprone by oral administration, has been used successfully for removal of iron in thalassemia patients who could not comply with desferrioxamine." *Id.* at 1:63–66.

The '328 patent teaches

> data now reveal that iron-induced heart disease occurs even in patients who are compliant with desferrioxamine, and even some of those who do not have high levels of total body iron as assessed by serum ferritin or liver iron concentrations. It has thus become evident that lowering of the total body iron alone is insufficient to protect against iron-induced heart damage.

Id. at 2:48–54. The '328 patent teaches: "Nowhere is there taught the cardio selective/preferred function of deferiprone in relation to desferrioxamine and/or other chelating agents when administered to patients having iron overload." *Id*. at 9:40–43.

The '328 patent teaches the inventors "unexpectedly discovered that deferiprone has a cardio selective/preferred function when compared to desferrioxamine or alternative chelating agents utilized in patients suffering iron overload." *Id*. at 10:2–5.

D. Illustrative Claims

Of the challenged claims, claims 1, 2, and 4–10 are independent claims of the '328 patent. The remaining challenged claims 11–17 and 19 depend directly from claims 1, 2, and 4–10.[2] Claims 1 and 15 are illustrative of the challenged claims and recite:

> 1. A method of treating iron induced cardiac disease in a blood transfusion dependent patient experiencing an iron overload condition of the heart, said method comprising administering to the patient a therapeutically effective amount of deferiprone or a physiologically acceptable salt thereof sufficient to stabilize/reduce iron accumulation in the heart resulting from being transfusion dependent.
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> 15. The method of claims **1**, **2**, **3**, **4**, **5**, **6**, **7**, **8**, **9** or **10** wherein the administration frequency to the patient of a dosage amount of deferiprone or a physiologically acceptable salt thereof is daily in the range of 25 mg to 75 mg per kilogram of body weight.

Ex. 1001, 27:3–9, 28:33–37.

E. The Asserted Grounds of Unpatentability

Petitioner contends that the challenged claims are unpatentable based on the following grounds. Pet. 9–10.

Reference	Basis	Claims Challenged
MIMS 1998[3]	§ 102(b)	1, 2, 4–11, 13–17, 19

[2] Claims 18 and 20 were not challenged in this proceeding.
[3] *Monthly Index of Medical Specialties*, Vol. 18, No. 12, December 1998 ("MIMS 1998," Ex. 1009).

Hoffbrand 1998[4]	§ 102(b)	1, 2, 4–11, 13–17, 19
Olivieri Abstract 1995[5]	§ 102(b)	1, 2, 4–11, 13–17, 19
Agarwal 2000[6]	§ 102(b)	1, 2, 4–11, 13–17, 19
Olivieri 1995[7]	§ 102(b)	1, 2, 4–11, 13–17, 19
MIMS 1998	§ 103(a)	1, 2, 4–17, 19
Hoffbrand 1998	§ 103(a)	1, 2, 4–17, 19
Olivieri Abstract 1995	§ 103(a)	1, 2, 4–17, 19
Agarwal 2000	§ 103(a)	1, 2, 4–17, 19
Olivieri 1995	§ 103(a)	1, 2, 4–17, 19

Petitioner relies on the Declaration of Jayesh Mehta, M.D. Ex. 1002. Patent Owner relies upon two Declarations, that of Dr. Thomas D. Coates, M.D., Ex. 2001, and of Dr. Dudley J. Pennell, M.D., Ex. 2003.

II. ANALYSIS

A. Claim Interpretation

In an *inter partes* review, claim terms in an unexpired patent are given their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs.*,

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[4] Hoffbrand et al., *Long-Term Trial of Deferiprone in 51 Transfusion-Dependent Iron Overloaded Patients*, BLOOD, 91(1):295–300, 1998 ("Hoffbrand 1998," Ex. 1007).

[5] Olivieri et al., *First Prospective Randomized Trial of the Iron Chelators Deferiprone (L1) And Deferoxamine*, Abstract 983: Hemoglobinopathies and Thalassemias II, 249a, PROGRAM OF THE 37TH ANNUAL MEETING OF THE AMERICAN SOCIETY OF HEMATOLOGY, December 1995 ("Olivieri Abstract 1995," Ex. 1010).

[6] Agarwal, *Deferiprone (Kelfer): A Report of 22 Patients Who Have Taken It for over a Decade*, 10TH INTERNATIONAL CONFERENCE ON ORAL CHELATORS IN THE TREATMENT OF THALASSEMIA AND OTHER DISEASES AND BIOMED MEETING, March 2000 ("Agarwal 2000," Ex. 1011).

[7] Olivieri et al., *Iron-Chelation Therapy with Oral Deferiprone in Patients with Thalassemia Major*, N. ENGL. J. MED., 332:918–22, 1995 ("Olivieri 1995," Ex. 1012).

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