Trials@uspto.gov
Tel: 571-272-7822

Paper 17
Entered: August 14, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PHARMACOSMOS A/S,
Petitioner,

v.

AMERICAN REGENT, INC.
Patent Owner.

PGR2020-00009
Patent 10,478,450 B2

Before ERICA A. FRANKLIN, JON B. TORNQUIST, and JAMIE T. WISZ, *Administrative Patent Judges.*

WISZ, *Administrative Patent Judge*.

DECISION
Denying Institution of Post-Grant Review
35 U.S.C. § 325(d)

I. INTRODUCTION

Pharmacosmos A/S ("Petitioner") filed a Petition (Paper 1, "Pet.") requesting a post-grant review of claims 1–22 of U.S. Patent No. 10,478,450 B2 (Ex. 1001, "the '450 patent"). American Regent, Inc. ("Patent Owner") filed a Preliminary Response (Paper 12, "Prelim. Resp.").[1] With our authorization, Petitioner filed a Reply (Paper 14, "Reply"), and Patent Owner filed a Sur-Reply (Paper 16, "PO Sur-Reply").

Under 35 U.S.C. § 324(a), a post-grant review may not be instituted "unless . . . the information presented in the petition . . . , if such information is not rebutted, would demonstrate that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable." Upon considering the arguments and evidence, we exercise our discretion to deny institution of post-grant review under 35 U.S.C. §§ 324(a) and 325(d).

II. BACKGROUND

A. Real Parties-in-Interest

Petitioner identifies Pharmacosmos A/S and Pharmacosmos Therapeutics Inc. as the real parties-in-interest. Pet. 4. Patent Owner identifies American Regent, Inc., which is a subsidiary of Daiichi Sankyo Inc., as the real party-in-interest. Paper 5, 1.

B. Related Proceedings

The parties indicate that Petitioner has filed four petitions for *inter partes* review for related patents in the following proceedings, IPR2015-

[1] Pursuant to the Notice of Waiver of Patent-Related Timing Deadlines under the Coronavirus Aid, Relief, and Economic Security Act issued March 31, 2020, Patent Owner requested, and we granted, a 30-day extension of the deadline for Patent Owner to file its Preliminary Response. Ex. 3001.

01493 (U.S. Patent No. 8,431,549) ("the '549 patent") (claims 1–5, 9, 14, 16, and 19 held unpatentable); IPR2019-01142 (the '549 patent) (not instituted); IPR2015-01490 (U.S. Patent No. 7,754,702) ("the '702 patent") (claims 1–3, 10–15, 23, 25, 27, 30, and 41–43 held unpatentable); IPR2015-01495 (U.S. Patent No. 8,895,612) ("the '612 patent") (not instituted). *See* Pet. 5; Paper 5, 2. The '702 patent, which was the subject of IPR2015-01490, and the '549 patent, which was the subject of IPR2015-01493, were also involved in appeals and cross appeals to the Federal Circuit. Paper 5, 2.

According to Patent Owner, both the '612 and '702 patents were included in the following district court actions: Vifor (International) AG, et al. v. Sandoz, Inc., 3-19-cv-16305 (D. N.J.); Vifor (International) AG, et al. v. Mylan Laboratories Limited, 3-19-cv13955 (D. N.J.); and Vifor (International) AG, et al. v. Mylan Laboratories Limited 1-19-cv-00126 (N.D. W.Va.). Paper 5, 2.

Patent Owner also indicates that the '450 patent claims the benefit of U.S. Provisional Application No. 60/757,119 filed January 6, 2006; U.S. Patent Application No. 11/620,986, patented as the '702 patent; U.S. Patent Application No. 12/787,283, patented as the '549 patent; and U.S. Patent Application No. 13/847,254 (now abandoned). Paper 5, 1–2. U.S. Patent Application No. 14/100,717, patented as the '612 patent, also claims priority to U.S. Provisional Application No. 60/757,119 ("the '119 provisional"). *Id.* In addition, the following applications claim the benefit of the '450 patent: 16/192,681; 16/438,340; and 15/958,930. *Id.*

C. The '450 Patent

The '450 patent generally relates to the treatment of iron-related conditions with iron carbohydrate complexes. Ex. 1001, code (57), 1:20–21.

According to the Specification, parenteral iron therapy is known to be effective in a variety of diseases and conditions including, *inter alia*, severe iron deficiency and iron deficiency anemia. *Id*. at 1:25–27. However, iron dextran, the first parenteral product available in the United States, has been associated with an incidence of anaphylactoid-type reactions. *Id*. at 1:50–54. The Specification further notes that pharmacokinetic studies suggested that doses of iron complexes containing higher than 200 mg of iron are generally unsuitable, and that the conventional therapy model prescribes repeated applications of lower doses over several days. *Id*. at 2:14–18.

The Specification describes the administration of iron carbohydrate complexes at a relatively high single unit dosage, i.e., containing at least 0.6 grams of elemental iron, "thereby providing a safe and efficient means for delivery of a total dose of iron in fewer sessions over the course of therapeutic treatment." Ex. 1001, 2:28–42. According to the Specification, the inventors discovered that certain characteristics of iron carbohydrate complexes make them amenable to administration at dosages far higher than contemplated by current administration protocols. *Id*. at 11:5–8. Among these preferable characteristics are: a nearly neutral pH (e.g., about 5 to about 7); physiological osmolarity; a stable carbohydrate component; an iron core size no greater than about 9 nm; mean diameter particle size no greater than about 35 nm, preferably about 25 nm to about 30 nm; slow and competitive delivery of the complexed iron to endogenous iron binding sites; serum half-life of over about 7 hours; low toxicity; a non-immunogenic carbohydrate component; no cross reactivity with anti-dextran antibodies; and/or low risk of anaphylactoid/hypersensitivity reactions. *Id*. at 11:8–21.

D. Illustrative Claim

Petitioner challenges claims 1–22 of the '450 patent. Claim 1, which is the only independent claim of the '450 patent, is illustrative of the challenged claims, and is reproduced below:

> 1. A method of treating a disease, disorder, or condition characterized by iron deficiency or dysfunctional iron metabolism resulting in reduced bioavailability of dietary iron, comprising administering to a subject in need thereof an iron carbohydrate complex in a single dosage unit of at least 0.7 grams of elemental iron, wherein:
>
> the iron carbohydrate complex is substantially non-immunogenic, and has substantially no cross reactivity with anti-dextran antibodies; and
>
> the iron carbohydrate complex is an iron polyisomaltose complex.

Ex. 1001, 27:7–17. Challenged claims 2–22 depend from claim 1, either directly or indirectly.

E. The Asserted Grounds of Unpatentability

Petitioner contends claims 1–22 of the '450 patent are unpatentable in view of the following grounds. Pet. 8–9.

Ground	Claims Challenged	35 U.S.C. §	References/Basis
1	1–22	112(a)	Written Description
2	1–22	112(a)	Enablement
3	1–22	112(b)	Indefiniteness
4	1–4, 6, 7, 11, 12, 15, 19–22	102	Jahn[2]

[2] Jahn et al., A comparative study of the physicochemical properties of iron isomaltoside 100 (Monofer®), a new intravenous iron preparation and its

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