

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

Ground	Claims Challenged	35 U.S.C. §	References/Basis
5	5	103	Jahn, Helenek ³
6	13	103	Jahn, Wikström ⁴
7	14	103	Jahn, CKD Guidelines ⁵
8	17	103	Jahn, '668 patent ⁶

Petitioner submits the Declarations of Lee Josephson, Ph.D. (Ex. 1102) and N. Franklin Adkinson, M.D. (Ex. 1103) in support of institution of post-grant review. Patent Owner submits the Declarations of Dr. Todd Lowary, Ph.D. (Ex. 2001) and Daniel Coyne, M.D. (Ex. 2003) in support of its Preliminary Response.

III. DENIAL UNDER 35 U.S.C. § 325(d)

Patent Owner asserts that we should deny the Petition under 35 U.S.C. § 325(d) because “the Petitioner presents the same or substantially the same arguments previously presented during prosecution and related post-grant proceedings.” Prelim. Resp. 68. We have discretion to deny review when

clinical implications, 78 Eur. J. of Pharm. and Biopharm., 480–491 (2011) (Ex. 1048, “Jahn”).

³ Helenek et al., U.S. Patent No. 6,960,571 B2, issued Nov. 1, 2005 (Ex. 1012, “Helenek”).

⁴ Wikström et al., Iron isomaltoside 1000: a new intravenous iron for treating iron deficiency in chronic kidney disease, 24(5) J. Nephrol., 589–596 (2011) (Ex. 1101, “Wikström”).

⁵ National Kidney Foundation - K/DOQI Clinical Practice Guidelines for Anemia of Chronic Kidney Disease. Am. J. Kidney Dis. 37:S182–238, 2001 (Suppl. 1) (Ex. 1100, “CKD Guidelines”).

⁶ Lawrence et al., U.S. Patent No. 5,624,668, issued Apr. 29, 1997 (Ex. 1011, “’668 patent”).

“the same or substantially the same prior art or arguments previously were presented to the Office.” 35 U.S.C. § 325(d). In that respect, section 325(d) provides that the Director may elect not to institute a proceeding if the challenge to the patent is based on matters previously presented to the Office.⁷ *Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 7 (PTAB Feb. 13, 2020) (precedential) (“*Advanced Bionics*”).

In evaluating matters under § 325(d), the Board uses the following two-part framework: (1) determining whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and (2) if either condition of the first part of the framework is satisfied, determining whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims. *Advanced Bionics*, Paper 6 at 8.

In applying the two-part framework, we consider several non-exclusive factors, including:

- (a) the similarities and material differences between the asserted art and the prior art involved during examination;
- (b) the cumulative nature of the asserted art and the prior art evaluated during examination;
- (c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection;

⁷ The Board institutes trial on behalf of the Director. 37 C.F.R. § 42.4(a); *Advanced Bionics*, Paper 6 at 7 n.7.

- (d) the extent of the overlap between the arguments made during examination and the manner in which petitioner relies on the prior art or patent owner distinguishes the prior art;
- (e) whether petitioner has pointed out sufficiently how the examiner erred in its evaluation of the asserted prior art; and
- (f) the extent to which additional evidence and facts presented in the petition warrant reconsideration of the prior art or arguments.

Becton, Dickinson & Co. v. B. Braun Melsungen AG, IPR2017-01586, Paper 8 at 17–18 (PTAB Dec. 15, 2017) (precedential as to Section III.C.5, first paragraph) (“*Becton, Dickinson*”).

Factors (a), (b), and (d) of the *Becton, Dickinson* factors relate to whether the art or arguments presented in the Petition are the same or substantially the same as those previously presented to the Office. *Advanced Bionics*, Paper 6 at 10. Factors (c), (e), and (f) “relate to whether the petitioner has demonstrated a material error by the Office” in its prior consideration of that art or arguments. *Id.* Only if the same or substantially the same art or arguments were previously presented to the Office do we then consider whether petitioner has demonstrated a material error by the Office. *Id.* “At bottom, this framework reflects a commitment to defer to previous Office evaluations of the evidence of record unless material error is shown.” *Id.* at 9.

F. Relevant Prosecution History

The ’450 patent claims the benefit of: U.S. Provisional Application No. 60/757,119 filed January 6, 2006 (“the ’119 provisional”); U.S. Patent Application No. 11/620,986 filed January 8, 2007, patented as the ’702 patent; U.S. Patent Application No. 12/787,283 filed May 25, 2010, patented as the ’549 patent; and U.S. Patent Application No. 13/847,254 filed March

19, 2013 (now abandoned). Ex. 1001, codes (21), (60), (63). We discuss the prosecution of both the '549 patent and the '450 patent below.

1. The '549 Patent Prosecution History

During prosecution of the '549 patent, the Examiner rejected the claims for lack of enablement “because the specification does not reasonably provide enablement for [an] iron polyisomaltose complex having [a] substantially non-immunogenic carbohydrate complex and substantially no cross reactivity with anti-dextran antibodies.” Ex. 1007, 81.⁸ In discussing the factors from *In re Wands*, 858 F.2d 731, 736–737 (Fed. Cir. 1988) (“the *Wands* factors”), the Examiner asserted that “[o]ne of skill in the art would expect anti-dextran antibodies to cross react with polyisomaltose, which is a linear $\alpha(1-6)$ chain of dextran.” *Id.* at 82. The Examiner also asserted that “the specification does not provide specific guidance as to what structural features” give rise to the claimed characteristics and further contended that:

In order to practice the invention with the full range of all possible methods of administration beyond those known in the art, (such as those causing significant adverse reaction or cross reactivity with anti-dextran antibodies) one skilled in the art would undertake a novel and extensive research program into what specific structural features are recognized by each anti-dextran antibody and how to remove such structural recognition from iron polyisomaltose complex.

Id. at 83.

In response, Patent Owner argued that “an iron polyisomaltose is a type of iron carbohydrate complex that includes isomaltose units in the carbohydrate component” and that “[o]ne example of an iron polyisomaltose

⁸ The cited page numbers in Ex. 1007 refer to the page numbers added by Petitioner in the bottom-right corner of the page.

complex is an iron isomaltoside (e.g., Monofer[®]), where the carbohydrate component is a pure linear chemical structure of repeating α 1-6 linked glucose units.” Ex. 1007, 99. Patent Owner further argued:

It was understood at the time of filing that isomaltose oligomers prevent or block anaphylaxis to dextrans (Coulson and Stevens 1961 J Immun 86, 241; evidenced by Jahn et al. 2011 Eur J Pharma and Biopharma 78, 480-491, at 489, col. 1, ln. 53-58; see Lawrence Declaration, ¶5). It was also understood at the time of filing that isomaltose oligomers acted as haptens against circulating anti-dextran antibodies (retrospective summary in Jahn et al. 2011 Eur J Pharma and Biopharma 78, 480-491, at 489, col. 1, ln. 58-60; see Lawrence Declaration, ¶5). A hapten can bind an antibody without inducing anaphylaxis or an immune response (see term definition in retrospective summary of Jahn et al. 2011 Eur J Pharma and Biopharma 78, 480-491, at 489, col. 2, ln. 3-5; see Lawrence Declaration, ¶5).

Id. at 99–100.

Patent Owner also submitted the Declaration of Richard P. Lawrence (“the Lawrence Declaration”), one of the named inventors, who made similar statements. Ex. 1007, 110–113. For example, the Declaration stated, “[b]ased on my experience, an iron polyisomaltose is a type of iron carbohydrate complex that includes isomaltose units in the carbohydrate component.” *Id.* at 111. The Declaration also stated, “Jahn et al. evidences that even in the 1960s it was known that isomaltose oligomers prevent or block anaphylaxis and that later research in the 1970s and 1980s showed that isomaltose oligomers acted as haptens against circulating anti-dextran antibodies.” *Id.* at 112 (citing Ex. 1048, 489).

Following submission of the response and the Lawrence Declaration, the Examiner withdrew the enablement rejection and allowed the claims. *See* Ex. 1007, 137–146. In the Reasons for Allowance, the Examiner stated:

Applicant's Remarks and declaration of Richard P. Lawrence regarding the state of the art at the time of the instant invention as presented in post art Jahn et al. are [persuasive] that one of ordinary skill in the art at the time of the instant invention would have been able to practice the invention for iron polyisomaltose complex having substantially non-immunogenic carbohydrate complex and substantially no cross reactivity with anti-dextran antibodies. Post art Jahn et al. at page 489, left column, paragraph 5 provides evidence that at the time of the instant invention one of ordinary skill in the art would have been able to select isomaltose oligomers to block anaphylaxis to dextrans and that selection of isomaltose oligomers that were nonanaphylactogenic and desensitizing in animals sensitized against dextran.

Id. at 142.

2. *The '450 Patent Prosecution History*

During the prosecution of the '450 patent, the Examiner issued an indefiniteness rejection and asserted that the specification does not define the structure of "an iron polyisomaltose complex" and it is unclear if the term includes dextran. Ex. 1002, 187–189.⁹ In response, Patent Owner amended the claims to recite that the iron polyisomaltose carbohydrate complex "is substantially non-immunogenic, and has substantially no cross reactivity with anti-dextran antibodies," and argued that, in view of this amendment, "a person of skill in the art would understand 'polyisomaltose' does not refer to dextrans, which are distinguished in the application from the iron carbohydrate complexes used in the methods, disclosed and claimed." *Id.* at 201, 206. Patent Owner further stated:

Hence, "polyisomaltose" is not the same as dextran, which is a branched glucan polysaccharide. Thus, the skilled person

⁹ The cited page numbers in Ex. 1002 refer to the page numbers added by Petitioner in the bottom-right corner of the page.

would understand polyisomaltose refers to a linear chemical structure of repeating α -1,6 linked glucose units that optionally is reduced.

Id. at 207. Patent Owner also cited to prior art references to support its position that the skilled person would not understand polyisomaltose to include or be synonymous with dextran. *See id.* at 210.

Following the response, the Examiner withdrew the indefiniteness rejection and allowed the claims. *See Ex. 1002, 233–241.* In the Reasons for Allowance, the Examiner stated:

Applicant’s remarks are persuasive that language of the claim drawn to the method wherein the iron carbohydrate complex is an iron polyisomaltose complex having the properties as recited, when read in view of the instant specification makes reasonably clear that polyisomaltose as described in the instant application does not mean dextran and instead the term is given its regular meaning in the art which the cited Muller et al. acknowledges is different from dextran in that polyisomaltose is the degradation product of dextran consisting of polymerized glucose residues joined predominantly by 1,6 linkages

Id. at 237.

G. Same or Substantially the Same Art or Arguments Previously Presented to the Office

We first consider whether Petitioner asserts the same or substantially the same art or arguments that previously were presented to the Office. *Advanced Bionics*, Paper 6 at 8. As discussed below, we conclude that Petitioner asserts the same or substantially the same art and arguments that previously were before the Office.

According to Patent Owner, “the Petition is premised on (1) claim construction arguments regarding the term ‘iron polyisomaltose’ that the [Office has] repeatedly rejected, and (2) § 112 arguments that the examiner

squarely addressed during prosecution.” Prelim. Resp. 68. Patent Owner argues that Petitioner relies on its erroneous claim construction to argue that the ’450 patent lacks written description and fails to enable the full scope of the claims. *Id.* at 46, 58. Patent Owner also asserts that Petitioner’s claim construction arguments were previously addressed in the context of an indefiniteness rejection during prosecution of the ’450 patent. *Id.* at 21. We first address the parties’ arguments regarding claim construction in order to determine the impact of claim construction as previously considered with respect to the unpatentability challenges under § 112.¹⁰

1. Claim Construction

Petitioner asserts that the claim term “iron polyisomaltose complex” should be construed to mean “iron complexed to a carbohydrate that is a polysaccharide consisting of many (at least 20) glucose units joined predominantly by α -1, 6 linkages.” Pet. 31 (citing Ex. 1102 ¶¶ 92–96). Patent Owner proposes to construe this term to mean “iron complexed to a linear chemical structure of repeating α -1, 6 linked glucose units that optionally is reduced.” Prelim. Resp. 19. In contrast to Petitioner’s proposed construction, Patent Owner’s proposed construction requires that the iron polyisomaltose complex be linear and has no lower limitation on the number of glucose units that are joined; in other words, it includes oligoisomaltoses, while Petitioner’s construction does not.

Patent Owner asserts that the Office has “already addressed whether ‘polyisomaltose’ is linear and includes oligoisomaltoses and agreed with

¹⁰ This Decision does not address claim construction as a stand-alone argument under 35 U.S.C. § 325(d) but, rather, addresses the impact of claim construction on the Petitioner’s challenges under § 112.

Patent Owner on both points.” PO Sur-Reply 1 (citing Prelim. Resp. 20–26, 30–31, 55–57). According to Patent Owner, “[d]uring prosecution of the ’450 patent and its parent ’549 patent, the Examiner questioned the meaning of ‘polyisomaltose,’ and Patent Owner conclusively defined ‘iron polyisomaltose’ as linear.” *Id.* (citing Ex. 1002, 188, 206–207, 209–212; Ex. 1007, 99–101, 111). Patent Owner further asserts that the “Examiner then applied this definition and eventually allowed the claims.” *Id.* at 2 (citing Ex. 1002, 237).

Patent Owner also contends that, during prosecution of the ’549 patent, Patent Owner cited to Monofer, an iron oligosaccharide complex, as “[o]ne example of an iron polyisomaltose complex...where the carbohydrate component is a pure linear chemical structure of repeating α 1-6 linked glucose units.” PO Sur-Reply, 2 (citing Ex. 1007, 99–101, 111). The Examiner found Patent Owner’s arguments “persuasive” and further equated “polyisomaltose” and “isomaltose oligomers,” finding that “one of ordinary skill in the art ... would have been able to practice the invention for iron polyisomaltose complex ... [because] one of ordinary skill in the art would have been able to select isomaltose oligomers to block anaphylaxis to dextrans.” *Id.* (citing Ex. 1007, 142).

Petitioner asserts that “[t]he Examiner never formally construed ‘polyisomaltose’ or assessed whether, given the intrinsic and extrinsic evidence, it could cover oligomers (*Becton, Dickinson* factors (a)-(d)).” Reply 1.¹¹ Specifically, Petitioner contends that the Examiner’s

¹¹ While Petitioner challenges that the Examiner construed “polyisomaltose” to cover oligomers, Petitioner appears to accept that the Examiner found that “polyisomaltose” is linear in arguing that “‘linearity’ as a trait of polyisomaltose arose when the Examiner volunteered it, without support.”

“acceptance” of Patent Owner’s incorrect assertions regarding claim construction “at face value, leading him to erroneously withdraw an enablement rejection, does not establish that he considered and decided the matter such that the Board need not hear it.” *Id.* at 2.

We agree with Patent Owner that Petitioner’s arguments regarding construction of the claim term “polyisomaltose” are substantially the same as arguments previously before the Office. We are not persuaded by Petitioner’s assertion that the Examiner never “formally construed ‘polyisomaltose’” or assessed whether it could cover oligomers. In the Reasons for Allowance of the ’549 patent, the Examiner contemplated that the term “polyisomaltose” includes oligomers in stating that “one of ordinary skill in the art . . . would have been able to practice the invention for iron polyisomaltose complex . . . [because] one of ordinary skill in the art would have been able to select *isomaltose oligomers* to block anaphylaxis to dextrans.” Ex. 1007, 142 (emphasis added). Furthermore, as discussed above, the Examiner also considered the meaning of the term “polyisomaltose” in the prosecution of the ’450 patent and found the Patent Owner’s arguments “persuasive.” Ex. 1002, 188, 206–207, 209–21, 237.

We are, thus, persuaded by Patent Owner that Petitioner’s arguments regarding claim construction of “polyisomaltose” are substantially the same as issues previously before the Office.

Reply 4 (citing Ex. 1007, 82). Therefore, we address Petitioner’s arguments regarding whether “polyisomaltose” should properly be construed as a linear chain in the second part of the *Advanced Bionics* framework (i.e., whether the Office erred in a manner material to the patentability of challenged claims).

2. *Enablement*

Petitioner argues that the claims are unpatentable for lack of enablement given the breadth of the term “polyisomaltose” and the lack of guidance in obtaining a substantially non-immunogenic iron polyisomaltose complex. Pet. 55–67.

Patent Owner contends that the Examiner has already considered, and rejected, the enablement argument raised by Petitioner that the ’450 patent does not describe or enable the claimed substantially non-immunogenic iron polyisomaltose complex. PO Sur-Reply 5 (citing Pet. 39–67). Patent Owner points to the enablement rejection of the ’549 patent claims and the Examiner’s assertion that the specification did not identify or provide guidance as to the properties of the claimed iron polyisomaltose that rendered it substantially non-immunogenic with no cross reactivity with antidextran antibodies. *Id.* (citing Ex. 1007, 80–84). Patent Owner argues that it overcame the rejection by arguing the *Wands* factors and the claims were allowed. *Id.* at 5–6 (citing Ex. 1007, 97–104, 110–113).

In response, Petitioner argues that “the ’450 patent claims a substantially non-immunogenic iron carbohydrate *complex*, while the ’549 [patent] requires only that the individual carbohydrate *component*—prior to complexation with iron—be non-immunogenic.” Reply 7. Therefore, according to Petitioner, the enablement rejection from the ’549 patent’s prosecution is irrelevant. *Id.*

We agree with Patent Owner that Petitioner’s enablement arguments are substantially the same as arguments previously before the Office. Although the enablement rejection in the ’549 patent was directed to claims reciting a “substantially non-immunogenic carbohydrate component,” the

Examiner stated in the rejection that “the specification does not reasonably provide enablement for [an] iron polyisomaltose *complex* having [a] substantially non-immunogenic carbohydrate *complex* and substantially no cross reactivity with anti-dextran antibodies.” Ex. 1007, 48, 81 (emphasis added).

Furthermore, the Examiner’s discussion of the *Wands* factors include many of the same or substantially the same arguments advanced by Petitioner. For example, similar to arguments made in the Petition, the Examiner argued that the specification does not provide specific guidance as to what structural features are necessary for a non-immunogenic carbohydrate component and no cross reactivity with anti-dextran antibodies. *Compare* Pet. 58–61, *with* Ex. 1007, 82–83. Similarly, as asserted in the Petition, the Examiner argued that there were no working examples of “an iron polyisomaltose complex having [a] substantially non-immunogenic carbohydrate complex and substantially no cross reactivity with anti-dextran antibodies.” *Compare* Pet. 61–62, *with* Ex. 1007, 83.

Furthermore, as argued in the Petition, the Examiner asserted:

In order to practice the invention with the full range of all possible methods of administration beyond those known in the art, (such as those causing significant adverse reaction or cross reactivity with anti-dextran antibodies) one skilled in the art would undertake a novel and extensive research program into what specific structural features are recognized by each anti-dextran antibody and how to remove such structural recognition from iron polyisomaltose complex.

Compare Pet. 63–64, *with* Ex. 1007, 83.

As discussed *supra*, Patent Owner responded to the enablement rejection by providing an analysis of the *Wands* factors and by submitting the Lawrence Declaration. *See* Ex. 1007, 97–104, 110–113. The Examiner

found Patent Owner's arguments and the Lawrence Declaration to be "persuasive" and further stated that:

one of ordinary skill in the art at the time of the instant invention would have been able to practice the invention for iron polyisomaltose complex having substantially non-immunogenic carbohydrate complex and substantially no cross reactivity with anti-dextran antibodies. . . . [A]t the time of the instant invention one of ordinary skill in the art would have been able to select isomaltose oligomers to block anaphylaxis to dextrans and that selection of isomaltose oligomers were nonanaphylactogenic and desensitizing in animals sensitized against dextran.

Ex. 1007, 142.

Based on the above, we are persuaded by Patent Owner that Petitioner's enablement arguments are substantially the same as issues previously before the Office.

3. *Indefiniteness*

Petitioner argues that the term "iron polyisomaltose complex" is indefinite because it is not defined in the '450 patent and it is unclear whether this term encompasses dextran. Pet. 67–69. Petitioner also argues that the term "substantially non-immunogenic" is indefinite because "it is impossible to ascertain the claims' scope" and the patent lacks "any guidance on how (if at all) the claimed iron polyisomaltose complex differs from prior art iron dextran or other iron polyisomaltoses that were known to be immunogenic." *Id.* at 71.

Patent Owner asserts that the indefiniteness challenges raised in the Petition were previously before the Office. PO Sur-Reply 4. Specifically, Patent Owner contends that, "Petitioner's challenge—that the relationship between 'iron polyisomaltose' and 'dextran' is unclear and that a skilled

artisan could not identify the claimed substantially non-immunogenic polyisomaltose (Pet., 67–71)—has been conclusively decided by the Office.” *Id.* Petitioner does not address indefiniteness in its Reply brief regarding 35 U.S.C. 325(d). *See generally* Reply.

We agree with Patent Owner that Petitioner’s indefiniteness arguments are substantially the same as arguments previously before the Office. As discussed *supra*, during prosecution of the ’450 patent, the Examiner issued an indefiniteness rejection and stated, “it is unclear if the meaning of the term ‘polyisomaltose’ encompasses the meaning loosely ‘dextran’ as used in the prior art.” Ex. 1002, 188. In response, Patent Owner amended the claims to affirmatively recite that the iron polyisomaltose carbohydrate complex “is substantially non-immunogenic and has substantially no cross reactivity with anti-dextran antibodies” and argued that, in view of the amendments, “a person of skill in the art would understand ‘polyisomaltose’ does not refer to dextrans.” Ex. 1002, 201, 206–207.

In response, the Examiner withdrew the indefiniteness rejection and stated that Patent Owner’s remarks were “persuasive.” Ex. 1002, 236–237. The Examiner further stated that “the instant specification makes reasonably clear that polyisomaltose as described in the instant application does not mean dextran and instead the term is given its regular meaning in the art.” *Id.* at 237. Therefore, during prosecution of the ’450 patent, the Examiner addressed the issue of whether the term “polyisomaltose” was indefinite and also specifically addressed whether dextran was encompassed by the term.

We are, thus, persuaded by Patent Owner that Petitioner's indefiniteness arguments are substantially the same as issues previously before the Office.

4. *Written Description*

Petitioner argues that the claims are unpatentable for lack of written description because “[t]he ’450 patent does not describe or exemplify any iron polyisomaltose complex, let alone the claimed substantially non-immunogenic iron polyisomaltose complex that does not cross-react with anti-dextran antibodies.” Pet. 39–55. Petitioner also argues that a “substantially non-immunogenic complex” is not described in the ’450 patent specification. *Id.* at 43–44.

Patent Owner asserts that, “[a]lthough the Office has not expressly addressed written description of the ’450 patent claims, Petitioner’s written description arguments substantially overlap [with] its incorrect claim construction and enablement positions” PO Sur-Reply 7 (citing Pet. 39–55). Petitioner asserts that “written description was *never* raised before, much less decided (*Becton, Dickinson* factors (a), (b), (d)).” Reply 5.

We agree with Petitioner that the Examiner never issued a written description rejection during prosecution of the ’450 or ’549 patents. However, we also agree with Patent Owner that many of the issues involved in Petitioner’s claim construction and enablement arguments (which were previously before the Office), overlap with issues Petitioner raises in connection with written description. For example, Petitioner argues that the ’450 patent does not describe or exemplify any iron polyisomaltose complex, nor such a complex that is substantially non-immunogenic and does not cross react with anti-dextran antibodies. Pet. 39. As discussed

supra, a similar argument was made by the Examiner in the enablement rejection of the '549 patent. *See* Ex. 1007, 83. Petitioner also argues that “[t]he '450 patent provides no structural information, physicochemical characteristics, or study data for any iron polyisomaltose complex, let alone a ‘substantially non-immunogenic’ and ‘substantially non-cross-reactive’ one,” similar to arguments made by the Examiner. *Compare* Pet. 40, with Ex. 1007, 82–83. Petitioner also discusses the '450 patent's failure to provide details on how the claimed iron polyisomaltose differs from iron dextran, which was discussed by the Examiner in relation to the indefiniteness rejection during prosecution of the '450 patent. *Compare* Pet. 40–41, with Ex. 1002, 187–189, 206–213, 236–237.

Based on the above, we find that there is substantial overlap between the arguments made in Petitioner's written description analysis and those previously presented to the Office. We address how this finding impacts our overall section 325(d) analysis below.

5. *Jahn*

Ground 4 of the Petition asserts that most of the challenged claims are anticipated by *Jahn*. Pet. 73–86. In grounds 5–8, Petitioner asserts that dependent claims 5, 13, 14, and 17, respectively, are rendered obvious by *Jahn* in combination with one additional reference. *Id.* at 86–94. Although neither party discusses the *Jahn* reference in their section § 325(d) briefing, we note that *Jahn* was before the Examiner during prosecution of the '549 and '450 patents.

As discussed *supra*, *Jahn* was discussed by Patent Owner in response to an enablement rejection in the '549 patent prosecution and the Examiner also discussed *Jahn* in the Reasons for Allowance. *See* Ex. 1007, 99–103,

142. Jahn was also submitted on an Information Disclosure Statement (“IDS”) during prosecution of the ’450 patent, which was considered by the Examiner, and is listed under “References Cited” on the ’450 patent. See Ex. 1001, code (56); Ex. 3002; Ex. 3003. Thus, Jahn previously was presented to the Office.

H. Whether the Office Erred in a Manner Material to Patentability

Because we find that the same or substantially the same art and arguments previously were presented to the Office, we turn to whether Petitioner demonstrates that the Office erred in a manner material to the patentability of the challenged claims. *Advanced Bionics*, Paper 6 at 8, 10; see *Becton, Dickinson*, Paper 8 at 24. As discussed below, we conclude that Petitioner does not demonstrate such an error material to patentability.

1. Claim Construction

Petitioner argues that “even if the Examiner did ‘accept’” Patent Owner’s “lexicographic [re]definition,” of the term “polyisomaltose” to include iron oligoisomaltose, that was an error. Reply 3. Petitioner cites to ten pages of the Petition as evidence of the Examiner’s alleged error. *Id.* at 2 (citing Pet., 31–36, 46–50). The Petition asserts that the Examiner “apparently never considered the key distinction between oligoisomaltoses and polyisomaltoses” and contends that the claims and specification of the ’450 patent distinguish the two. Pet. 35. Specifically, Petitioner asserts that the claims require the use of polyisomaltose rather than oligoisomaltose wherein “poly means ‘many’ and oligo means ‘few.’” *Id.* at 32 (citing Ex. 1102 ¶ 93; Ex. 1015, 3–4)

Petitioner also contends that the specification classifies polysaccharides and oligosaccharides separately, listing “iron

monosaccharide complexes, iron disaccharide complexes, iron *oligosaccharide* complexes, and iron *polysaccharide* complexes” as examples of “commercially available” complexes. Pet. 32–33 (citing Ex. 1001, 10:63–65). According to Petitioner, “when the patent lists the ‘various embodiments’ of the alleged invention, it specifically omits oligosaccharides, mentioning only ‘an iron monosaccharide complex, and iron disaccharide complex, or an iron polysaccharide complex.’” *Id.* at 32–33 (citing Ex. 1001, 3:39–41). Petitioner also cites to extrinsic evidence that purportedly shows that polysaccharides and oligosaccharides are distinct and do not encompass each other. *See id.* at 33–34.

We are not persuaded by Petitioner’s arguments that the Examiner materially erred. There is no indication in the prosecution history that the Examiner misapprehended or overlooked the potential differences between oligoisomaltoses and polyisomaltoses. As discussed *supra*, in responding to an enablement rejection in the ’549 patent prosecution, Patent Owner stated that “[o]ne example of an *iron polyisomaltose complex* is an *iron isomaltoside* (e.g., Monofer[®]), where the carbohydrate component is a pure linear chemical structure of repeating α 1-6 linked glucose units.” Ex. 1007, 99 (emphasis added). The Lawrence Declaration submitted by Patent Owner during the ’549 patent prosecution similarly stated that “[b]ased on my experience, an *iron polyisomaltose* is a type of iron carbohydrate complex that *includes isomaltose units* in the carbohydrate component.” Ex. 1007, 111 (emphasis added). Patent Owner further argued that “[i]t was also understood at the time of filing that *isomaltose oligomers* acted as haptens against circulating anti-dextran antibodies,” which was also supported by the Lawrence Declaration. Ex. 1007, 99, 11–113 (emphasis added). In response

to these arguments, the Examiner withdrew the enablement rejection and stated the following in the Reasons for Allowance:

[Jahn] provides evidence that at the time of the instant invention one of ordinary skill in the art would have been able to select *isomaltose oligomers* to block anaphlaxis to dextrans and that selection of *isomaltose oligomers* that were nonanaphylactogenic and desensitizing in animals sensitized against dextran.

Id. at 142 (italicized emphasis added).

These excerpts from the prosecution history indicate that the Examiner viewed isomaltose oligomers as being encompassed by polyisomaltose, as argued by Patent Owner during prosecution and in the Preliminary Response. *See* Ex. 1007, 99–101, 111–113; Prelim. Resp. 27–34. Petitioner does not present persuasive evidence that there was material error in this interpretation.

Petitioner also argues that the Examiner erred by interpreting “polyisomaltose” to be linear and dextran to be branched and that the Examiner “incorrectly assumed linearity was key, without truly considering it.” Reply 4. As discussed *supra*, the distinction between dextran as being branched and iron polyisomaltose as being linear was discussed by Patent Owner and the Examiner during prosecution. Ex. 1002, 207–213; Ex. 1007, 82, 99–100, 119–113. Therefore, based on the art and arguments presented during prosecution distinguishing dextran from polyisomaltose, the Examiner found “iron polyisomaltose” to be linear. *See, e.g.*, Ex. 1002, 207–213; Ex. 1007, 82, 99–100, 119–113. Petitioner has not persuaded us that there was a material error in the Examiner’s finding.

Petitioner further asserts that the Examiner “never addressed the arguments and evidence” that Petitioner offers here and that “[t]hese errors

support institution.” Reply 4. Petitioner fails to provide a sufficient explanation as to why the additional arguments and evidence warrant reconsideration of this claim construction. Thus, this argument also fails to persuade us that the Office erred in a manner material to patentability.

2. *Enablement*

Petitioner argues that the Examiner was wrong to withdraw the enablement rejection and cites to thirteen pages of its Petition as “explain[ing] this in detail.” Reply 7 (citing Pet., 55–67). The cited pages refer to the enablement rejection in the ’549 patent prosecution in a few places. First, in assessing the second *Wands* factor, Petitioner states that, in response to the enablement rejection, Patent Owner identified two references cited in the specification that could be used to assess hypersensitivity, safety, efficacy, and toxicity. See Pet. 59 (citing Ex. 1007, 101; Ex. 1001, 11:40–45). According to Petitioner, these references illustrate that “determining whether a given complex falls within the claims would require the post-hoc review of years of testing.” *Id.* at 59–60 (citing Ex. 1102 ¶ 123; Ex. 1103 ¶¶ 97–98, 100). However, Petitioner provides no discussion of how the Examiner analyzed these references or why the Examiner materially erred in such consideration.

Similarly, Petitioner references Patent Owner’s identification of Examples 4 and 5 in the specification as relevant working examples in response to the Examiner’s enablement rejection. Pet. 62 (citing Ex. 1007, 102–103). Petitioner contends that these examples, which describe eleven clinical trials in thousands of patients, are evidence of “undue experimentation.” *Id.* Petitioner also contests Patent Owner’s statement that there was an “increased level of predictability in the art” in response to the

enablement rejection. *Id.* at 64. However, again, Petitioner fails to provide any analysis of how the Examiner viewed these arguments or materially erred in such analysis.

Lastly, Petitioner argues that Patent Owner incorrectly relied on post-filing art, Jahn, in responding to the enablement rejection. Pet. 65–67. However, Petitioner fails to show that Patent Owner and the Examiner incorrectly relied on Jahn to show what was known at the time of filing based on Jahn’s retrospective teachings. Specifically, Patent Owner discussed Jahn’s teachings of the ability of isomaltose oligomers to prevent or block anaphylaxis to dextrans and act as haptens against circulating anti-dextran antibodies as described in references from the 1960’s, 1970’s, and 1980’s. *See* Ex. 1007, 99–101, 112 (citing Ex. 1048; Ex. 1034). In response to these arguments, the Examiner withdrew the enablement rejection and cited to Jahn in the Reasons for Allowance as providing evidence that “at the time of the instant invention one of ordinary skill in the art would have been able to select isomaltose oligomers to block anaphylaxis to dextrans.” Ex. 1007, 142. Petitioner does not discuss these statements by Patent Owner or the Examiner and fails to show how the Examiner materially erred in considering this retrospective art.

Petitioner further asserts that they have never before presented their arguments and evidence on enablement (Reply 7); however, this general statement is not enough to show that the Examiner erred in a manner that is material to patentability.

3. *Indefiniteness*

As mentioned *supra*, Petitioner did not make any arguments regarding indefiniteness in its Reply regarding section 325(d). Thus, on this record,

we determine that Petitioner does not demonstrate that the Office erred in a manner material to the patentability of the challenged claims with regard to indefiniteness.

4. Written Description

Petitioner does not present specific arguments as to why the Office materially erred with respect to written description because it argues that written description was never addressed by the Office. Reply 5. As stated above, many of the issues involved in Petitioner's claim construction, enablement, and indefiniteness arguments (which were previously before the Office), overlap with issues raised with respect to written description. For the reasons discussed above, to the extent the issues overlap, we find no material error in the Examiner's analysis.

5. Jahn

As discussed *supra*, Jahn was before the Examiner during prosecution of the '549 and '450 patents. The Examiner clearly considered this reference by discussing it in the Reasons for Allowance of the '549 patent and indicating consideration of it when it was submitted on an IDS during prosecution of the '450 patent. See Ex. 1007, 99–103, 142; Ex. 3003. Despite this consideration, the Examiner did not apply Jahn in any rejections against the claims of the '549 or '450 patents. Ex. 1007, 142.

We note that Petitioner's assertion that Jahn is prior art depends primarily on its arguments that the '450 patent claims lack section 112 support. Pet. 73 (referencing discussion at Pet. 29–31). Petitioner has not persuaded us that the Examiner erred in deciding not to reject the challenged claims over Jahn.

6. *Conclusion as to § 325(d)*

For the reasons set forth above, we do not institute review of claims 1–22 under grounds 2–8 because, under 35 U.S.C. § 325(d), the same or substantially the same prior art and arguments previously were presented to the Office, and Petitioner has not shown that the Office erred in a manner material to patentability.

IV. U.S.C. § 324(a)

Pursuant to 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.” But even when a petitioner demonstrates a reasonable likelihood of prevailing with respect to one or more claims, institution of review remains discretionary. *See SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1356 (2018) (“[Section] 314(a) invests the Director with discretion on the question whether to institute review” (emphasis omitted)); *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016) (“[T]he PTO is permitted, but never compelled, to institute an IPR proceeding.”).

In exercising that discretion, we are guided by the statutory requirement, in promulgating regulations for post-grant review, to consider the effect of any regulations on “the efficient administration of the Office [and] the ability of the Office to timely complete proceedings,” 35 U.S.C. § 326(b), as well as the requirement to construe our rules to “secure the just, speedy, and inexpensive resolution of every proceeding,” 37 C.F.R. § 42.1(b). Office guidance, issued June 5, 2018, also explains that the Board “will evaluate the challenges and determine whether § 325(d) is sufficiently

implicated that its statutory purpose would be undermined by instituting on all challenges” and, if so, “evaluate whether the entire petition should be denied.” SAS Q&A’s, Part D, Effect of SAS on Future Challenges that Could Be Denied for Statutory Reasons (June 5, 2018), *available at* https://www.uspto.gov/sites/default/files/documents/sas_qas_20180605.pdf (answer to Question D1).

Here, as discussed above, we determine that § 325(d) is sufficiently implicated to deny institution of grounds 2–8. The remaining ground, ground 1, asserts that claims 1–22 are unpatentable for lack of written description. As discussed above, many of the issues raised by Petitioner with respect to written description overlap with arguments previously before the Office regarding claim construction, enablement, and indefiniteness.

On this record, and based on the particular facts of this proceeding, instituting a trial with respect to all grounds based on evidence and arguments directed to only one ground, with overlapping issues to those already considered by the Office, would not be an efficient use of the Board’s time and resources. *See, e.g., Deeper, UAB v. Vexilar, Inc.*, IPR2018-01310, Paper 7 at 41–43 (PTAB Jan. 24, 2019) (informative); *Chevron Oronite Co. v. Infineum USA L.P.*, IPR2018-00923, Paper 9 at 10–11 (PTAB Nov. 7, 2018) (informative). Further, we find that § 325(d) is sufficiently implicated by grounds 2–8 that its statutory purpose would be undermined by instituting on all challenges. Thus, we do not institute a post-grant review.

V. CONCLUSION

For the foregoing reasons, we exercise our discretion not to institute post-grant review.

VI. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Petition is *denied* and no post-grant review is instituted.

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