

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DR. REDDY'S LABORATORIES, LTD. and
DR. REDDY'S LABORATORY, INC.,
Petitioner,

v.

HELSINN HEALTHCARE S.A.,
Patent Owner.

Case PGR2016-00008
Patent 9,173,942 B2

Before TONI R. SCHEINER, LORA M. GREEN, and
JACQUELINE WRIGHT BONILLA, *Administrative Patent Judges*.

SCHEINER, *Administrative Patent Judge*.

DECISION
Denying Institution of Post-Grant Review
35 U.S.C. § 324; 37 C.F.R. § 42.208

I. INTRODUCTION

Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "Petitioner" or "DRL") filed a Petition on February 5, 2016 (Paper 2; "Pet.") requesting post-grant review of claims 1–19 of U.S. Patent No. 9,173,942 B2 (Ex. 1001; "the '942 patent"). Helsinn Healthcare S.A. ("Patent Owner" or "Helsinn") filed a Patent Owner Preliminary Response. Paper 9 ("Prelim. Resp.").¹

We have authority to determine whether to institute a post-grant review. 35 U.S.C. § 324(c); 37 C.F.R. § 42.4(a). The standard is set forth in § 324(a), which provides that a post-grant review shall not be instituted unless "the Director determines that the information presented in the petition filed under section 321, 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."

After considering the Petition and the Preliminary Response, we determine that Petitioner has failed to demonstrate that it is more likely than

¹ Helsinn represents that

Roche Palo Alto LLC, which was previously a co-assignee of U.S. Patent No. 9,173,942 . . . and a real party-in-interest in this proceeding, has assigned to Helsinn all right, title, and interest in and to the '942 patent. Accordingly, for purposes of this proceeding, Helsinn is the only remaining real party-in-interest.

Paper 8 (Updated Mandatory Notices, filed May 18, 2016), 2.

not that at least one claim of the '942 patent is unpatentable. Accordingly, we do not institute a post-grant review.

A. Related Proceedings

The '942 patent has been asserted against Petitioner in *Helsinn Healthcare S.A. v. Dr. Reddy's Labs., Ltd.*, Civil Action No. 15-8662 (D.N.J.), filed December 15, 2015. Pet. 2; Paper 7, 2.

In addition, several parents of the '942 patent and other related patents have been asserted by Patent Owner in a number of civil actions. For example, U.S. Patent No. 7,947,724 has been asserted in *Helsinn Healthcare S.A. v. Dr. Reddy's Labs., Ltd.*, Civil Action No. 12-2867 (D.N.J.); and U.S. Patent Nos. 7,947,724, 7,947,725, 8,518,981, 8,598,218, and 8,598,219 have been asserted in *Helsinn Healthcare S.A. v. Dr. Reddy's Labs., Ltd.*, Civil Action Nos. 11-3962, 11-5579, 13-5815 (consolidated) (D.N.J.). See Pet. 2–3; Paper 7, 2–3.

Finally, Petitioner filed concurrently a Petition for post-grant review of claims 1–6, 10, and 11 of the '942 patent, on obviousness grounds. PGR2016-00007.

B. The '942 Patent (Ex. 1001)

The '942 patent is directed to formulations “for the treatment and prevention of emesis using palonosetron,” where the formulations “are shelf stable for periods greater than 24 months at room temperature.” Ex. 1001, 2:65–3:1. According to the specification, “palonosetron can be formulated

in some instances at concentrations of only about $1/10^{th}$ the amount of other previously known compounds for treating emesis, [which] surprisingly allows the use of concentrations of palonosetron far below those that would ordinarily be expected.” *Id.* at 4:54–58.

[I]n one embodiment . . . a pharmaceutically stable solution for preventing or reducing emesis compris[es] a) from about 0.01 mg/mL to about 5 mg/mL palonosetron or a pharmaceutically acceptable salt thereof; and b) a pharmaceutically acceptable carrier. . . . In alternative embodiments, the formulation includes palonosetron or a pharmaceutically acceptable salt thereof in a concentration from about 0.02 mg/mL to about 1.0 mg/mL, from about 0.03 mg/mL to about 0.2 mg/mL, and most optimally about 0.05 mg/mL.²

Id. at 4:58–5:6.

In one particular embodiment the palonosetron is supplied in vials that comprise 5 ml. of solution, which equates to about 0.25 mg of palonosetron at a concentration of about 0.05 mg/ml.

Id. at 5:12–15.

[F]urther . . . by adjusting the formulation’s pH and/or excipient concentrations it is possible to increase the stability of palonosetron formulations. Therefore, in another embodiment, . . . a pharmaceutically stable solution for preventing or reducing emesis compris[es] a) palonosetron or a pharmaceutically active salt thereof; and b) a pharmaceutically acceptable carrier, at a pH from about 4.0 to about 6.0. . . . In alternative embodiments,

² According to the specification of the ’942 patent, “[w]hen concentrations of palonosetron are given herein, the concentration is measured in terms of the weight of the free base. Concentrations of all other ingredients are given based on the weight of ingredient added to the solution.” Ex. 1001, 4:14–18.

the pH is from about 4.5 to about 5.5, and most optimally about 5.0.

Id. at 5:16–30.

[I]n another embodiment . . . a pharmaceutically stable solution of palonosetron compris[es] . . . from about 0.01 to about 5.0 mg/ml palonosetron or a pharmaceutically acceptable salt thereof and (i) from about 10 to about 100 millimoles citrate buffer, and/or (ii) from about 0.005 to about 1.0 mg/ml EDTA.

Id. at 5:40–46.

[I]n another embodiment . . . a pharmaceutically stable solution of palonosetron compris[es] . . . a) palonosetron or a pharmaceutically acceptable salt thereof and b) a pharmaceutically acceptable carrier . . . compris[ing] a chelating agent and mannitol. . . . In various embodiments the mannitol is present in a concentration of from about 10.0 mg/ml to about 80 mg/ml, from about 20 mg/mL to about 60.0 mg/ml, or from about 40.0 to about 45.0 mg/ml.

Id. at 6:4–18.

Finally, the specification teaches that “palonosetron concentration was also a critical factor in chemical stability, with greatest stability seen at the lowest palonosetron concentrations.” *Id.* at 7:40–43.

C. Illustrative Claim

Of the challenged claims, claims 1 and 12 are independent. Claim 1, reproduced below, is illustrative.

1. A formulation comprising a pharmaceutical sterile aqueous intravenous solution, wherein said pharmaceutical sterile aqueous intravenous solution comprises:

palonosetron hydrochloride or another pharmaceutically acceptable salt of palonosetron at a concentration of 0.05 mg/mL based on the weight of the palonosetron free base; and from 10 mg/mL to 80 mg/mL mannitol;
wherein the pharmaceutical sterile aqueous intravenous solution has a pH of 4.0 to 6.0.

D. The Asserted Grounds of Unpatentability

Petitioner asserts the challenged claims are unpatentable on the following grounds. Pet. 24–61.³

Basis	Claims Challenged
§ 112(a) Written Description	1–19
§ 102(a)(1) On-Sale Bar	1–19

II. ANALYSIS

A. Eligibility for Post-Grant Review

The post-grant review provisions set forth in Section 6(d) of the AIA⁴ apply only to patents subject to the first-inventor-to-file provisions of the AIA. *See* AIA § 6(f)(2)(A) (“The amendments made by subsection (d) . . . shall apply only to patents described in section 3(n)(1).”). Transitional provision AIA section 3(n)(1) is as follows:

³ Petitioner also relies on the Declaration of Dr. Christopher Fausel (Ex. 1038).

⁴ Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (“AIA”).

(n) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as otherwise provided in this section, the amendments made by this section shall take effect upon the expiration of the 18-month period beginning on the date of the enactment of this Act, and shall apply to any application for patent, and to any patent issuing thereon, that contains or contained at any time—

(A) a claim to a claimed invention that has an effective filing date as defined in section 100(i) of title 35, United States Code, that is on or after the [March 16, 2013] effective date . . . ; or

(B) a specific reference under section 120, 121, or 365(c) of title 35, United States Code, to any patent or application that contains or contained at any time such a claim.

AIA § 3(n)(1), 125 Stat. 293.

The term “effective filing date” for a claimed invention in a patent or application for patent means “the filing date of the earliest application for which the patent is entitled, as to such invention, to a right of priority under section 119, 365(a), or 365(b) or to the benefit of an earlier filing date under section 120, 121, or 365(c).” 35 U.S.C. § 100(i)(1); *see also* AIA § 3(a), 125 Stat. at 285 (amending 35 U.S.C. § 100).

Entitlement to the benefit of an earlier date under §§ 119, 120, 121, and 365 is premised on disclosure of the claimed invention in the manner provided by § 112(a)⁵ (other than the requirement to disclose the best mode)

⁵ Section 4(c) of the AIA redesignated 35 U.S.C. § 112 ¶ 1 as 35 U.S.C. § 112(a). 125 Stat. at 296.

in the application for which the benefit of the earlier filing date is sought.
See 35 U.S.C. §§ 119(e), 120.

The '942 patent issued on November 3, 2015, from U.S. Application No. 13/901,830 (“the '830 application”), filed on May 24, 2013. Ex. 1001, [21], [22], [45]. The '942 patent is a continuation of U.S. Application No. 13/901,437 (“the '437 application”), filed on May 23, 2013, now U.S. Patent No. 8,598,219 (“the '219 patent”). *Id.* at [63]. The '437 application, in turn, is a continuation-in-part of U.S. Application No. 13/087,012, filed on April 14, 2011, now U.S. Patent No. 8,518, 981.⁶ *Id.* Petitioner contends that claim 9 of the '437 application had support only in newly added Example 8 of the '437 application—i.e., claim 9 of the '437 application was not disclosed in the manner provided by § 112(a) prior to May 23, 2013. Pet. 4–6. The record appears to support Petitioner’s contention, and Patent Owner does not dispute that the effective filing date of claim 9 of the '437 application is no earlier than May 23, 2013. *See* Ex. 1002 (Prosecution History of the '830 application), 154–156 (Applicants of the '942 patent discussing the AIA status of the '830 and '437 applications.). Under the provisions of AIA sections 3(n)(1)(A) and (B), then, both the '219 patent

⁶ In addition, U.S. Application No. 13/087,012 is a continuation of U.S. Application No. 11/186,311, filed on July 21, 2005, now U.S. patent No. 7,947,724, which is a continuation of Application No. PCT/EP2004/000888, filed on January 30, 2004. Finally, Provisional Application No. 60/444,351 was filed on January 30, 2003. Ex. 1001, [63], [64].

and the '942 patent (which claims benefit to the '219 patent) are AIA first-inventor-to-file patents.

An additional requirement for post-grant review eligibility is that “[a] petition for a post-grant review may only be filed not later than the date that is 9 months after the date of the grant of the patent.” 35 U.S.C. § 321(c); see 37 C.F.R. § 42.202(a).

The Petition was filed on February 5, 2016 (Paper 4, 1), within nine months of the grant of the '942 patent. See 35 U.S.C. § 321(c). Petitioner further certifies that it has standing to seek a post-grant review of the '942 patent. Pet. 4.

Accordingly, on this record, we determine that the '942 patent is an AIA first-inventor-to-file patent and is eligible for post-grant review.

B. Claim Construction

In a post-grant review, the claims of an unexpired patent are interpreted using the broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.200(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). Under that standard, claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

We determine that no claim term requires express construction for purposes of deciding whether to institute a review in this case. See, e.g.,

Wellman, Inc. v. Eastman Chem. Co., 642 F.3d 1355, 1361 (Fed. Cir. 2011) (“[C]laim terms need only be construed ‘to the extent necessary to resolve the controversy.’”) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

*C. Claims 1–19—Asserted Unpatentability under the
Written Description Provision of 35 U.S.C. § 112(a)*

1. Analysis

Petitioner contends that “the broadly drafted claims of the ’942 Patent are not fully supported by the narrow specification,” because the specification “repeatedly and emphatically states that the invention is directed to *stable* formulations and methods, [yet] the inventors have procured claims that have no requirement of stability whatsoever.” Pet. 27 (citing Ex. 1038 ¶¶ 22, 24). According to Petitioner, “[t]his is a classic violation of the written description requirement of 35 U.S.C. § 112(a).” *Id.* at 26.

Patent Owner contends that an objective of the ’942 patent “was to provide a formulation of Palonosetron hydrochloride with increased pharmaceutical stability for preventing and/or reducing emesis,” and that the specification discloses the ingredients of formulations—as well as the amounts, concentrations, and combinations of the ingredients—that achieve this two-part objective. Patent Owner contends that these are the same ingredients required by the challenged claims, in the same amounts, concentrations, and combinations. Prelim. Resp. 21–22 (citing Ex. 1001,

2:50–52). For example, the formulation of claim 1 comprises palonosetron hydrochloride at a concentration of 0.05 mg/mL and 10–80 mg/mL mannitol, and has a pH of 4.0–6.0. Claim 2, which depends from claim 1, requires palonosetron hydrochloride in an amount of 0.25 mg. Patent Owner points out that the specification identifies “the optimal palonosetron concentration to be 0.05 mg/mL . . . and disclose[s] a vial with 0.25 mg of palonosetron in 5 mL of solution (*i.e.*, a 0.05 mg/mL concentration) as ‘one particular embodiment’ of the invention.” Prelim. Resp. 22 (citing Ex. 1001, 5:1–6, 12–15). Similarly, Patent Owner points out that the specification discloses that it is possible to increase the stability of a palonosetron formulation by adjusting the formulation’s pH and/or excipient concentrations, and the specification discloses that the preferred pH of the formulation is from about 4.0 to about 6.0, and the preferred concentration of mannitol is from about 10.0 mg/mL to about 80 mg/mL. *Id.* at 24 (citing Ex. 1001, 3:16–18, 5:19–23, 6:14–16, Example 3).⁷ Patent Owner contends “because the ’942 patent claims are directed to these ingredients in amounts described as optimal, they are fully supported by the written description.” *Id.* at 21.

The written description requirement is satisfied when the specification “set[s] forth enough detail to allow a person of ordinary skill in the art to understand what is claimed and to recognize that the inventor invented what

⁷ Patent Owner additionally provides Appendix A to the Preliminary Response. Appendix A purportedly maps the requirements of claims 1–19 to the specification.

is claimed.” *University of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916, 928 (Fed. Cir. 2004). Here, it is undisputed that the specification describes formulations comprising the same ingredients, in the same amounts, concentrations, and combinations required by the challenged claims. Given this disclosure, one of ordinary skill in the art could hardly fail to recognize a description of the claimed formulations in the specification, whether or not the claims recite that the formulations are stable.

We are not persuaded otherwise by Petitioner’s reliance on *Cooper Cameron Corp. v. Kvaerner Oilfield Products, Inc.*, 291 F.3d 1317, 1323 (Fed. Cir. 2002) for the proposition that “[a] ‘broad claim is invalid when the entirety of the specification clearly indicates that the invention is of a much narrower scope.’” Pet. 24. The *Cooper Cameron* court, in elucidating an earlier decision in *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473 (Fed. Cir. 1998), made clear that the statement quoted by Petitioner was made in the context of the location of a structural element—i.e., controls for a recliner—where “[t]here was no description or support whatever in the *Gentry* patent of the controls being other than on the console.” *Cooper Cameron*, 291 F.3d at 1323. That circumstance is not relevant here, where the specification describes formulations comprising the same ingredients, in the same amounts and concentrations, required by the challenged claims.

Nor are we persuaded by Petitioner’s contention that the inventors of the ’942 patent have engaged in “the very type of ‘overreaching’ that the

Federal Circuit warned against” in *University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916 (Fed. Cir. 2004). Pet. 27. In that case, the court reiterated that “the purpose of the written description requirement is to ‘ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor’s contribution to the field of art as described in the patent specification.’” *University of Rochester*, 358 F.3d at 920 (quoting *Reiffin v. Microsoft Corp.*, 214 F.3d 1342 (Fed. Cir. 2000)). The claims at issue in *University of Rochester*, however, all required a COX-2 selective compound, but no COX-2 selective compound was disclosed in the patent. *Id.* at 930. Moreover, it was undisputed that there was no pre-existing awareness in the art of any compound having COX-2 selective activity. *Id.* Here, again, that lack of disclosure is not relevant because the specification describes formulations comprising the same ingredients, in the same amounts and concentrations, required by the challenged claims—and moreover, describes them as optimal or preferred for stability.

Accordingly, we determine that Petitioner has failed to show that it is more likely than not that claims 1–19 are unpatentable for failure to meet the written description requirement of 35 U.S.C. § 112(a).

*D. Claims 1–19—Asserted Unpatentability under
35 U.S.C. § 102(a)(1), On-Sale Bar*

1. Analysis

Petitioner contends that claims 1–19 are “invalid by virtue of an on-sale bar” under 35 U.S.C. § 102(a)(1). Pet. 8. According to Petitioner,

“[t]o bar patentability under the on-sale provision § 102(a)(1), the claimed invention must be sold or be the subject of a commercial offer for sale, and be ready for patenting more than one year prior to the earliest effective filing date, which in this case, is January 30, 2003.”⁸ *Id.* at 9, 32 (citing *Pfaff v. Wells Elec., Inc.* 525 U.S. 55, 67 (1998) (holding that the on-sale bar applies when two conditions are satisfied before the critical date: “the product must be the subject of a commercial offer for sale” and “the invention must be ready for patenting”)). Petitioner contends that “those conditions are satisfied here.” *Id.*

Specifically, Petitioner contends that Patent Owner’s subsidiary, Helsinn Birex Pharmaceuticals Ltd. (“HBP”), entered into a Supply and Purchase Agreement with MGI Pharma, Inc. (“MGI”). Pet. 30 (citing Ex. 1042 (“Supply Agreement”)). According to Petitioner, the Supply Agreement required MGI to purchase exclusively from HBP, and HBP to sell to MGI, MGI’s entire requirements of “Products,” where those Products were defined as:

[P]harmaceutical preparations for human use in I.V. dosage form containing the Compound . . . in the formulation that will be described in the Registration. The current formulation as submitted to the Food and Drug Administration of the United States of America in the IND 39,797 Amendment # 64 . . . is described in the First Appendix hereto.

⁸ See *supra* page 8, note 6.

Id. at 30–31 (citing Ex. 1042, Art. 1.9). The “Compound” was identified as palonosetron hydrochloride. *Id.* at 31 (citing Ex. 1042, Art. 1.3).

Petitioner contends that Patent Owner additionally “entered into a License and Distribution Agreement (‘License Agreement’) with MGI for exclusive rights in the United States and Canada for the sale of palonosetron formulations, which included the same ‘requirements’ contract terms” and “[i]n return, Patent Owner received a total of \$11 million upon the signing of the License Agreement and a previous letter of intent, with additional payments promised at later milestones.” Pet. 31 (citing Ex. 1043, Art. 2.5).

Petitioner contends that “[r]edacted versions” of both the Supply Agreement and the License Agreement “were made publicly available through MGI’s Form 8-K SEC Filings submitted on April 25, 2001.” *Id.* at 31 (citing Ex. 1044). In addition, Petitioner contends that “the Supply Agreement . . . was clearly and deliberately made public through . . . press releases prior to the critical date.” *Id.* at 32 (citing Ex. 1047).

Petitioner argues, in any case, “[u]nder longstanding law, the on-sale bar applies not only to . . . ‘public’ sales, but also to ‘private’ sales made before the critical date.” *Id.* at 39 (citing *Woodland Trust v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1370 (Fed. Cir. 2002)). Petitioner contends that “[t]he AIA did not change this.” *Id.* Moreover, Petitioner contends that even if the on-sale bar is triggered only by public sales, “the Supply Agreement would remain proof of invalidating on-sale activity under 35

U.S.C. § 102[(a)(1)], because MGI was a member of the public and the agreement was publicly disclosed.” Pet. 39.

Patent Owner contends that “[t]he AIA effected sweeping changes to the patent laws” and the plain language and legislative history of 35 U.S.C. § 102(a)(1) confirm that “a confidential offer for sale no longer qualifies as a potentially invalidating activity; an offer for sale must have made the claimed invention ‘available to the public.’” Prelim. Resp. 33.

Patent Owner acknowledges that it entered into the aforementioned Supply and License Agreements with MGI.⁹ *Id.* at 10. Patent Owner contends however, that “[t]he License and MGI Agreements both contained strict confidentiality provisions” and “MGI was . . . obliged to ‘treat as strictly confidential, and use solely for the purpose of and in accordance with this Agreement, the Know-how, Improvements and/or any information and/or document received hereunder. . . .’” *Id.* at 11–12 (citing Ex. 1042, Art. 9.1; Ex. 1043, Art. 14.1). Patent Owner contends that the SEC Form 8-K filings relied on by Petitioner were “heavily redacted and did not disclose any relevant formulation information, such as the palonosetron dose, concentration, or any excipients.”¹⁰ *Id.* at 50; *see* Ex. 1044. Patent Owner

⁹ The “Supply Agreement” discussed by Petitioner is the same as the “MGI Agreement” discussed by Patent Owner.

¹⁰ We note that the press release relied on by Petitioner (Pet. 32) announces a “definitive agreement granting MGI PHARMA exclusive North American license and distribution rights to palonosetron,” but is similarly devoid of detail. *See* Ex. 1047.

contends, “[s]ince the MGI Agreement did not make the claimed invention ‘available to the public,’ as required by AIA § 102(a)(1), the ’942 patent claims are not unpatentable under the on-sale bar.” Prelim. Resp. 34.

Thus, the facts surrounding the MGI agreements are undisputed, but Petitioner and Patent Owner disagree on the applicability of the post-AIA on-sale bar to those facts.

Before the AIA was signed into law, § 102 of the Patent Act provided, in relevant part, that:

A person shall be entitled to a patent unless . . . (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States

35 U.S.C. § 102, *amended by* 125 Stat. at 285–86.

The Court of Appeals for the Federal Circuit has held that commercial sales, even if confidential, trigger the on-sale bar under the pre-AIA § 102. *See, e.g., Medicines Co. v. Hospira, Inc.*, 2016 WL 3670000, at *10 (Fed. Cir. 2016) (*en banc*) (“[T]he confidential nature of the transactions is a factor which weighs against the conclusion that the transactions were commercial in nature. Again, this factor is not disqualifying in all instances Indeed, we, and our predecessors, have found confidential transactions to be patent invalidating sales under § 102(b).”); *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353, 1357–58 (Fed. Cir. 2001) (in finding that on-sale

bar invalidated patent claims, stating that the on-sale bar applies to “sales for the purpose of the commercial stockpiling of an invention, even if they took place in secret”); *Woodland Trust*, 148 F.3d at 1370 (“Thus an inventor’s own prior commercial use, albeit kept secret, may constitute a public use or sale under § 102(b), barring him from obtaining a patent.”).

The AIA enlarged the scope of prior art under § 102 with respect to territory, and also added the clause “otherwise available to the public.” In relevant part, § 102(a)(1) provides:

A person shall be entitled to a patent unless—(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention

As an AIA first-inventor-to-file patent, the ’942 patent is subject to AIA § 102(a)(1). Thus, the dispositive issue in this case is whether § 102(a)(1) requires a public sale or offer for sale of the claimed invention to trigger the on-sale bar.

This issue was recently addressed in *Helsinn Healthcare S.A. v. Dr. Reddy’s Labs., Ltd.*, No. 11–3962, 2016 WL 832089, at *39 (D.N.J. March 3, 2016), a case involving three pre-AIA patents, and one AIA first-inventor-to-file patent—specifically U.S. Patent No. 8,598,219, the immediate parent of the ’942 patent. The parties in that case, as in this case, disagreed as to “whether the last clause of § 102(a)(1), ‘otherwise available to the public,’ modifies the section’s previous clauses or serves as its own category of prior art.” *Helsinn Healthcare*, 2016 WL 832089, at *40.

The court in *Helsinn Healthcare*, guided at least in part “by the Supreme Court’s ‘common sense’ approach to statutory interpretation,” the USPTO’s non-binding published “Examination Guidelines for Implementing the First Inventor to File Provisions of the [AIA],” and the legislative history of the AIA, determined that the phrase “otherwise available to the public” does indeed modify the section’s previous clauses. *Id.* at *40–*44, *51 n.52. Specifically, the court concluded “that § 102(a)(1) requires a public sale or offer for sale of the claimed invention” and “[t]he new requirement that the on-sale bar apply to public sales comports with the plain language meaning of the amended section, the USPTO’s interpretation of the amendment, and the legislative history of the AIA.” *Id.* at *45. Moreover, the court emphasized that “the post-AIA on-sale bar inquiry is not focused on the public disclosure of the sale or offer for sale; rather, the ‘sale’ prong of the on-sale bar requires that the sale make the claimed invention available to the public one year prior to its critical date.” *Id.* at *52.

Having considered the parties’ arguments in this case, which are essentially the same as those in *Helsinn Healthcare*, we reach the same conclusion. That is, we agree with the district court that § 102(a)(1) requires a public sale or offer for sale of the claimed invention, and that the post-AIA on-sale bar inquiry is not focused merely on the public disclosure of the existence of a sale or offer for sale; rather, the sale must make the claimed invention available to the public in order to trigger the on-sale bar.

Here, as in *Helsinn Healthcare*, Petitioner has established that MGI's Form 8-K SEC filings and Helsinn's press releases made public the existence of the Supply and Licensing Agreements, but Petitioner has not shown that the heavily redacted SEC filings or the press releases, devoid of detail, made the claimed invention available to the public. Thus, we determine that the Supply and Licensing Agreements did not make the claimed invention available to the public one year prior to the critical date at issue here.¹¹

Accordingly, we determine that Petitioner has failed to show that it is more likely than not that claims 1–19 are in violation of the on-sale bar under 35 U.S.C. § 102(a)(1).

III. CONCLUSION

For the foregoing reasons, we determine that Petitioner has not established that it is more likely than not that claims 1–19 of U.S. Patent No. 9,173,942 are unpatentable.

IV. ORDER

It is hereby

ORDERED that the Petition is denied, and no trial is instituted.

¹¹ As we have determined that the Supply and Licensing Agreements did not make the claimed invention available to the public one year prior to the critical date, we need not determine whether the Agreements satisfied the “commercial sale” and “ready for patenting” prongs of the on-sale bar.

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