Supreme Court to Review *Helsinn Healthcare*: Confidential Sale as Prior Art

On June 25, 2018, the Supreme Court granted certiorari in *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc*., No. 17-1229, *proceedings below,* 855 F.3d 1356 (Fed. Cir. 2017), to determine whether a *confidential* sale triggers the 35 USC § 102(b) "on sale" patentability bar.

***Question Presented*:** "Whether, under the Leahy-Smith America Invents Act, an inventor's sale of an invention to a third party that is obligated to keep the invention confidential qualifies as prior art for purposes of determining the patentability of the invention."

Merits Decision by the End of June 2019: The case will be argued in the October 2018 Term that runs from that month through the end of June 2019, with argument and merits decision expected before the end of June 2019.

Naples Roundtable Involvement: The Naples Roundtable, Inc., has participated as an *amicus curiae* in this case; therefore, no editorial comment will be provided with this note.

The Federal Circuit opinion in this case is reproduced below.

Regards,

Hal

Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.,
855 F.3d 1356 (Fed. Cir. 2017)(Dyk, J.)
on appeal to the Supreme Court
[turquoise emphasis added]

Dyk, Circuit Judge.

* * *

Helsinn brought suit against Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd. (collectively, "Teva") alleging that the filing of Teva's Abbreviated New Drug Application ("ANDA") constituted an infringement of various claims of those patents. Teva defended, inter alia, on the ground that the asserted claims were invalid under the on-sale bar provision of 35 U.S.C. § 102. The district court found that the patents-in-suit were not invalid.

With respect to three of the patents, which are governed by the pre-Leahy-Smith America Invents Act ("pre-AIA") version of § 102, the district court concluded that there was a commercial offer for sale before the critical date, but that the invention was not ready for patenting before the critical date. With respect to the fourth patent, which is governed by the AIA version of § 102, Pub. L. No. 112-29, § 3(b), 125 Stat. 284, 285–86 (2011), the district court concluded that there was no commercial offer for sale because the AIA changed the relevant standard and that, in any event, the invention was not ready for patenting before the critical date.

We reverse. The asserted claims of the patents-in-suit were subject to an invalidating contract for sale prior to the critical date of January 30, 2002, and the AIA did not change the statutory meaning of "on sale" in the circumstances involved here. The asserted claims were also ready for patenting prior to the critical date.

Background

Helsinn owns four patents, U.S. Patent Nos. 7,947,724 ("'724 patent"), 7,947,725 ("'725 patent"), 7,960,424 ("'424 patent"), and 8,598,219 ("'219 patent") (collectively, "the patents-in-suit"), directed to reducing the likelihood of CINV. CINV is a serious side effect of chemotherapy treatment.

The use of palonosetron to treat CINV was not new. Indeed, U.S. Patent No. 5,202,333 ("'333 patent") taught that an intravenous formulation of palonosetron is "useful in the prevention and treatment of emesis," '333 patent, col. 9 ll. 56–57, including "emesis induced by ... treatment for cancer with ... chemotherapy," id. col. 10 ll. 7–9. The '333 patent is now expired. The patents-in-suit purport to disclose novel intravenous formulations using unexpectedly low concentrations of palonosetron that were not taught by the prior art. All four of the patents-in-suit claim priority to a provisional patent application filed on January 30, 2003. The critical date for the on-sale bar is one year earlier, January 30, 2002. The significance of the critical date is that a sale of the invention before that date can be invalidating.

Helsinn alleged infringement of claims 2 and 9 of the '724 patent, claim 2 of the '725 patent, claim 6 of the '424 patent, and claims 1, 2, and 6 of the '219 patent (collectively, "the asserted claims"). Claim 2 of the '725 patent is representative of the asserted claims of the '724, '725, and '424 patents.

2. A pharmaceutically stable solution for reducing emesis or reducing the likelihood of emesis comprising:

a) 0.05 mg/mL palonosetron hydrochloride, based on the weight of the free base, in a sterile injectable aqueous carrier at a pH of from 4.5 to 5.5;

*1361 b) from 0.005 mg/mL to 1.0 mg/mL EDTA; and

c) mannitol in an amount sufficient to tonicify said solution, in a concentration of from about 10 mg/ml to about 80 mg/ml

'725 patent, col. 10 ll. 11–19.

Claim 1 is representative of the asserted claims of the '219 patent.

1. A pharmaceutical single-use, unit-dose formulation for intravenous administration to a human to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting, comprising a 5 mL sterile aqueous isotonic solution, said solution comprising:

palonosetron hydrochloride in an amount of 0.25 mg based on the weight of its free base;

from 0.005 mg/mL to 1.0 mg/mL EDTA; and

from 10 mg/mL to about 80 mg/mL mannitol,

wherein said formulation is stable at 24 months when stored at room temperature.

'219 patent, col. 10 ll. 2–12. The claims of the patents-in-suit to some extent all express the same concepts in different terms. For instance, the '724, '725, and '424 patents claim a 0.05 mg/ml concentration of palonosetron, which equates to a total dose of 0.25 mg when administered in a 5 ml solution. The '219 patent expressly claims a fixed dose of 0.25 mg of palonosetron in a 5 ml solution. It is undisputed that each asserted claim covers the 0.25 mg dose of palonosetron. In order to simplify the relevant discussion, we refer to the patents as covering the 0.25 mg dose.

In 1998, Helsinn acquired a license under the '333 patent from Roche Palo Alto LLC ("Roche") to palonosetron and all intellectual property resulting from ongoing palonosetron research. Roche and its predecessor, Syntex (U.S.A.) Inc. ("Syntex"), had already conducted Phase I and Phase II clinical trials. A Phase II trial—Study 2330—found that the 0.25 mg dose "was effective in suppressing chemotherapy-induced emesis for 24 hours." J.A. 32, 1636. Helsinn then submitted safety and efficacy protocols for Phase III clinical trials to FDA in early 2000, proposing to study two dosages—0.25 mg and 0.75 mg. By early 2001 the Phase III trials were ongoing but not yet completed.

On April 6, 2001, almost two years before applying for a patent, Helsinn and MGI Pharma, Inc. ("MGI"), an oncology-focused pharmaceutical company that markets and distributes in the United States, entered into two agreements: (1) a License Agreement and (2) a Supply and Purchase Agreement. These agreements were announced in a joint press release of the two corporations and in MGI's Form 8-K filing with the Securities and Exchange Commission ("SEC"), which included partially-redacted copies of both agreements. See MGI Pharma Inc., Current Report (Form 8-K) Ex. 99.1 (Apr. 25, 2001) [hereinafter License Agreement]; MGI Pharma Inc., Current Report (Form 8-K) Ex. 99.2 (Apr. 25, 2001) [hereinafter Supply and Purchase Agreement].

Under the terms of the License Agreement, MGI agreed to pay $11 million in initial payments to Helsinn, plus additional future royalties on distribution of "products" in the United States. The parties agree that the "products" covered by the License Agreement were 0.25 mg and 0.75 mg doses of palonosetron.

Under the Supply and Purchase Agreement, MGI agreed to purchase exclusively from Helsinn, and Helsinn agreed to supply MGI's requirements of the 0.25 mg and 0.75 mg palonosetron products, or whichever of the two dosages were approved for sale by FDA. The agreement required MGI to submit purchase forecasts to Helsinn and to place firm orders at least 90 days before delivery. It also specified that such orders would be "subject to written acceptance and confirmation by [Helsinn] before becoming binding." Supply and Purchase Agreement, supra, art. 4.2. But, in the event that Helsinn were unable to meet MGI's firm orders and to the extent they fell within the previously forecasted amount, Helsinn would then be obligated to designate a third party manufacturer to supply MGI with the product. The agreement specified price (29% of the gross sales price by MGI with a minimum of $28.50 per vial), method of payment (wire

transfer within 30 days of receipt of an invoice), and method of delivery (DDU—which means delivery duty unpaid). See Black's Law Dictionary 481, 521 (10th ed. 2014) (defining "DDU" and "delivery duty unpaid").

The License Agreement made reference to the ongoing clinical trials and stated that in the event that the results were unfavorable and FDA did not approve the sale of either dosage of the product, Helsinn could terminate the agreement. If the License Agreement were terminated, the Supply and Purchase Agreement would "terminate automatically." Supply and Purchase Agreement, supra, art. 11.1.

All of the above information about the transaction was publicly disclosed with two exceptions. The two features of the agreements that were not publicly disclosed were the price terms and the specific dosage formulations covered by the agreements—that is the 0.25 and 0.75 mg doses.

Helsinn admitted at oral argument that the agreement was binding as of its effective date, April 6, 2001, and that it would cover either or both of the 0.25 and 0.75 mg doses, subject to FDA approval. Helsinn also agreed that, if the Phase III trials were successful and the products were approved by FDA, then the agreement obligated MGI to purchase and Helsinn to supply the approved doses. But if FDA did not approve either dose, then the agreement likewise would terminate automatically with the License Agreement. As Helsinn stated, in such a scenario "both parties [could] accept that fact and walk away."2 Oral Arg. at 36:37–40, http://oralarguments.cafc.uscourts.gov/default.aspx?fl=2016-1284.mp3.

After the signing of the agreements, and still before the critical date, Helsinn prepared preliminary statistical analysis of the earliest Phase III trial on January 7, 2002. The data showed that 81% of patients who received the 0.25 mg dose of palonosetron experienced relief from CINV for 24 hours. After the critical date of January 30, 2002, Helsinn submitted its preliminary Phase III data to FDA in early February. In September 2002, after the successful completion of all Phase III trials, Helsinn filed its New Drug Application for the 0.25 mg dose, but did not seek FDA approval of the 0.75 mg dose. On January 30, 2003, Helsinn filed a provisional patent application covering the 0.25 mg dose (and also the 0.75 mg dose). FDA issued approval for the 0.25 dose on July 2003. From 2005 to 2006, Helsinn filed three patent applications and these issued as the '724, '725, and '424 patents. In May 2013, after the effective date of the AIA, Helsinn filed a fourth patent application which issued as the '219 patent. All four patents cover the 0.25 mg

dose, are listed in FDA's "Orange Book," and claim priority to the January 30, 2003 date of the provisional application.

In 2011, Teva filed an ANDA seeking FDA approval to market a generic 0.25 mg palonosetron product.3 Teva's ANDA filing included a Paragraph IV certification that the claims of the patents-in-suit were invalid and/or not infringed. Helsinn then brought suit under the Hatch–Waxman Act, 35 U.S.C. § 271(e)(2)(A), alleging infringement of the patents-in-suit by the ANDA filing.

The district court held a bench trial. The district court held that Teva's 0.25 mg dose infringed all of the patents-in-suit. In addressing the on-sale issue, the court applied the two-step framework of Pfaff v. Wells Electronics, Inc., 525 U.S. 55, 119 S.Ct. 304, 142 L.Ed.2d 261 (1998), which requires that there was a sale or offer for sale and that the claimed invention was ready for patenting for the on-sale bar under 35 U.S.C. § 102 to apply. As to the '724, '725, and '424 patents, the court found that pre-AIA law applied under § 102(b) and that the MGI Supply and Purchase Agreement was a contract for a future sale of a commercial product embodying the 0.25 mg dose and therefore constituted a sale under § 102(b). But, the court found that the claimed invention was not reduced to practice before the critical date of January 30, 2002, and therefore was not ready for patenting under the second prong of Pfaff. The district court did not address whether the invention was ready for patenting on the alternative theory that Teva had shown that the inventor had created enabling descriptions before the critical date. See Pfaff, 525 U.S. at 67–68, 119 S.Ct. 304.

As to the '219 patent governed by the AIA, the court held that the AIA changed the meaning of the on-sale bar and § 102(a)(1) now "requires a public sale or offer for sale of the claimed invention." J.A. 113 (emphasis added [by the Court omitted]). The court concluded that, to be "public" under the AIA, a sale must publicly disclose the details of the invention. The court found that the MGI Supply and Purchase Agreement did not constitute a public sale or commercial offer for sale because, although it disclosed the sale agreement and substance of the transaction, it failed to publicly disclose the 0.25 mg dose. The '219 patent also was not ready for patenting before the critical date. Therefore, the district court found that the asserted claims of the four patents were not invalid.

Teva appeals. We have jurisdiction under 28 U.S.C. § 1295(a).

Discussion

Application of the on-sale bar under 35 U.S.C. § 102 is ultimately a question of law that we review de novo. *Robotic Vision Sys., Inc. v. View Eng'g, Inc*., 249 F.3d 1307, 1310 (Fed. Cir. 2001). The factual findings underlying the district court's conclusion are reviewed for clear error. Id. Under *Pfaff*, application of the on-sale bar requires that (1) "the product must be the subject of a commercial offer for sale" and (2) "the invention must be ready for patenting." 525 U.S. at 67, 119 S.Ct. 304.

I

We first address whether the invention of the '724, '725, and '424 patents was subject to a sale or offer for sale prior to the critical date. We recently had occasion to address the pre-AIA on-sale bar en banc in *Medicines Co. v. Hospira, Inc.*, 827 F.3d 1363 (Fed. Cir. 2016). There we established a framework for determining whether there is an offer for sale. We explained that the question must be "analyzed under the law of contracts as generally understood" and "must focus on those activities that would be understood to be commercial sales and offers for sale 'in the commercial community.' " Id. at 1373 (quoting G*rp. One, Ltd. v. Hallmark Cards, Inc.*, 254 F.3d 1041, 1047 (Fed. Cir. 2001)). While acknowledging that it is not of "talismanic significance" to our inquiry, "[a]s a general proposition, we will look to the Uniform Commercial Code ('UCC') to define whether ... a communication or series of communications rises to the level of a commercial offer for sale." 827 F.3d at 1373 (alteration in original) (quoting Grp. One, 254 F.3d at 1047). A sale occurs when there is a "contract between parties to give and to pass rights of property for consideration which the buyer pays or promises to pay the seller for the thing bought or sold." *Trading Techs. Int'l, Inc. v. eSpeed, Inc*., 595 F.3d 1340, 1361 (Fed. Cir. 2010) (internal quotation marks omitted).

In *Medicines* we also pointed to other factors that are important to this analysis, but noted that, like the UCC itself, none is determinative individually. We noted that the absence of the passage of title, the confidential nature of a transaction, and the absence of commercial marketing of the invention all counsel against applying the on-sale bar. Id. at 1375–76.

We deemed these factors important because they helped shed light on whether a transaction would be understood "in the commercial community" to constitute a commercial offer for sale. Id. at 1373 (quoting Grp. One, 254 F.3d at 1047). But those additional factors are not at issue in this case. There is no suggestion that the Supply and Purchase Agreement did not involve transfer of title; it expressly contemplated it. And, while certain details were redacted from the publicly disclosed copy of the Supply and Purchase Agreement, Helsinn does not argue that the transaction itself between Helsinn and MGI remained confidential. Helsinn also commercially marketed its invention before the critical date. It publicly sought "marketing partners for its patented [palonosetron] product," J.A. 63–64 n.26, and ultimately contracted with MGI "to distribute, promote, market, and sell" the claimed invention, J.A. 2255.

We agree with the district court that there was a sale for purposes of pre-AIA § 102(b) prior to the critical date because there was a sale of the invention under the law of contracts as generally understood.

Helsinn admits that the Supply and Purchase Agreement was binding as of its effective date, April 6, 2001, and that, if FDA approved the 0.25 mg dose and/or the 0.75 mg dose of palonosetron, the agreement obligated Helsinn to sell and MGI to purchase those products. The Supply and Purchase Agreement bears all the hallmarks of a commercial contract for sale.4 It obligated MGI to purchase exclusively from Helsinn and obligated Helsinn to supply MGI's requirements of the 0.25 and 0.75 mg doses if approved by FDA.

The agreement here included other specific terms, such as price, method of payment, and method of delivery. Even though MGI's firm orders pursuant to the agreement were ostensibly "subject to written acceptance and confirmation by [Helsinn] before becoming binding," J.A. 2260, Helsinn was nonetheless obligated to meet or designate a third party manufacturer to meet MGI's firm orders. The public 8-K filing described the Supply and Purchase Agreement as obligating Helsinn to supply MGI's "requirements of finished product." MGI Pharma Inc., Current Report (Form 8-K), at 2 (Apr. 25, 2001). Under our decision in Enzo Biochem, Inc. v. Gen-Probe, Inc., 424 F.3d 1276 (Fed. Cir. 2005), the fact that an agreement covered one party's requirements as opposed to a specified quantity does not prevent application of the on-sale bar. Id. at 1281–82.

Despite these facts, Helsinn argues that the Supply and Purchase Agreement is not invalidating because at the critical date it was uncertain whether FDA would approve the 0.25 mg dose, and FDA approval was a condition precedent to the sale.

There can be no real dispute that an agreement contracting for the sale of the claimed invention contingent on regulatory approval is still a commercial sale as the commercial community would understand that term. The UCC expressly provides that a "purported present sale of future goods ... operates as a contract to sell." UCC § 2–105(2) (defining "future goods" as "[g]oods which are not both existing and identified"). This is true irrespective of whether those future goods have yet to receive necessary regulatory approval. A contract for sale that includes a condition precedent is a valid and enforceable contract. See *BG Grp., PLC v. Republic of Argentina*, ––U.S. ––––, 134 S.Ct. 1198, 1207 (2014). Indeed, conditions precedent such as regulatory approval are a basic feature of contract law.5 See, e.g., 25 Williston on Contracts § 67:73, at 462 (4th ed. 2013) ("Particular construction or development projects may also require specific governmental or regulatory approvals as conditions precedent to the consummation of the project."); 8 Corbin on Contracts § 31.11, at 99–101 (1999) ("In many contracts it is expressly provided that some act of a third person shall be a condition of a promisor's duty ... [such as a duty] to buy property contingent on a zoning board's approval....").

It has been implicit in our prior opinions that the absence of FDA or other regulatory approval before the critical date does not prevent a sale or offer for sale from triggering the on-sale bar. For instance, in *Enzo*, we applied the on-sale bar even though the contract for sale covered the buyer's reasonable requirements for "perform[ing] all preclinical and clinical studies," by definition before FDA approval, because the "claimed invention, the polynucleotide probe, is a tangible item or product that can be sold or offered for sale." 424 F.3d at 1279, 1282 (emphasis added). Similarly, in *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340 (Fed. Cir. 1998), we affirmed a jury verdict of invalidity based on a sale even though the product sold was subject to regulatory approval.

There was no majority opinion, but through two separate individual opinions a majority of the panel held that the on-sale bar applied. Id. at 1354 n.4. One opinion explicitly addressed the patentee's argument that the offer to sell did not trigger the statutory bar because "FDA approval had not been obtained" before the critical date, concluding that "FDA approval is not required before a sale can bar patent rights." Id. at 1376 (Mayer, C.J.). The dissent recognized that the majority was rejecting the argument that the product was not on sale because at the time of the sale it was "still being developed [and] tested" for FDA approval. Id. at 1357 (Newman, J.). Thus, while the absence of FDA approval may be a relevant consideration depending upon the other circumstances surrounding a transaction relating to a pharmaceutical formulation, the fact that a transaction was subject to regulatory approval would not, absent more, prevent it from being a sale for purposes of the on-sale bar. We do not find that it does so here. This is not a case like *Elan Corp., PLC v. Andrx Pharm., Inc.*, 366 F.3d 1336 (Fed. Cir. 2004), where the purported offer concerned a product when and if it had been developed, and there was no price or quantity term. Id. at 1341.

Helsinn also argues that, even if the agreement of sale for the 0.25 mg dose could be an invalidating sale, the agreement was uncertain because it covered the 0.25 mg dose, the 0.75 mg dose, and both doses. Helsinn is correct that the agreement covered either dose or both doses. Under established contract law, even if the agreement had given MGI, as the purchaser, the option of choosing between the two doses, as opposed to making the decision dependent on actions of third party regulators, there would still be a binding agreement.6

In any event, here there is no ambiguity introduced by the provision for the purchase of either or both doses. This contract is indistinguishable from a situation involving two otherwise identical contracts, one covering the 0.25 mg dose and the other covering the 0.75 mg dose, each contingent on FDA approval. It is clear that these two hypothetical agreements would individually trigger the on-sale bar for the 0.25 mg dose and the 0.75 mg dose, respectively. It cannot be that combining them into a single agreement somehow thwarts application of the on-sale bar. We see no valid reason based in contract law, patent law, or otherwise, to distinguish between a single agreement that covers two potential products—like the one between Helsinn and MGI—and two separate agreements, one for each product.

Our en banc decision in *Medicines* also made clear that the offer or contract for sale must unambiguously place the invention on sale, as defined by the patent's claims. 827 F.3d at 1374. As discussed below, that is clearly the case here. The Supply and Purchase Agreement described the palonosetron formulation in detail and Helsinn does not assert that the 0.25 mg dose described in the Supply and Purchase Agreement does not embody the asserted claims of the patents-in-suit. The fact that the contract made the selection of which doses to supply contingent on regulatory approval did not create an ambiguity with respect to whether what was on sale fell within the bounds of the patents' claims.

At oral argument for the first time, Helsinn contended that applying the on-sale bar would be unfair because it would distinguish between vertically-integrated manufacturers that have in-house distribution capacity and smaller entities like Helsinn that must contract for distribution services from a third party. Helsinn asserts that Medicines stands for the proposition that we should not allow commercial activities to be invalidating if those same activities could be performed in-house without triggering the on-sale bar. Such a broad principle would largely eviscerate the on-sale bar provision except as to sales to end users; that was not the holding of Medicines. There we concluded that "stockpiling," including purchases from a supplier, "does not trigger the on-sale bar." 827 F.3d at 1374. We also expressed concern over a policy of "penalizing a company for relying, by choice or by necessity, on the confidential services of a contract manufacturer." Id. at 1378. But the concern that Medicines focused on is not applicable here. Helsinn did not contract for MGI's confidential marketing or distribution services as Medicines contracted for Ben Venue's confidential manufacturing services. Instead, the Supply and Purchase Agreement between Helsinn and MGI unambiguously contemplated the sale by Helsinn of MGI's requirements of the claimed invention.

It is clear that the Supply and Purchase Agreement constituted a commercial sale or offer for sale for purposes of § 102(b) as to the asserted claims of the '724, '725, and '424 patents.

II

We next address whether the AIA changed the meaning of the on-sale bar under 35 U.S.C. § 102 so that there was no qualifying sale as to the '219 patent. The parties agree that the '219 patent is governed by the AIA. See 35 U.S.C. § 102(a)(1); AIA, Pub. L. No. 112-29, § 3(n), 125 Stat. 284, 293 (2011).

Before the AIA, § 102(b) barred the patentability of an invention that 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." 35 U.S.C. § 102(b) (2006) (emphasis added). Under that earlier provision, we concluded that, although confidentiality weighs against application of the on-sale bar, see *Medicines*, 827 F.3d at 1376, 1377 n.2, that fact alone is not determinative. For instance, in In re Caveney, a British company offered to sell the claimed invention to an American company that would be its exclusive seller in the United States before the critical date. *In re Caveney*, 761 F.2d 671, 673–74 (Fed. Cir. 1985). The court rejected the argument that a sale or offer for sale did not trigger the on-sale bar when it had been "kept secret from the trade," concluding that "sales or offers by one person of a claimed invention ... bar another party from obtaining a patent if the sale or offer to sell is made over a year before the latter's filing date." Id. at 675.

By enacting the AIA, Congress amended § 102 to bar the patentability of an "invention [that] 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." 35 U.S.C. § 102(a)(1) (emphasis added [by the Court omitted[).

Teva and various amici assert that by reenacting the existing statutory term, "on sale," Congress did not change the meaning of the on-sale bar or disturb settled law. Helsinn, the government, and other amici argue that the AIA changed the law by adding the "otherwise available to the public" phrase. They argue that the on-sale bar now does not encompass secret sales and requires that a sale make the invention available to the public in order to trigger application of the on-sale bar. Apart from the additional statutory language, this argument primarily relies on floor statements made by individual members of Congress. While recognizing that such floor statements are typically not reliable as indicators of congressional intent, see, e.g., *Exxon Mobil Corp. v. Allapattah Servs., Inc.*, 545 U.S. 546, 568, 125 S.Ct. 2611, 162 L.Ed.2d 502 (2005), they argue that here we should look to the floor statements to determine the meaning of the provision. These floor statements include material such as the following:

"[S]ubsection 102(a) was drafted in part to do away with precedent under current law that private offers for sale or private uses or secret processes practiced in the

United States that result in a product or service that is then made public may be deemed patent-defeating prior art. That will no longer be the case."

157 Cong. Rec. 3415 (2011) (remarks of Sen. Leahy) (emphasis added).

"[T]he current on-sale bar imposes penalties not demanded by any legitimate public interest. There is no reason to fear 'commercialization' that merely consists of a secret sale or offer for sale but that does not operate to disclose the invention to the public.... The present bill's new section 102(a) precludes extreme results such as these...."

157 Cong. Rec. 3424 (2011) (remarks of Sen. Kyl) (emphasis added).8

We decline the invitation by the parties to decide this case more broadly than necessary. At most the floor statements show an intent "to do away with precedent under current [§ 102] law," 157 Cong. Rec. 3415 (2011) (remarks of Sen. Leahy). Such precedent had held certain secret uses to be invalidating under the "public use" prong of § 102(b). Senator Kyl explicitly referenced cases such as *Egbert v. Lippman*, 104 U.S. 333, 26 L.Ed. 755 (1881), *Beachcombers International, Inc. v. Wildewood Creative Products, Inc*., 31 F.3d 1154 (Fed. Cir. 1994), and *JumpSport, Inc. v. Jumpking, Inc.*, Nos. 05–1182, 05–1196, 05–1197, 2006 WL 2034498 (Fed. Cir. July 21, 2006), and stated that "new section 102(a) precludes extreme results such as these." 157 Cong. Rec. 3424 (2011) (remarks of Sen. Kyl). Each of those cases involved a public use where the invention was not, as a result of the use, disclosed to the public. This public use issue is not before us, and we decline to address it.

The floor statements do not identify any sale cases that would be overturned by the amendments. Even if the floor statements were intended to overrule those secret or confidential sale cases discussed above and cited in footnote 7, that would have no effect here since those cases were concerned entirely with whether the existence of a sale or offer was public. Here, the existence of the sale—i.e., the Supply and Purchase Agreement between Helsinn and MGI—was publicly announced in MGI's 8-K filing with the SEC. The 8-K filing also included a copy of the contract for sale as an attachment, albeit partially redacted. Detailed information about palonosetron, its benefits and uses in treating CINV were also disclosed.

The statements disclosed the chemical structure of palonosetron and specified that the covered products were "pharmaceutical preparations for human use in [intravenous] dosage form, containing [palonosetron] as an active ingredient." Supply and Purchase Agreement, supra, art. 1.9.9 And, as described above, the agreements disclosed all the pertinent details of the transaction other than the price and dosage levels.

Helsinn argues that the AIA did more than overrule the "secret sale" cases, and relies on the "otherwise available to the public" language in the statute and the floor statements. Helsinn argues that those statements suggest that the on-sale bar does not apply unless the sale "disclose[s] the invention to the public" before the critical date. 157 Cong. Rec. 3424 (2011) (remarks of Sen. Kyl). It urges that since the 0.25 mg dose was not disclosed, the invention was not disclosed and the on-sale bar does not apply. The suggestion is that Congress required that the details of the claimed invention be publicly disclosed before the on-sale bar is triggered.

Requiring such disclosure as a condition of the on-sale bar would work a foundational change in the theory of the statutory on-sale bar. Indeed, the seminal Supreme Court decision in *Pennock* addressed exactly such a situation—the public sale of an item but the withholding from "the public the secrets of [the] invention." *Pennock v. Dialogue*, 27 U.S. (2 Pet.) 1, 19, 7 L.Ed. 327 (1829). Failing to find such a sale invalidating, said the Court, "would materially retard the progress of science and the useful arts, and give a premium to those who should be least prompt to communicate their discoveries." Id.

So too under our cases, ***an invention is made available to the public when there is a commercial offer or contract to sell a product embodying the invention and that sale is made public.*** Our cases explicitly rejected a requirement that the details of the invention be disclosed in the terms of sale. See *RCA Corp. v. Data Gen. Corp.*, 887 F.2d 1056, 1060 (Fed. Cir. 1989), overruled in part on other grounds by *Grp. One*, 254 F.3d at 1048 (rejecting the argument "that the bid documents themselves must disclose the invention with respect to all claim elements" since that is "clearly not legally correct" and there can be "a definite offer for sale or a sale of a claimed invention even though no details are disclosed").

A primary rationale of the on-sale bar is that ***publicly offering a product for sale that embodies the claimed invention places it in the public domain, regardless of when or whether actual delivery occurs***. The patented product need not be on-hand or even delivered prior to the critical date to trigger the on-sale bar. And, as previously noted, we have never required that a sale be consummated or an offer accepted for the invention to be in the public domain and the on-sale bar to apply, nor have we distinguished sales from mere offers for sale. We have also not required that members of the public be aware that the product sold actually embodies the claimed invention. For instance, in *Abbott Laboratories v. Geneva Pharmaceuticals, Inc.*, 182 F.3d 1315 (Fed. Cir. 1999), at the time of the sale, neither party to the transaction knew whether the product sold embodied the claimed invention and had no easy way to determine what the product was. Id. at 1317–18.

Thus, ***our prior cases have applied the on-sale bar even when there is no delivery, when delivery is set after the critical date, or, even when, upon delivery, members of the public could not ascertain the claimed invention.*** There is no indication in the floor statements that these members intended to overrule these cases. In stating that the invention must be available to the public they evidently meant that the public sale itself would put the patented product in the hands of the public. Senator Kyl himself seems to have agreed with this proposition, stating explicitly that "once a product is sold on the market, any invention that is inherent to the product becomes publicly available prior art and cannot be patented." 157 Cong. Rec. 3423 (2011) (remarks of Sen. Kyl).14 There are no floor statements suggesting that the sale or offer documents must themselves publicly disclose the details of the claimed invention before the critical date. If Congress intended to work such a sweeping change to our on-sale bar jurisprudence and "wished to repeal ... [these prior] cases legislatively, it would do so by clear language." *Dir., OWCP v. Perini N. River Assocs.*, 459 U.S. 297, 321 (1983).

We conclude that, after the AIA, if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms of sale. For the reasons already stated, the Supply and Purchase Agreement between Helsinn and MGI constituted a sale of the claimed invention—the 0.25 mg dose—before the critical date, and therefore both the pre-AIA and AIA on-sale bars apply. We do not find that distribution agreements will always be invalidating under § 102. We simply find that this particular Supply and Purchase Agreement is.

III

We finally address whether the invention was ready for patenting as of the critical date of January 30, 2002. Under *Pfaff*, there are at least two ways in which an invention can be shown to be ready for patenting: "by proof of reduction to practice before the critical date; or by proof that prior to the critical date the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention." Pfaff, 525 U.S. at 67–68. We conclude that the invention here was ready for patenting because it was reduced to practice before the critical date, and we need not address the alternative enablement approach, not addressed by the district court.

A. Reduction to Practice

An invention is reduced to practice when "the inventor (1) constructed an embodiment ... that met all the limitations and (2) determined that the invention would work for its intended purpose." *In re Omeprazole Patent Litig.*, 536 F.3d 1361, 1373 (Fed. Cir. 2008) (internal quotation marks and citations omitted) (citing *Z4 Techs., Inc. v. Microsoft Corp.*, 507 F.3d 1340, 1352 (Fed. Cir. 2007)). Reduction to practice occurs if "the claimant had possession of the subject matter of the [claim] and that it was shown or known to work for its intended purpose." S*treck, Inc. v. Research & Diagnostic Sys., Inc*., 659 F.3d 1186, 1193 (Fed. Cir. 2011); accord *Sanofi-Aventis v. Pfizer Inc*., 733 F.3d 1364, 1367–68 (Fed. Cir. 2013).

Before trial, the parties stipulated that they would contest ready for patenting "only with respect to the limitations and intended uses of 'reducing emesis or reducing the likelihood of emesis' and 'to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting' of the asserted claims" and not "for any other reason." J.A. 26081. Thus, for instance, it is uncontested that the formulation had been made and was stable prior to the critical date. Accordingly, the only issue with respect to ready for patenting before the district court and on appeal is whether Helsinn had determined that the invention would work for its intended purpose, which, according to the claims, is "reducing the likelihood" of emesis and CINV.

Our cases distinguish between the standard required to show that a particular invention would work for its intended purpose and the standard that governs FDA approval of new drugs, including the various stages of clinical trials. See, e.g., *Scott v. Finney*, 34 F.3d 1058, 1063–64 (Fed. Cir. 1994) (addressing reduction to practice in the priority context). In patent law, the requisite testing, if any, for showing that an invention will "work for its intended purpose" varies depending on "the character of the invention," including the claim language and the "nature and complexity of the problem" the invention seeks to solve. Id. at 1061–62; see also *Slip Track Sys., Inc. v. Metal-Lite, Inc.*, 304 F.3d 1256, 1265 (Fed. Cir. 2002). Generally there must be some "demonstration of the workability or utility of the claimed invention." *Honeywell Int'l Inc. v. Universal Avionics Sys. Corp.*, 488 F.3d 982, 997 (Fed. Cir. 2007). This must show that the invention works for its intended purpose "beyond a probability of failure" but not "beyond a possibility of failure." *Scott*, 34 F.3d at 1062. "[L]ater refinements do not preclude reduction to practice, [and] it is improper to conclude that an invention is not reduced to practice merely because further testing is being conducted." *Atlanta Attachment Co. v. Leggett & Platt, Inc.*, 516 F.3d 1361, 1367 (Fed. Cir. 2008).

Approval of a new drug by FDA, however, is a more demanding standard than that involved in the patents-in-suit. The patents here make no reference to FDA standards and broadly claim a palonosetron formulation for reducing the likelihood of emesis and CINV. For FDA approval, however, an applicant must submit, inter alia, "adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use" and "substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed." 21 U.S.C. § 355(d). This requires "adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof." Id. This is understood to be "a rigorous standard." *Ams. for Safe Access v. DEA*, 706 F.3d 438, 451 (D.C. Cir. 2013).

Here, the district court based its finding that the invention was not reduced to practice before the critical date on insufficient testing for Helsinn to have "determined that the invention would work for its intended purpose." J.A. 159. The district court appeared to believe that Teva needed to meet the FDA standard, which requires finalized reports with fully analyzed results from successful Phase III trials. This is clear from the district court's reliance on the testimony of Helsinn's expert who "referred to FDA standards in forming his opinions in this case" and stated that FDA "articulated a statistical framework for being able to really know from the [clinical trial] data ... that a drug is working." J.A. 148. Through-out its opinion the district court found lack of reduction to practice for failure to establish "efficacy" under FDA standards, and the lack of fully analyzed Phase III studies as required by FDA. J.A. 159. The district court was influenced particularly by the fact that FDA found the so-called Study 2330 insufficient to demonstrate efficacy.17 See, e.g., J.A. 34, 48–50, 56, 147, 151, 154–55.

The district court clearly erred by applying too demanding a standard. The completion of Phase III studies and final FDA approval are not pre-requisites for the invention here to be ready for patenting. The evidence is overwhelming that before the critical date of January 30, 2002, it was established that the patented invention would work for its intended purpose of reducing the likelihood of emesis.

• The 1995 report from Study 2330 demonstrated that three different doses, including the 0.25 mg dose, produced statistically significant results at the 5% level for the median time it took patients to experience an emetic episode after administration of palonosetron. While this study did not show statistical significance for complete control of emesis or CINV for 24 hours, complete control is not a claim requirement. The invention is for reducing the likelihood of emesis, not necessarily completely preventing it, and the statistical significance for mean time to failure demonstrates that the product reduced the likelihood of emesis. Indeed, the Study 2330 final report concluded that the relevant dose of palonosetron "was effective in suppressing" CINV. J.A. 1636. Under our cases this is sufficient to establish that the invention here would work for its intended purpose of reducing the likelihood of CINV. See, e.g., Z4 Techs., 507 F.3d at 1352 (concluding that the intended purpose of the invention at issue was to reduce piracy, not to completely stop its occurrence).

• Giorgio Calderari, one of the named inventors of the patents-in-suit, characterized the results of the Phase II trial, Study 2330, as "yes, the product was showing some efficacy clearly." J.A. 524.

• Minutes from a July 1998 meeting of Helsinn's palonosetron team indicated that their "proposal [wa]s to test effec *1374 tive doses seen in Phase 2," including the 0.25 mg dose. J.A. 1424 (emphasis added).

• The proposed protocols for Phase III trials that Helsinn submitted to FDA in November 1999 stated that the "[r]esults achieved in Phase II CINV studies suggest that palonosetron is safe and effective in preventing nausea and vomiting following emetogenic chemotherapy," J.A. 3846, and "[d]ata from this study clearly demonstrate that the 3 μg/kg dose of palonosetron is the minimal effective dose in preventing CINV," J.A. 3851.

• On September 14, 2000, Helsinn announced in a press release that "Phase II trials [had] demonstrated the efficacy of Palonosetron in the prevention of emesis with no significant side effects." J.A. 9983.

• On January 7, 2002, Helsinn prepared preliminary data tables analyzing the results from the first Phase III trial.18 "[T]he preliminary data for Complete Response, which is the primary efficacy outcome measure for acute CINV, was 81.0% (153/189) for palonosetron 0.25 mg." J.A. 81. This means that 81% of patients who received the 0.25 mg dose of palonosetron experienced relief from CINV for 24 hours. As one of the named inventors of all four patents explained, these data showed that the 0.25 mg dose of palonosetron "reduced the likelihood of CINV in those subjects." J.A. 593.

• In a 2007 declaration submitted to overcome an initial rejection by the examiner during prosecution, Giorgio Calderari and four of the other named inventors of the patents-in-suit stated that "[t]he formulations ... were completed sometime before March 24, 1999" and that they "had invented and were in possession of all of the subject matter currently claimed ... as of March 24, 1999." J.A. 1411–12. This was clarified at trial as referring to the claimed invention, i.e., "a pharmaceutically stable solution for reducing emesis or reducing the likelihood of emesis." J.A. 527 (154:16–22; 156:1–9).

• In a 2010 declaration corresponding to another related palonosetron patent application,19 Sergio Cantoreggi and two named inventors of the '724, '725, and '424 patents submitted a declaration stating that they "had conceived the invention ..., and reduced it to practice, before November 16, 2001," J.A. 2921 ¶ 2, and "had conceived the idea to use palonosetron for the treatment of acute and delayed-onset CINV, and had conducted clinical trials in humans to test this idea, at least as early as October 2, 2001," J.A. 2921 ¶ 3. The declaration concluded that "[m]ost important, [they] had successfully tested the method in human patients, and [they] had done so before October 2, 2001 (the date the [Phase III] study was completed)." J.A. 2923 *1375 ¶ 18. The district court found that these statements in the 2010 declaration "were literally true." J.A. 158.

These results consistently showed that the invention worked for its intended purpose, from the final report for the 1995 Phase II trial to the preliminary results in January 2002 from a Phase III trial. Under the district court's unduly restrictive standard, Helsinn could not have filed a valid patent application before the critical date of January 30, 2002. Such a standard would preclude the filing of meritorious patent applications in a wide variety of circumstances. The evidence that the formulation was ready for patenting is overwhelming, and the District Court's contrary conclusion—applying the wrong standard—was clearly erroneous. There is simply no tenable argument that, before the critical date, Helsinn was unable to file a patent application that met the requirements of 35 U.S.C. § 112.20

The district court and Helsinn on appeal rely on our decision in Omeprazole to argue that the results from Phase III trials must be analyzed in order to draw a valid conclusion regarding whether the invention works for its intended purpose. See Omeprazole, 536 F.3d 1361. But there is no general rule that Phase III trials must be completed before a product is ready for patenting, just as there is no general rule that Phase III trials are irrelevant. Each case must be decided based on its own facts. And this case is not like Omeprazole. In Omeprazole, there was significant uncertainty going into Phase III trials regarding whether the formulation would "solve the twin problems of in vivo stability and long-term storage" that had been identified after Phase II trials. Id. at 1373 (internal quotation marks omitted).

Indeed, between Phase II and Phase III the researchers needed to attempt "a number of modifications to the Phase II formulation" since achieving the "two goals seemingly conflicted." Id. Here, of course, there was no similar need to modify the formulation in between the Phase II and Phase III trials, as Helsinn stipulated to the formulation's stability.

We conclude that the invention was reduced to practice and therefore was ready for patenting before the critical date.

Conclusion

We hold that the asserted claims, claims 2 and 9 of the '724 patent, claim 2 of the '725 patent, claim 6 of the '424 patent, and claims 1, 2, and 6 of the '219 patent, are invalid under the on-sale bar.

REVERSED