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Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.: 35 U.S.C. § 102 Looks Like a New Duck and Sounds like a New Duck, but the On-Sale Bar is the Same Ole Goose

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In *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*,[1] the Supreme Court of the United States addressed whether the America Invents Act ("AIA") changed the meaning of the on-sale bar to allow an invention to be considered not on sale when it is subject to a commercial sale to a third party that is required to keep the invention confidential.[2] The Court correctly held that the on-sale bar applied to Helsinn Healthcare S.A.'s patent governed by the AIA because Congress did not clearly express its intent to change the years of pre-AIA precedent,[3] Helsinn and MGI's transaction was not secret and placed the invention on sale as defined by its claims,[4] and the holding furthers the promotion of the progress of science and useful arts.[5]

I. THE CASE

Helsinn Healthcare S.A. ("Helsinn") is the owner of the four patents-in-suit, 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"), which are directed to reducing the likelihood of chemotherapy-induced nausea and

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1. Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc., 139 S. Ct. 628 (2019).
2. *Id.* at 629.
3. *See infra* Section IV.A.
4. *See infra* Section IV.B.
5. *See infra* Section IV.C.

vomiting ("CINV").[6] Helsinn brought suit under the Hatch-Waxman Act[7] against Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd. (collectively, "Teva") alleging that Teva's Abbreviated New Drug Application ("ANDA") infringed various patent claims.[8] One of Teva's defenses was that Helsinn entered into a sale more than one year prior to the critical date patent, so the asserted claims were invalid under the on-sale bar provision of 35 U.S.C. § 102.[9]

Between 2005 and 2006, before the effective date of the AIA, Helsinn filed three patent applications that issued as the '724, '725, and '424 patents.[10] In May 2013, after the effective date of the AIA of March 16, 2013, Helsinn filed a fourth patent application that issued as the '219 patent.[11] All of Helsinn's patents-in-suit claimed priority to a provisional patent filed on January 30, 2003; thus the critical date for the on-sale bar would be one year prior, January 30, 2002.[12] Under the on-sale bar, an invention that is subject to a sale before the critical date can be invalidating prior art.[13] On April 6, 2001, approximately nine months before the critical date, Helsinn and MGI Pharmaceuticals, Inc. ("MGI") entered into a License Agreement and a Supply and Purchase Agreement.[14] Under the License Agreement, MGI agreed to pay $11 million plus additional future royalties on distribution of 0.25 mg and 0.75 mg doses of palonosetron in the United States.[15] Under the Supply and Purchase Agreement, MGI agreed to purchase exclusively from Helsinn, and Helsinn agreed to supply MGI the two dosages of palonosetron that were approved by the FDA.[16] These agreements were announced in a joint press release between the two corporations, as well as in a partially redacted copy of the License Agreement, and a partially redacted copy of the Supply and Purchase Agreement included in MGI's Form 8-K filing with the Securities and Exchange Commission ("SEC").[17]

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6. Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc., 855 F.3d 1356, 1359–60 (Fed. Cir. 2017).
7. *See* 35 U.S.C. § 271(e)(2)(A) (2012).
8. *Helsinn*, 855 F.3d at 1360.
9. *Id*.
10. *Id*. at 1362.
11. *Id.* at 1362.
12. *Id*. at 1360.
13. *Id*.
14. Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc., 855 F.3d 1356, 1361 (Fed. Cir. 2017).
15. *Id*.
16. *Id.*
17. *Id*.; *See* MGI Pharma Inc., Current Report (Form 8-K) Ex. 99.1 (Apr. 25, 2001) ("the redacted License Agreement"); MGI Pharma Inc., Current Report (Form 8-K) Ex. 99.2 (Apr. 25, 2001) ("the redacted Supply and Purchase Agreement").

In a bench trial, the district court held the claims of the patents-in-suit were valid and were infringed by Teva's 0.25 mg dose.[18] To address the on-sale issue, the court applied the two-step framework from *Pfaff v. Wells Electronics, Inc.*[19, 20] When analyzing the pre-AIA patents, '724, '725, and '424, under pre-AIA § 102(b), the district court found the Supply and Purchase Agreement was a "contract for future sale of a commercial product embodying the 0.25 mg dose and therefore constituted a sale under § 102(b)," satisfying the first prong of *Pfaff v. Wells Electronics* ("Pfaff").[21] However, the district court found that the claimed invention was not reduced to practice before the critical date, January 30, 2002, and thus was not on sale because the invention was not ready for patenting at that time, failing the second prong of *Pfaff*.[22]

With respect to the '219 patent, governed by the AIA, the district court held "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.'"[23] The district court concluded that a sale must publicly disclose the details of the invention for the sale to be "public" under the AIA, and found that although the Supply and Purchase Agreement "disclosed the sale agreement and substance of the transaction, it failed to publicly disclosed the 0.25 mg dose."[24] Because the district court did not find the Supply and Purchase Agreement to publicly disclose the 0.25 mg dose, the court held it did not constitute a public sale or commercial offer for sale.[25] Finally, the court concluded that the '219 patent also was not ready for patenting before the critical date, and thus held "the asserted claims of the four patents were not invalid."[26]

Teva appealed to the United States Court of Appeals for the Federal Circuit, which had jurisdiction under 25 U.S.C. § 1295(a).[27] The Federal Circuit reversed the district court and found the asserted claims were invalid under the on-sale bar.[28] In finding the asserted claims invalid, the court found the claims of the pre-AIA patents were subject to the on-sale bar under pre-AIA 35 U.S.C. § 102,[29] the

18. Helsinn Healthcare S.A. v. Reddy's Labs., Ltd., 2015 U.S. Dist. LEXIS 167048, 167056 (D.N.J. 2015).

19. 525 U.S. 55, 67 (1998). ("We conclude, therefore that the on-sale bar applies when two conditions are satisfied before the critical date. First, the product must be the subject of a commercial offer for sale. . . . Second, the invention must be ready for patenting.")

20. Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc., 855 F.3d 1356, 1363 (Fed. Cir. 2017).

21. *Id*. (citing Pfaff v. Wells Elecs., 525 U.S. 55, 67 (1998)).

22. *Id*.

23. *Id*. (quoting J.A. 113 (emphasis added)).

24. Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc., 855 F.3d 1356, 1363 (Fed. Cir. 2017).

25. *Id*.

26. *Id*.

27. *Id*.

28. Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc., 855 F.3d 1356, 1375 (Fed. Cir. 2017).

29. *Id*. at 1367.

claims of the '219 patent were subject to the on-sale bar under AIA 35 U.S.C. § 102,[30] and the invention was ready for patenting as of the critical date.[31]

To determine if the pre-AIA patents were subject to a sale or offer for sale prior to the critical date, the court applied the two-step framework[32] from *Pfaff* .[33] When addressing the first prong of *Pfaff*, the court used the analysis from *Medicines Co. v. Hospira, Inc.*[34] where the court reaffirmed the general proposition that it will look to the Uniform Commercial Code ("UCC") to define a commercial offer for sale,[35] and "that '[a] sale 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.'"[36]

To determine "whether the transaction would be understood 'in the commercial community' to constitute a commercial offer for sale" the court considered three factors: confidentiality of the transaction, marketing of the invention, and transfer of title.[37] The court then noted that while some of the details were redacted in the publicly disclosed Supply and Purchase Agreement between Helsinn and MGI, Helsinn did not argue the transaction itself remained confidential.[38] The court also found that Helsinn contracted MGI "'to distribute, promote, market, and sell' the claimed invention," Helsinn commercially marketed the invention before the critical date, and the Supply and Purchase Agreement expressly contemplated the transfer of title.[39] The court rejected Helsinn's argument that there was no sale due to the uncertainty in the Supply and Purchase Agreement regarding which dosage would be approved by the FDA,[40] and held "there was a sale for purposes of pre-AIA § 102(b) prior to the critical

30. *Id*. at 1371.

31. *Id*. at 1375.

32. *See supra* note 19.

33. Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc., 855 F.3d 1356, 1363 (Fed. Cir. 2017) (citing Pfaff v. Wells Elecs., 525 U.S. 55, 67 (1998)).

34. 827 F.3d 1363 (Fed. Cir. 2016).

35. *Id*. at 1365.

36. *Id*. at 1373 (quoting Trading Techs. Int'l v. eSpeed, Inc., 595 F.3d 1340, 1361 (Fed. Cir. 2010) (internal quotation marks omitted)).

37. Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc., 855 F.3d 1356, 1364 (Fed. Cir. 2017) (citing Medicines Co. v. Hospira, Inc., 827 F.3d at 1375–76 (quoting Group One, Ltd. v. Hallmark Cards, Inc., 254 F.3d 1041, 1047 (Fed. Cir. 2001))).

38. *Helsinn*, 855 F.3d at 1364.

39. *Id*. (quoting J.A. 2255).

40. *Id*. at 1365–66 (explaining that regulatory approval is just a type of conditional precedent which is a basic feature of contract law, and stating "[t]his 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.").

date because there was a sale of the invention under the law of contracts as generally understood."[41]

Next, the Federal Circuit Court addressed whether the '219 patent was subject to the on-sale bar under 35 U.S.C. § 102, similar to the pre-AIA patents, or if the AIA changed the meaning of the on-sale bar.[42] Teva argued that when Congress chose to reenact the existing statutory term "on sale," Congress did not change the law of the on-sale bar.[43] Helsinn argued that the AIA changed the law of the on-sale bar by adding in the phrase "otherwise available to the public" to not cover secret sales, but the additional language required that a sale make the invention available to the public for the on-sale bar to apply.[44] Helsinn's argument rested on the additional statutory language added to § 102 under the AIA and floor comments made by individual members of Congress.[45]

The court concluded that the intent of the floor statements was "to do away with precedent under current § 102 law,"[46] but the floor statements only refereed to precluding extreme results from cases [47] where the "public use" prong of § 102(b) held certain secret uses to be invalidating.[48] The court found the floor statements did not reference any on sale cases that would be overturned by the amendments, and even if the amendments intended to overrule secret sale cases, it would not apply in this case.[49] In this case, the Supply and Purchase Agreement between Helsinn and MGI was publicly announced in MGI's 8-K filing with the SEC, and it included "all the pertinent details of the transaction other than the price and dosage levels."[50]

The court concluded that if Congress intended to make the drastic change to the on-sale bar jurisprudence that Helsinn suggested, the on-sale bar not applying unless the sale "discloses the invention to the public" before the critical date, it would do so by clear language.[51] The court found:

> 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

41. *Id*. at 1364.

42. Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc., 855 F.3d 1356, 1367 (Fed. Cir. 2017).

43. *Id*. at 1368.

44. *Id*. (quoting 35 U.S.C. § 102(a)(1) (2012)).

45. *Id*.

46. *Id*. at 1368 (citing 157 Cong. Rec. 3415 (2011) (remarks of Sen. Leahy)).

47. *See* Egbert v. Lippmann, 104 U.S. 333 (1881); Beachcombers Int'l, v. Wildewood Creative Products, Inc., 31 F.3d 1154 (Fed. Cir. 1994); JumpSport, Inc. v. Jumpking, Inc., 191 F. App'x 926 (Fed. Cir. 2006).

48. *Helsinn*, 855 F.3d at 1368.

49. *Id*. at 1369.

50. *Id*.

51. *Id*. at 1371.

> 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.[52]

The court held that the '219 patent was on sale under the AIA because "after the AIA, if the existence of the sale is public," like the Supply and Purchase Agreement in this case due to MGI's 8-K filing with the SEC, "the details of the invention need not be publicly disclosed in terms of sale."[53]

The last step in *Pfaff's* two-step framework was for the court to determine if the invention was ready for patenting prior to the critical date.[54] The court found the second step of *Pfaff* was satisfied when it concluded "the invention here was ready for patenting because it was reduced to practice before the critical date."[55] Thus, the Federal Circuit found both the pre-AIA patents and the AIA patent to be invalid under the on-sale bar.[56]

The Supreme Court of the United States granted certiorari to address if the AIA changed the meaning of the on-sale bar to allow an invention to be considered not on sale when it is subject to a commercial sale to a third party that is required to keep the invention confidential.[57]

II. LEGAL BACKGROUND

The United States Constitution grants Congress the enumerated power to "promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writing and discoveries."[58] To help achieve this goal, Congress created the federal patent law system. Since the inception of the federal patent laws, Congress has tried to achieve a "balance between the interest in motivating innovation and enlightenment by rewarding invention with patent protection on the one hand, and the interest in avoiding monopolies that unnecessarily stifle competition on

52. *Id*. at 1370–71.

53. Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc., 855 F.3d 1356, 1371 (Fed. Cir. 2017).

54. *Id*.

55. *Id*. (While this is a step of the *Pfaff v. Wells* analysis, the Reduction to Practice aspect will not be discussed in this case note.).

56. *Id*. at 1375.

57. Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc., 139 S. Ct. 628, 630 (2019).

58. U.S. CONST. art I, § 8, cl. 8.

the other."[59] The on-sale bar has been a tool used by Congress to achieve this balance since it was first codified in the Patent Act of 1836.[60] Throughout the life of the on-sale bar, it has evolved from an absolute bar to one that strives to create certainty for inventors for when the filing of a patent should occur.[61]

A. The On-Sale Bar Prior to the America Invents Act (Pre-AIA)

The on-sale bar was first codified in the Patent Act of 1836, where an absolute bar existed for any invention that was subject to a sale that occurred with the "consent or allowance of the inventor" prior to applying for a patent.[62] The Patent Act of 1839 removed the requirement of consent or allowance from the inventor and introduced a two-year grace period.[63] Under the Patent Act of 1839, the two-year grace period was measured "from the completion of [the] invention,"[64] allowing the inventor to sell the invention before applying for a patent.[65] The Court went on to state completion of an invention requires conception and reduction to practice.[66] The main purpose of this amendment "was 'to fix a period of limitation which should be certain'; it required the inventor to make sure that a patent application was filed 'within two years from the completion of his invention.'"[67]

The on-sale bar remained unchanged for almost a century until the Patent Act of 1939, where the grace period was reduced from two years to one year.[68] However, the Patent Act of 1939 retained the principle that the grace period is measured from the completion of the invention.[69]

The on-sale bar under the Patent Act of 1952 was codified at Title 35, Section 102(b) of the United States Code.[70] This version of 35 U.S.C. § 102(b) stated "[a] person shall be entitled to a patent unless 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 application for patent in the United States."[71] When evaluating the on-sale bar, the Federal Circuit took

59. Pfaff v. Wells Elecs., 525 U.S. 55, 63 (1998).

60. 5 Stat. 117 (1836).

61. *See* Andrews v. Hovey, 123 U.S. 267, 274 (1887).

62. 5 Stat. 117 (1836).

63. 5 Stat. 353 (1839).

64. *Hovey*, 123 U.S. at 274.

65. Pfaff v. Wells Elecs., 525 U.S, 55, 65 (1998).

66. *See, e.g.*, Clark Thread Co. v. Willimantic Linen Co., 140 U.S. 481, 489 (1891); Corona Cord Tire Co. v. Dovan Chemical Corp., 276 U.S. 358, 382–83 (1928).

67. *Pfaff*, 525 U.S. at 65 (quoting Andrews v. Hovey, 123 U.S. 267, 274 (1887)).

68. 53 Stat. 1212 (1939).

69. *Id*.

70. 35 U.S.C. § 102(b) (2006).

71. *Id*.

the approach that "[a]ll the circumstances surrounding the sale or offer to sell, including the stage of development of the invention and the nature of the invention, must be considered and weighed against the policies underlying section 102(b)."[72]

When the Federal Circuit's holistic view reached the Supreme Court in *Pfaff*, the Court rejected the totality of circumstances approach when evaluating the on-sale bar.[73] The Court found that the totality of the circumstances approach "seriously undermines the interest in certainty"[74] because it made the "timeliness of an application depend on the date when an invention is 'substantially complete.'"[75] The Court concluded that for the on-sale bar to apply, two conditions must be met: (1) the product must be the subject of a commercial offer for sale and (2) the invention must be ready for patenting.[76]

While the Court in *Pfaff* did not go in detail with respect to the first prong of the two-part test it developed, it did analyze the second prong.[77] The Court found the "word 'invention' must refer to a concept that is complete, rather than merely one that is 'substantially complete,'" and that proof of reduction is not necessary in every case.[78,79] The Court found the second condition could be satisfied "by proof of reduction to practice before the critical date; or by proof that prior to the critical date the invention 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."[80]

The Federal Circuit in *Medicines Co. v. Hospira, Inc.*[81] analyzed the first prong developed in *Pfaff* by defining what it meant for a patent to be subject to a commercial sale or offer for sale.[82] In coming to the definition of a commercial sale, the court referenced prior cases to shed light on the matter.[83] In *Group One Ltd. v. Hallmark Cards, Inc.*, the court stated there was "no binding precedent" in the circuit that required the court to "accept something less than an offer to

72. UMC Elecs. Co. v. United States, 816 F.2d 647, 656 (Fed. Cir. 1987); *see* Micro Chem., Inc. v. Great Plains Chem. Co., 103 F.3d 1538, 1544 (Fed. Cir. 1997); *In re* Brigance, 792 F.2d 1103, 1107–08 (Fed. Cir. 1986).

73. Pfaff v. Wells Elecs., 525 U.S. 55, 65–67 (1998).

74. *See supra* text accompanying note 61.

75. *Pfaff*, 525 U.S. at 65–66.

76. *Id*. at 67–68.

77. Meds. Co. v. Hospira, Inc., 827 F.3d 1363, 1372–73 (Fed. Cir. 2016).

78. *See* Dolbear v. Am. Bell Tel. Co., 126 U.S. 1, 535–36 (1888) (demonstrating that an invention is complete and ready for patenting before it has actually been reduced to practice).

79. Pfaff v. Wells Elecs., 525 U.S. 55, 66 (1998).

80. *Id*. at 67–68.

81. 827 F.3d 1363 (Fed. Cir. 2016).

82. *Id*. at 1365.

83. *Id*. at 1373.

contract as constituting an offer for sale as that term is construed for the purposes of the on-sale bar of 35 U.S.C. § 102(b)."[84] The court in *Medicines Co. v. Hospira* also referenced *Trading Techs. Int'l, Inc. v. eSpeed, Inc.*, where the court stated "[t]he transaction at issue must be a 'sale' in a commercial law sense."[85] The court in *Medicines* held "a commercial sale is one that bears the general hallmarks of a sale pursuant to Section 2-106 of the Uniform Commercial Code ."[86, 87] The court went on to state that even "when no actual sale is present, '[o]nly an offer which rises to the level of a commercial offer for sale, one which the other party could make into a binding contract by simple acceptance (assuming consideration)' triggers the on-sale bar."[88] In addition, the Federal Circuit has rejected the idea that a sale or offer for sale "kept secret from the trade" did not trigger the on-sale bar.[89] The Federal Circuit has concluded that "sales or offers by one person of a claim 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."[90]

The two-part test for analyzing the on-sale bar under the Patent Act of 1952, established in *Pfaff v. Wells*, is the governing rule for patents filed before March 16, 2013. Analyzing the on-sale bar for patents filed on or after March 16, 2013 must be done under the Leahy-Smith America Invents Act.

B. The On-Sale Bar Under the Leahy-Smith America Invents Act (AIA)

The Leahy-Smith America Invents Act modified the language of 35 U.S.C. § 102, as well as the entire patent filing system of the United States.[91] Under the AIA, the United States moved from a first-to-invent system to a first-inventor-to-file system.[92] The United States did not adopt a pure first-inventor-to-file system, as it retained a one-year grace period in certain instances.[93]

Under the AIA, the statute that now contains the on-sale bar, § 102(a), states "[a] person shall be entitled to a patent unless the claimed invention was

84. 254 F.3d 1041, 1046 (Fed. Cir. 2001).

85. 595 F.3d 1340, 1361 (Fed. Cir. 2010) (citing Allen Eng'g Corp. v. Bartell Indus., Inc., 299 F.3d 1336, 1352 (Fed. Cir. 2002)).

86. U.C.C. § 2-106(1) (AM. LAW INST. & UNIF. LAW COMM'N 2002) ("A 'sale' consists in the passing of title from the seller to the buyer for a price (Section 2-401)."); *see also In re* Caveney, 761 F.2d 671, 676 (Fed. Cir. 1985) ("It is well settled that a sale 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.").

87. 827 F.3d at 1365.

88. *Id*. at 1378 (quoting Group One Ltd. v. Hallmark Cards, Inc., 254 F.3d 1041, 1048 (Fed. Cir. 2001)).

89. *In re* Caveney, 761 F.2d 671, 675 (Fed. Cir. 1985).

90. *Id*. at 675.

91. 157 Cong. Rec. 1362 (2011) (remarks of Sen. Leahy).

92. *Id*.

93. 157 Cong. Rec. 1366 (2011) (remarks of Sen. Kyl).

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."[94]

III. THE COURT'S REASONING

Writing for a unanimous Court, Justice Thomas held that "an inventor's sale of an invention to a third party who is obligated to keep the invention confidential can qualify as prior art under § 102(a)" because Congress did not alter the meaning of the on-sale bar when it enacted the AIA.[95] During its analysis, the Court considered the history of Congress' pursuit in promoting "the Progress of Science and useful Arts,"[96] the statutory interpretation of 35 U.S.C § 102(a)(1), and the Federal Circuit's determination that Helsinn's AIA patent would have been considered on sale under the on sale pre-AIA precedent.[97]

When considering Congress' approach to creating a federal patent system, the Court noted that "Congress has imposed several limiting conditions on the 'limited opportunity to obtain a property right in an idea,'"[98] in its "goal of 'motivating innovation and enlightenment' while also 'avoiding monopolies that unnecessarily stifle competition.'"[99] The Court identified the on-sale bar as one of those limiting conditions, and stated that since 1836, the on-sale bar has reflected "Congress' 'reluctance to allow an inventor to remove existing knowledge from public use' by obtaining a patent covering that knowledge."[100]

Next the Court considered the statutory interpretation of 35 U.S.C. § 102(a)(1) under the AIA.[101] The Court found that by reenacting the language "on sale" in the AIA, Congress intended to bring the judicial construction of that phrase into the AIA.[102] The Court found that Congress simply adding the catchall phrase "otherwise available to the public" was not enough for the Court to determine Congress intended to alter the meaning of the reenacted language of "on sale."[103] The Court decided the phrase "otherwise available to the public" was added to capture materials that do "not fit neatly into the statute's enumerated categories but are nevertheless meant to be covered."[104]

94. 35 U.S.C. § 102(a)(1) (2012).
95. Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc., 139 S. Ct. 628, 634 (2019).
96. U.S. CONST. art. I, § 8, cl. 8.
97. *Helsinn*, 139 S. Ct. at 633–34.
98. *Id*. at 632 (quoting Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 151 (1989)).
99. *Id.* at 632 (citing Pfaff v. Wells Elecs., 525 U.S. 55, 63 (1998)).
100. *Id.* (citing *Pfaff*, 525 U.S. at 64).
101. *Id.*
102. *Id*.
103. Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc., 139 S. Ct. 628, 634 (2019).
104. *Id*.

Finally, the Court visited the fact that Helsinn did not dispute "the Federal Circuit's determination that the invention claimed in the '219 patent was 'on sale' within the meaning of the pre-AIA statute."[105] Because Helsinn did not dispute this determination by the Federal Circuit, and the Court found Congress did not change the meaning of the on-sale bar under the AIA, the Court determined that the invention claimed in the '219 patent qualified as prior art under § 102(a).[106]

Using this analysis, the Court held "that an inventor's sale of an invention to a third party who is obligated to keep the invention confidential can qualify as prior art under § 102(a)," and affirmed the Federal Circuit's judgment that the invention claimed in the '219 patent was subject to the on-sale bar under the AIA.[107]

IV. ANALYSIS

In *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, the Supreme Court held "an inventor's sale of an invention to a third party who is obligated to keep the invention confidential can qualify as prior art under § 102(a)," and affirmed the Federal Circuit's judgment that the invention claimed in the '219 patent was invalid under the on-sale bar of the AIA.[108] The Court's holding was correct because Congress did not clearly express its intent to change the years of pre-AIA precedent, Helsinn and MGI's transaction was not secret and placed the invention on sale as defined by its claims, and it furthers the promotion of the progress of science and useful arts.

A. The Court's Holding is Correct Because Congress did not Clearly Express its Intent to Change the Years of Pre-AIA Precedent

Under the Patent Act of 1952, 35 U.S.C. § 102(b) stated "[a] person shall be entitled to a patent unless 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 application for patent in the United States."[109] Under the AIA, the statute that contains the on-sale bar now states "[a] person shall be entitled to a patent unless 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."[110] In this case, the Court held that Congress did not alter the meaning of the on-sale bar when it enacted the AIA.[111] The Court's holding is correct because the floor

105. *Id.*
106. *Id*.
107. *Id*.
108. *Id*.
109. 35 U.S.C. § 102(b) (2006).
110. 35 U.S.C. § 102(a)(1) (2012).
111. Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc., 139 S. Ct. 628, 634 (2019).

statements did not reflect a desire to change the on-sale bar and Congress chose to reenact the terms "on sale" which have developed a specific judicial interpretation.

Helsinn argued that Congress intended to change the meaning of the on-sale bar based on the addition of the phrase "otherwise available to the public" and extrinsic materials, such as floor statements made by individual members of Congress.[112] While "[e]xtrinsic materials have a role in statutory interpretation . . . . Not all extrinsic materials are reliable sources of insight into legislative understandings . . . ."[113] As the Court has "repeatedly held, the authoritative statement is the statutory text, not . . . any other extrinsic material."[114] It has been long settled that when Congress chooses to reenact language, "[t]he words, having received such a construction under" the previous statute, "must be given the same meaning when used" in the new statute "on the theory, that, in using the phrase in the later statute, Congress adopted the construction already given to it by this court."[115] Therefore, the Court was correct to hold Congress did not change the meaning of the on-sale bar when Congress chose to reenact the well-developed term of "on sale."

B. The Court's Holding is Correct Because the Transaction Itself was not Private and Helsinn and MGI's Agreements Placed the Invention On Sale as Defined by the Patent Claims

In their argument, Helsinn relied on floor statements made by individual members of Congress, extrinsic materials,[116] about the on-sale bar.[117] Many of the floor statements considering an alteration to the meaning of the on-sale bar included administrative concerns of monitoring secret sales.[118]

When addressing the relationship between secret sales and the AIA on-sale bar, Senator Kyl stated:

> A contrary construction of section 102(a)(1), which allowed private and non-disclosing . . . sales to constitute invalidating prior art, would be

112. Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc., 855 F.3d 1356, 1368 (Fed. Cir. 2017).

113. Exxon Mobil Corp. v. Allapattah Servs., 545 U.S. 546, 568 (2005).

114. *Id*.

115. Latimer v. United States, 223 U.S. 501, 504 (1912) (citing United States v. Baruch, 223 U.S. 191 (1912)); *see also* Shapiro v. United States, 335 U.S. 1, 16 (1948) ("Moreover, there is a presumption that Congress, in reenacting the immunity provision of the 1893 Act, was aware of the settled judicial construction of the statutory immunity."); Hecht v. Malley, 265 U.S. 144, 153 (1924) ("In adopting the language used in an earlier act, Congress must be considered to have adopted also the construction given by this Court to such language, and made it a part of the enactment.").

116. *See supra* text accompanying note 114.

117. *Helsinn*, 855 F.3d at 1368.

118. 157 Cong. Rec. 3424 (2011) (remarks of Sen. Kyl).

> fairly disastrous for the U.S. patent system. First, the bill's new post-grant review, in which any validity challenge can be raised, would be utterly unmanageable if the validity of all patents subject to review under the new system continued to depend on discovery-intensive searches for secret offers for sale . . . by third parties.[119]

In continuing on the topic of administrative concerns for monitoring secret sales under the on-sale bar, Senator Kyl went on to state that:

> A sale . . . that discloses an invention to the public is relatively hard to falsify. If the invention truly was made available to the public by sale . . . independent validation of that sale . . . should be readily available. By contrast, the existence of a secret offer for sale . . . largely will turn on the affidavits or statements of the parties to such an occurrence.[120]

The scenarios seemingly focused on in the floor statements relate to the situation where the sale of an invention is so secret that the only evidence of the sale would be internal to the two companies. This type of secret sale would likely occur where two companies are so related, have such a familiar business relationship, or are so intertwined in dealings that it would be impossible for outsiders to know of the existence of this sale.

In contrast, Helsinn and MGI engaged in an arm's length transaction. It can hardly be said that Helsinn and MGI engaged in a secret sale where they publicly announced their agreements in a joint press release and filed partially redacted copies of the agreements in MGI's Form 8-K filing with the SEC.[121] Therefore, even if the Court gave these statements that were focused on "secret sales" more weight in determining the meaning of the on-sale bar under the AIA, the transaction itself between Helsinn and MGI was not a private agreement, and thus, the administrative concerns of the floor statements would not apply in this case.

To specifically address some of Senator Kyl's concerns, discovering the existence of these agreements would not involve a "discovery-intensive search," and the sale could easily be independently validated. Further, it was not only the knowledge of the sale that was available to the public, but detailed information about palonosetron was available as well.[122] The agreements included the benefits and uses of palonosetron in treating CINV, the chemical structure of palonosetron,

119. *Id*.

120. *Id*.

121. Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc., 139 S. Ct. 628, 631 (2019).

122. Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc., 855 F.3d 1356, 1369 (Fed. Cir. 2017).

and described the products as: "pharmaceutical preparations for human use in [intravenous] dosage form, containing [palonosetron] as an active ingredient."[123]

An invention may only be on sale if it is the invention as defined by the patent's claims.[124] In this case, the invention was placed on sale as defined by its claims,[125] due to the inclusion of the benefits and uses, the chemical structure, and the description of the invention in the agreements.[126] Therefore, not only was the transaction itself not private, but the invention that was on sale under the transaction, defined by the patent's claims, was not private.[127] Thus, the Court's holding that the '219 patent was invalid under the AIA on-sale bar was correct because even if the Court considered the floor statements more heavily in determining the meaning of the on-sale bar under the AIA, it would be unlikely for this sale to be deemed of the kind, "private and non-disclosing,"[128] that congressional floor statements had administrative concerns over.

C. The Court's Holding is Correct Because it Furthers the Promotion of the Progress of Science and Useful Arts

The United States Constitution grants Congress the enumerated power to "promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writing and discoveries."[129] In pursuing this goal, Congress created the federal patent system that "represents a carefully crafted bargain that encourages both the creation and the public disclosure of new and useful advances in technology, in return for an exclusive monopoly for a limited period of time."[130] "Moreover, the ultimate goal

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123. *Id*. (quoting MGI Pharma Inc., Current Report (Form 8-K) Ex. 99.2 (Apr. 25, 2001)).

124. Meds. Co. v. Hospira, Inc., 827 F.3d 1363, 1374 (Fed. Cir. 2016).

125. *Helsinn*, 855 F.3d at 1361.

("Claim 1 is representative of the asserted claims of the '219 Patent.

'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 compromising:

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

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

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

wherein said formulation is stable at 24 months when stored at room temperature.'") (citing U.S. Patent No. 8,598,219 col. 10 l. 1–12 (filed May 23, 2013)).

126. *Helsinn*, 855 F.3d at 1369 (quoting MGI Pharma Inc., Current Report (Form 8-K) Ex. 99.2 (Apr. 25, 2001)).

127. *Id.* at 1362–64 (With the exception that the dosage was the only piece of information about the palonosetron that was redacted in the publicly available agreements.).

128. *See supra* text accompanying note 119.

129. U.S. CONST. art I, § 8, cl. 8.

130. Pfaff v. Wells Elecs., 525 U.S. 55, 63 (1998) (citing Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 151 (1989)).

of the patent system is to bring new designs and technologies into the public domain through disclosure."[131]

Patent laws are structured to "protect the public's right to retain knowledge already in the public domain and the inventor's right to control whether and when he may patent his invention."[132] The on-sale bar in particular is "primarily concerned with the policy that encourages an inventor to enter the patent system promptly,"[133] and strives to create a degree of certainty for when the inventor must file for a patent to receive the benefit of the monopoly.[134] With patent law striving to prevent knowledge being taken from the public domain and the on-sale bar focusing on encouraging inventors to promptly enter the patent system, which leads to more knowledge in the public domain, it is no surprise that the on-sale bar has a history of applying no matter who put the invention in the public domain.[135] Courts have stated the on-sale bar would be triggered even when the invention is put on sale by an innocent third party, fraudulent third party, or even if a thief stole the invention, passed it on to an innocent buyer and that innocent buyer offered to the sell the invention.[136]

In this case, the Court held that Congress did not alter the meaning of the on-sale bar when it enacted the AIA, thus "an inventor's sale of an invention to a third party who is obligated to keep the invention confidential can qualify as prior art under § 102(a)."[137] This holding furthers the progress of science and useful arts because it does not allow for knowledge to be taken from the public domain by an inventor. Under the facts of the case, nearly two years before applying for a patent, the Supply and Purchase Agreement between Helsinn and MGI was included in MGI's 8-K filing with the SEC, as well as a partially redacted copy of the contract for sale (excluding the dosage level and the price).[138] The public filings included "[d]etailed information about palonosetron, its benefits and uses in treating CINV," and the chemical structure of palonosetron.[139] This is a similar situation to the one the Court faced in *Pennock v. Dialogue* where the Court addressed a public sale that withheld "the secrets of the invention."[140] The Court

131. Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 151 (1989).

132. *Pfaff*, 525 U.S. at 65.

133. Woodland Trust v. Flowertree Nursery, Inc., 148 F.3d 1368, 1370 (Fed. Cir. 1998) (stating that in addition, the on-sale bar grace period also recognizes an inventor's interest in seeking commercial exploitation before filing a patent application).

134. *See supra* text accompanying note 61.

135. Special Devices, Inc. v. OEA, Inc., 270 F.3d 1353, 1355 (Fed. Cir. 2001).

136. *See* Special Devices, Inc. v. OEA, Inc. 270 F.3d 1353, 1355 (Fed. Cir. 2001); Zacharin v. United States, 213 F.3d 1366, 1371 (Fed. Cir. 2000); Abbott Labs. v. Geneva Pharm.,182 F.3d 1315, 1318 (Fed. Cir. 1999).

137. Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc., 139 S. Ct. 628, 634 (2019).

138. Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc., 855 F.3d 1356, 1361–62 (Fed. Cir. 2017).

139. *Id*. at 1369.

140. 27 U.S. (2 Pet.) 1, 19 (1829).

in that case explained that it "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."[141]

V. CONCLUSION

In *Helsinn Healthcare v. Teva Pharm. USA, Inc.*, the Supreme Court of the United States addressed whether the AIA changed the meaning of the on-sale bar to allow an invention to not be considered on sale when it is subject to a commercial sale to a third party that is required to keep the invention confidential.[142] The Court held "an inventor's sale of an invention to a third party who is obligated to keep the invention confidential can qualify as prior art under § 102(a)," and affirmed the Federal Circuit's judgment that the invention claimed in the '219 patent was subject to the on-sale bar.[143] The Court's holding was correct because Congress did not clearly express its intent to change the years of pre-AIA precedent,[144] Helsinn and MGI's transaction was not secret and placed the invention on sale as defined by its claims,[145] and the holding furthers the promotion of the progress of science and useful arts.[146]

141. *Pennock v. Dialogue*, 27 U.S. (2 Pet.) 1, 19 (1829).

142. Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc., 139 S. Ct. 628, 630 (2019).

143. *Id*. at 634.

144. *See supra* Section IV.A.

145. *See supra* Section IV.B.

146. *See supra* Section IV.C.