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## Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.: “Sale” Keeps Its Old Meaning under the Leahy–Smith America Invents Act

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## Note

### ***Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.*: “Sale” Keeps Its Old Meaning under the Leahy–Smith America Invents Act**

*Sherrie Holdman\**

Petitioner Helsinn developed a new drug for treating cancer patients suffering from chemotherapy-induced nausea and vomiting.<sup>1</sup> Before filing a patent application for the new drug, Helsinn entered into a license agreement and a supply and purchase agreement with MGI Pharma, Inc. (“MGI”).<sup>2</sup> The agreements bound MGI to keep all the proprietary information confidential, including the novel formulations of the new drug.<sup>3</sup> As a public company, MGI filed a Form 8-K with the Securities and Exchange Commission (“SEC”) disclosing a redacted version of the agreements, omitting the details of the formulations.<sup>4</sup> Respondents Teva Pharmaceuticals USA, Inc. (“Teva”) filed an Abbreviated New Drug Application (“ANDA”) with the Food and Drug Administration (“FDA”), seeking to market generic versions of the same new drug.<sup>5</sup> Teva challenged Helsinn’s patents as invalid or unenforceable.<sup>6</sup> Following a bench trial, the United States District Court for the District of New Jersey found that Helsinn’s patents were valid and infringed.<sup>7</sup> Teva appealed

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1. See *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 855 F.3d 1356, 1360 (Fed. Cir. 2017), *aff’d*, 139 S. Ct. 628 (2019).

2. *Id.* at 1361.

3. *Id.*

4. *Id.*

5. *Id.* at 1363.

6. *Id.*

7. See *Helsinn Healthcare S.A. v. Dr. Reddy’s Laboratories Ltd.*, No. 11-3962 (MLC), 2016 WL 832089, at \*51–52 (D.N.J. Mar. 3, 2016) (holding that the

to the Court of Appeals for the Federal Circuit which then reversed and found that the agreements between Helsinn and MGI constituted a “sale” of the claimed invention prior to the “critical date,” rendering the patents invalid.<sup>8</sup> The Supreme Court affirmed the Federal Circuit’s decision, holding that the Leahy-Smith America Invents Act (AIA) did not change the meaning of the term “on-sale” under the pre-AIA § 102(b).<sup>9</sup>

The major issue presented to the Supreme Court was whether, under the AIA, the “sale” remains the old meaning under the pre-AIA § 102 where even a “secret sale” would be enough to bar inventors from filing patent applications of their inventions.<sup>10</sup> In other words, did Helsinn forfeit its patent rights by entering into agreements with MGI even though the agreements prohibited MGI from disclosing the invention? The Supreme Court answered both questions in the affirmative.<sup>11</sup>

This Comment will analyze the Supreme Court’s decision on *Helsinn* as to the “secret sale” under the AIA. Part I will briefly examine the judicial interpretation of on-sale bar under the pre-AIA § 102(b) and the AIA § 102(a)(1). Part II will introduce the Federal Circuit’s holding, the Supreme Court’s oral hearing, and its decision in *Helsinn*. Part III will discuss the Supreme Court’s *Helsinn* decision and the prospects for future small business owners and patent attorneys. This Comment concludes that the Supreme Court is likely correct in its conclusion although it did not discuss certain aspects in its opinion, including statutory text interpretation, relevant legislative history, and the overall goal of implementation of the AIA; instead, its reasoning was solely based on the weight of the Federal Circuit and Supreme Court precedents.

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post-AIA on-sale bar inquiry is not focused on the public disclosure of the existence of a sale or offer for sale, but on the public disclosure of the claimed invention made in a sale), *rev’d sub nom.* *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 855 F.3d 1356 (Fed. Cir. 2017), *aff’d*, 139 S. Ct. 628 (2019).

8. *See Helsinn Healthcare S.A.*, 855 F.3d, at 1370 (concluding that under the AIA, if the existence of a sale is made public, the details of the invention are not required to trigger the on-sale bar).

9. *See Helsinn Healthcare S.A.*, 139 S. Ct. 628, 630 (2019).

10. *See id.* at 633 (affirming the circuit decision that “secret sales” can invalidate a patent under the on-sale bar to patentability).

11. *Id.* at 630.

## I. HISTORY OF ON-SALE BAR IN PATENT LAW AND JUDICIAL INTERPRETATIONS

The paramount authority for the patent right comes from the U.S. Constitution.<sup>12</sup> Under Article I Section 8, the Constitution expressly vests Congress the power to “promote the progress of science and useful arts, by securing for limited times to . . . inventors the exclusive right to their respective . . . discoveries.”<sup>13</sup> Congress authorizes issuing patents to inventors of new and useful inventions or improvements on inventions.<sup>14</sup> However, the inventions have to meet numerous patentability requirements in exchange for their “exclusive right.”<sup>15</sup> These requirements include patentable subject matter,<sup>16</sup> utility,<sup>17</sup> novelty<sup>18</sup>, non-obviousness,<sup>19</sup> enablement,<sup>20</sup> written description requirement<sup>21</sup>, claim definiteness,<sup>22</sup> and best mode.<sup>23</sup>

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12. U.S. CONST. art. I, § 8, cl. 8.

13. *Id.*

14. *See* 35 U.S.C. § 101 (2015) (“Whoever invents or discovers any new and useful process, machine, manufacturer, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”).

15. U.S. CONST. art. I, § 8, cl. 8.

16. *See* 35 U.S.C. § 101 (2015) (intending the statutory subject matter to include “process, machine, manufacturer, or composition of matter, or any improvement thereof). *See, e.g.,* *Diamond v. Diehr*, 450 U.S. 175, 182 (1981) (“Congress intended statutory subject matter to ‘include anything under the sun that is made by man.’”).

17. *See* 35 U.S.C. § 101 (2015) (intending the inventions or improvements to be “useful”).

18. *See* 35 U.S.C. § 101 (2015) (intending the inventions or improvements to be “new”); *see also* 35 U.S.C. § 102(a) (2015).

19. *See* 35 U.S.C. § 103 (2015) (“A patent for a claimed invention may not be obtained, . . . if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains.”).

20. *See* 35 U.S.C. § 112(a) (2015) (requiring the specification to “enable any person skilled in the art to which it pertains” to make and use the same).

21. *See id.* (requiring the specification to contain a “written description of the invention”).

22. *See id.* (requiring the written description to be in “full, clear, concise, and exact terms”).

23. *See id.* (requiring the specification to “set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention”).

## A. ON-SALE BAR UNDER THE PRE-AIA § 102(B)

The on-sale bar is a limitation on patentability under the novelty requirement. Under the statutory language of the pre-AIA § 102(b), an inventor should be entitled to a patent if “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.”<sup>24</sup> Under the pre-AIA § 102(b), the combination of the “on sale” bar to patentability and the one-year grace period is “an attempt by Congress to balance the interests of the inventor with the interests of the public.”<sup>25</sup> If an invention was commercially exploited more than one year before filing, the invention would become ineligible for a patent because otherwise concealing would be encouraged and the statutory patent term would be unjustly extended.<sup>26</sup> Indeed, the primary policy of on-sale bar is “to prevent inventors from exploiting commercial value of their invention while deferring beginning of statutory patent term.”<sup>27</sup> Other policies include “encouraging prompt and widespread disclosure of inventions to the public, discouraging the removal of inventions from the public domain when the public has come to rely on their ready availability, and giving inventors a reasonable period to discern potential value of invention.”<sup>28</sup>

The *Pfaff* two-factor test was often used by courts to determine whether a “sale” existed under the pre-AIA § 102(b).<sup>29</sup> Specifically,

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. That condition may be satisfied in at least two ways: 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

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24. 35 U.S.C. § 102(b) (2000), amended by Pub. L. No. 112-29, § 3(b)(1), (n), 125 Stat. 285, 293 (2011).

25. *Gould Inc. v. U.S.*, 579 F.2d 571, 580 (Ct. Cl. 1978).

26. See generally *Monon Corp. v. Stoughton Trailers, Inc.*, 915 F. Supp. 13 (N.D. Ill. 1996) (holding that commercialization of invention more than one year before the patent application invalidated the patent).

27. *James River Corp. of Virginia v. Hallmark Cards, Inc.*, 915 F. Supp. 968, 997 (E.D. Wis. 1996) (internal citation omitted).

28. *Id.*

29. See *Helsinn Healthcare S.A.*, 2016 WL 832089, at \*38.

descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention.<sup>30</sup>

Therefore, under the pre-AIA § 102(b), not only does the on-sale bar prohibit a public commercial sale, it also bars a “secret” sale as long as it meets the two conditions in *Pfaff*. In other words, a prior sale could invalidate a patent regardless of whether it was kept secret or not.<sup>31</sup>

#### B. ON-SALE BAR UNDER THE AIA § 102(A)(1)

On September 16, 2011, Congress passed the AIA which was signed into law.<sup>32</sup> The purpose of the AIA was “to ensure that the patent system in the 21<sup>st</sup> century reflects the constitutional imperative.”<sup>33</sup> In promulgating the AIA, Congress focused their attention on the value of harmonizing the U.S. patent system with the best parts of other major patent systems in the industrialized world for the benefit of U.S. patent holders, improving patent quality and providing a more efficient system for challenging patents, and reducing unwarranted litigation costs.<sup>34</sup> In addition, a House Report emphasized that the AIA was promulgated to maintain the United States’ competitive edge in the global economy.<sup>35</sup>

Among other significant changes in the patent system made by the AIA, the on-sale bar provision under the pre-AIA § 102(b) has been changed to a new provision.<sup>36</sup> Under the new § 102(a)(1), one is not entitled to a patent if “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.”<sup>37</sup> The specific changes made in § 102(a)(1) as compared to the old pre-AIA § 102(b) include: removing the phrase “in this country” limitations as applied to “public use” and “on sale,” and adding

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30. *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 67–68 (1998).

31. *Id.*

32. Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 285 (2011).

33. H.R. REP. NO. 112-98, at 40 (2011).

34. *See id.* at 39–40 (discussing various arguments for changes to the patent law).

35. *See id.* at 40. (“If the United States is to maintain its competitive edge in the global economy, it needs a system that will support and reward all innovators with high quality patents.”).

36. *See* 35 U.S.C. § 102(a)(1) (2015) (amending 35 U.S.C. § 102(b) (2000)).

37. *Id.*

a catch-all phrase “available to the public.”<sup>38</sup> The House Report also explained that the catch-all phrase is added “to clarify the broad scope of relevant prior art, as well as to emphasize the fact that it must be publicly accessible.”<sup>39</sup> The United States Patent and Trademark Office (“USPTO”) interpreted the addition of the catch-all phrase as excluding secret sales and requiring public disclosure of the details of the claimed invention for the purpose of the on-sale bar.<sup>40</sup> The Federal Circuit did not directly answer this question; instead it limited its *Helsinn* holding to the extent 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 the sale.”<sup>41</sup> The meaning of “sale” in the AIA § 102(a)(1) and its effect on triggering the on-sale bar under the AIA remained unclear until the recent Supreme Court’s *Helsinn* decision.<sup>42</sup>

## II. HELSINN HEALTHCARE S.A. V. TEVA PHARM. USA, INC.

### A. THE AGREEMENTS MADE BEFORE THE CRITICAL DATE AND THE HATCH-WAXMAN LITIGATION KEPT HELSINN’S INVENTION CONFIDENTIAL FROM THE PUBLIC

Helsinn was the owner of the four patents-in-suit related to intravenous formulations of palonosetron for treating cancer patients with chemotherapy-induced nausea and vomiting.<sup>43</sup> Almost two years before applying for a patent, Helsinn entered

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38. *See id.*; H.R. REP. NO. 112-98, at 43 (2011) (removing the geographic limitations of prior art).

39. *Id.*

40. MANUAL OF PATENT EXAMINING PROCEDURE § 2152.02(d) (9th ed. 2018) (“The pre-AIA 35 U.S.C. 102(b) ‘on sale’ provision has been interpreted as including commercial activity even if the activity is secret . . . . AIA 35 U.S.C. 102(a)(1) uses the same ‘on sale’ term as pre-AIA 35 U.S.C. 102(b). The ‘or otherwise available to the public’ residual clause of AIA 35 U.S.C. 102(a)(1), however, indicates that AIA 35 U.S.C. 102(a)(1) does not cover secret sales or offers for sale. For example, an activity (such as a sale, offer for sale, or other commercial activity) is secret (non-public) if it is among individuals having an obligation of confidentiality to the inventor.”).

41. *Helsinn Healthcare S.A.*, 855 F.3d at 1371. 1

42. *See generally Helsinn Healthcare S.A.*, 139 S. Ct. at 630 (“The addition of the catchall phrase ‘or otherwise available to the public’ is not enough of a change for the Court to conclude that Congress intended to alter the meaning of ‘on sale.’”).

43. *Helsinn Healthcare S.A.*, 855 F.3d at 1359–60.

into two agreements with MGI, an oncology-focused pharmaceutical company.<sup>44</sup> These two agreements constitute a license agreement and a supply and purchase agreement.<sup>45</sup> While the agreements were announced in a joint press release of the two corporations and redacted copies of both agreements were filed by MGI with the SEC, nothing regarding the specific inventions was disclosed to the public.<sup>46</sup> According to the supply and purchase agreement, MGI agreed to purchase exclusively from Helsinn, and Helsinn agreed to supply MGI's requirements of the invented products, if approved by the FDA.<sup>47</sup> The price, method of payment, and method of delivery were all specified in the supply and purchase agreement.<sup>48</sup> The license agreement further stated that, if in the event that the FDA denied the sale of the product, Helsinn could terminate the license agreement, and if the license agreement were terminated, the supply and purchase agreement would "terminate automatically."<sup>49</sup>

After signing of the agreements, but before the critical date, Helsinn continued its Phase III trial and filed its New Drug Application in September 2002.<sup>50</sup> On January 30, 2003, Helsinn filed a provisional patent application directed to its invention products, and other related patent applications subsequently.<sup>51</sup> All patents were listed in the FDA's "Orange Book."<sup>52</sup>

Teva filed an ANDA seeking FDA approval to market a generic product of Helsinn's patented new drugs in 2011.<sup>53</sup> A "Paragraph IV" certification was included in the ANDA filing, asserting that the patents-in-suit were invalid and/or not infringed.<sup>54</sup> Hence, Helsinn brought a suit under the Hatch-Waxman Act, 35 U.S.C. § 271(e)(2)(A).<sup>55</sup>

After a bench trial, the district court found, among other things, that the AIA changed the meaning of the on-sale bar and

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44. *Id.* at 1361.

45. *Id.*

46. *Id.*

47. *Id.*

48. *Id.* at 1362.

49. *Id.*

50. *Id.*

51. *Id.*

52. *Id.*

53. *Id.* at 1363.

54. *Id.*

55. *Id.*



the AIA § 102(a)(1) now “requires a *public* sale or offer for sale of the claimed invention.”<sup>56</sup> That is, under the AIA, a sale could trigger the on-sale bar only when the details of the invention were disclosed publicly.<sup>57</sup>

#### B. THE FEDERAL CIRCUIT REVERSED AND HELD THAT A SECRET SALE CONSTITUTES PRIOR ART UNDER THE AIA

Teva appealed to the Court of Appeals of the Federal Circuit. On May 1, 2017, the Federal Circuit decided that an invention was made available to the public and thus triggered the bar when there was a commercial offer or contract to sell a product embodying the invention and that sale was made public, regardless whether the details of the invention were disclosed in the terms of sale or not.<sup>58</sup> There should be no need for the public to be aware of the subject matter of the invention from a sale disclosure to trigger the on-sale bar under the AIA; a disclosure of the existence of the transaction would suffice.

The Federal Circuit started its reasoning by citing to an earlier case law, *In re Caveney*.<sup>59</sup> The court stated that following *In re Caveney*, “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.”<sup>60</sup> The court refused to interpret the floor statements as related to anything more than the sale’s accompanying public uses.<sup>61</sup> Finally, the court rejected Helsinn’s interpretation of the phrase “otherwise available to the public” to exclude a secret sale under the AIA by explaining that such a reading “would work a foundational change in the theory of the statutory on-sale bar.”<sup>62</sup>

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56. *Id.*

57. *See id.* (finding 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.”).

58. *Id.* at 1370–71.

59. *Id.* at 1367–68 (citing to *In re Caveney*, 761 F.2d 671 (Fed. Cir. 1985)).

60. *See id.* (citing *In re Caveney*, 761 F.2d at 675).

61. *See id.* at 1368. The Federal Circuit declined to interpret the floor statements as to on-sale bar generally, but held that “[a]t most the floor statements show an intent ‘to do away with precedent under current § 102 law’ and the precedent was referred to ‘certain secret uses to be invalidating under the ‘public use’ prong of § 102(b).” *Id.*

62. *See id.* at 1369.

Citing to numerous earlier cases,<sup>63</sup> the court concluded that since the earlier cases encompassed the application of the on-sale bar to secret sales based on policy reasons stated in *Pennock*,<sup>64</sup> the Congress would not have considered to overturn all the precedents with the addition of the phrase “otherwise available to public” under the AIA.<sup>65</sup>

C. THE SUPREME COURT GRANTED CERTIORARI TO ADDRESS THE ON-SALE BAR DISPUTE UNDER THE AIA AND HEARD THE CASE ON DECEMBER 4, 2018

On February 28, 2018, Helsinn filed the Petition for a Writ of Certiorari to the U.S. Supreme Court.<sup>66</sup> On June 25, 2018, the Supreme Court granted the petition.<sup>67</sup>

According to Helsinn’s brief filed on August 23, 2018, the presented question was directed to whether a secret sale triggered the on-sale bar under the AIA.<sup>68</sup> Helsinn focused on

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63. See *id.* at 1369–71. The Federal Circuit cited *Pennock v. Dialogue*, 27 U.S. (2 Pet.) 1, 19, 7 L. Ed. 327 (1829), which held that a secret sale “would materially retard the progress of science and useful arts, and give a premium to those who should be least prompt to communicate their discoveries.” The court further cited *RCA Corp. v. Data Gen. Corp.*, 887 F.2d 1056, 1060 (Fed. Cir. 1989), stating that the prior cases explicitly rejected a requirement to publicly disclose the details of the invention in the terms of sale to trigger the on-sale bar. Further, the court cited *Abbott Laboratories v. Geneva Pharmaceuticals, Inc.*, 182 F.3d 1315, 1317–18 (Fed. Cir. 1999), explaining that there was no requirement for the public to know that the product sold was the invention.

64. See *Helsinn Healthcare S.A.*, 855 F.3d at 1369. In *Pennock*, the Supreme Court explained that a sale of an invented product while withholding the invention from the public should be invalidated because failing to do so “would materially retard the progress of science and useful arts, and give a premium to those who should be least prompt to communicate their discoveries.” *Pennock*, 27 U.S. (2 Pet.) 1, 19, 7 L. Ed. 327.

65. See *Helsinn Healthcare S.A.*, 855 F.3d at 1371 (“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 . . .” and “[i]f 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.”).

66. *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 855 F.3d 1356 (Fed. Cir. 2017), *petition for cert. filed*, 86 U.S.L.W. 3635 (U.S. Feb. 28, 2018) (No. 17-1229).

67. *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 138 S. Ct. 2678 (Mem) (2018).

68. See Brief for Petitioner at (I), *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 139 S. Ct. 628 (2019) (No. 17-1229), 2018 WL 4043179, at \*I.

three arguments: the catch-all phrase,<sup>69</sup> the legislative history, and the USPTO's embraced interpretation.<sup>70</sup> The statutory interpretation was the major focus in Helsinn's argument. Helsinn read the AIA § 102(a)(1) as a provision enumerating two categories of patent-defeating prior art followed by a third category, which in turn set out three additional ways of putting an invention into the public domain, with two enumerated subcategories followed by a catch-all subcategory.<sup>71</sup> In other words, Helsinn argued that Congress intended to link the catch-all phrase to the preceding terms.<sup>72</sup> Helsinn further explained that under the *noscitur a sociis* canon, the term "on-sale" should be interpreted based on the terms surrounding it and here every subcategory, including the two patent-related subcategories and the immediate preceding subcategory ("in public use"), meant public availability.<sup>73</sup> Under such interpretation, "a sale qualifies as patent-defeating prior art only if it makes the claimed invention 'available to the public.'"<sup>74</sup>

Numerous special interest groups submitted *amicus* briefs for Helsinn about the same time, including Congressman Lamar Smith, who is one of the lead sponsors of the AIA.<sup>75</sup> Congressman Smith's brief explained and argued that the term "publicly disclosed" in § 102(b)(1)(B) and the term "disclosed" in § 102(a)(1) can be regarded as "perfect synonyms," and as a result the use of "disclosed" and "publicly disclosed" in the same section did not render "publicly disclosed" superfluous.<sup>76</sup> It

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("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.")

69. *See id.* at 4 ("The new catch-all provision informs the meaning of the language that precedes it, clarifying that a sale qualifies as prior art only if the sale makes the claimed invention 'available to the public.'").

70. *See id.*

71. *See id.* at 14.

72. *See id.* at 15.

73. *See id.*

74. *See id.*

75. *See, e.g.*, Brief for Congressman Lamar Smith as Amicus Curiae Supporting Petitioner, *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 139 S. Ct. 628 (2019) (No. 17-1229), 2018 WL 4043325.

76. *See id.* at 26–28. The Amicus Brief pointed out that the term "disclosed" imposed a drafting challenge to Congress because the term "disclosed" is used in the AIA as a generic term, which would cover both disclosures under § 102(a)(1) and § 102(a)(2). *Id.* at 27. Using "disclosure" would make a patent-

further argued that the mere repetition of the term “on sale” from the pre-AIA § 102(b) was not a sufficient basis for overriding the new statutory context and the old term must be construed in its new statutory context.<sup>77</sup> Additionally, it pointed out that the policy concerns by the Federal Circuit were not necessary under the AIA.<sup>78</sup>

The Pharmaceutical Research and Manufacturers of America (PhRMA) also submitted an *amicus* brief for *Helsinn*.<sup>79</sup> The PhRMA, representing the country’s leading innovative biopharmaceutical research companies, expressed its concerns about the impact of the *Helsinn* decision on innovation drugs given that every new drug in the U.S. has to be approved by FDA.<sup>80</sup> The brief distinguished *Helsinn*’s situation from the old

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filing disclosure under § 102(a)(2) trigger the start of the “grace period,” which it should not. *Id.* Adding the term “publicly” before “disclosure” helps Congress solve the problem: “the use of the term *publicly disclosed* in § 102(b)(1)(B) removed the possibility that its prior art exclusion would apply, for example, to the situation where the inventor had made a non-public disclosure in a provisional patent application that later was abandoned and had never become public.” *Id.* at 27–28 (emphasis added). In other words, as the Brief explained, *publicly disclosed* is the “perfect synonym” for *disclosed* under § 102(a)(1). *Id.* at 28 (emphasis added).

77. *See id.* at 29–30 (“Finding that ‘on sale’ carries with it every old meaning, . . . makes no sense in the context of a new patent statute. . . .”) The Brief provided the example of the term “prior art,” arguing that although Congress reused the term “prior art,” the term did not retain all of its old meaning under the new Patent Act. *Id.* at 29. “Like the term ‘prior art,’ the term ‘on sale’ must be construed in its new statutory context . . .” *Id.* at 30.

78. *See id.* at 30–33 (“The entire purpose of the patent system is to encourage disclosure over secrecy . . . . A patent act fulfilling this primary purpose of the patent laws would provide inventors with a continuing incentive to disclose rather than maintain secrecy. This first-inventor-to-file system operates to this end in part because prior art is measured based on the effective filing date of the claimed invention . . . the ‘on sale’ bar that the Federal Circuit imposed on this first-inventor-to-file system simply negates the incentive for public disclosure.”).

79. Brief for Pharmaceutical Research and Manufacturers of America Supporting Petitioner, *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 139 S. Ct. 628 (2019) (No. 17-1229), 2018 WL 4179033.

80. *See id.* at 1 (“In view of the risky biopharmaceutical research and development process, which has a significant failure rate, and the substantial requirements of the FDA to demonstrate safety and efficacy of new products, those results are not obtained cheaply. Since 2000, PhRMA member companies have invested more than \$600 billion in the search for new treatments and cures, including an estimated \$71.4 billion in 2017 alone.”).

cases cited by Teva,<sup>81</sup> and concluded that none of these cited cases suggested that the Supreme Court “affirmed the invalidation of a patent in which a prior sale kept confidential from the public some facet of the claimed invention.”<sup>82</sup>

The United States, representing the interests of the USPTO and several other agencies of the federal government, submitted its *amicus* brief supporting Helsinn.<sup>83</sup> In addition to the arguments that the statutory text and the legislative history supported Helsinn’s interpretation of the AIA § 102(a)(1), the brief also argued that the agreements between Helsinn and MGI did not make the invention “available to the public” because, for at least one reason, that an invention was “on sale” only when an invented product could be purchased by its expected ultimate customers.<sup>84</sup> Cautioning that treating a distributor as “the public” would place small companies that require assistance at an unwarranted disadvantage, the brief proposed that “[p]reparatory steps within such a company would not trigger the on-sale bar until the product’s expected ultimate purchasers were actually able to buy it.”<sup>85</sup>

Respondent Teva filed a brief on October 9, 2018. In Teva’s brief, two questions were presented: the first one was directed to the meaning of “on sale” under the AIA, and the second one was directed to whether the transaction in question nevertheless put the invention “on sale” under a new reading of “on sale.”<sup>86</sup> Teva’s

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81. *See id.* at 9–12 (“None of these cases addresses whether a sale of the invention, the terms of which sale bind the parties to confidentiality, bars a subsequent patent to the invention.”).

82. *Id.* at 9.

83. Brief for the United States as Amicus Curiae Supporting Petitioner, *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 139 S. Ct. 628 (2019) (No. 17-1229), 2018 WL 4179034.

84. *See id.* at 26 (responding to Teva’s suggestion that “even if an invention must be ‘available to the public’ in order for the on-sale bar to be triggered, that requirement is satisfied here in part because ‘MGI is a member of the public’”).

85. *Id.* at 28. The Brief further distinguished *Pfaff*, explaining that Texas Instruments in *Pfaff* was indeed the ultimate purchaser of the patented product, i.e., the sockets as discrete units of commerce, because Texas Instruments presumably intended to use the sockets to manufacture its own products. *See id.* at 29.

86. *See* Brief for Respondents at i, *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 139 S. Ct. 628 (2019) (No. 17-1229) (“The questions presented are . . . [w]hether the 2011 amendment changed the meaning of ‘on sale’ so that commercial sales no longer start the grace period unless they also make the invention ‘available to the public’ [and]. . . [i]f the 2011 amendment changed the meaning of ‘on sale,’ whether petitioner nonetheless placed its invention ‘on

argument focused on the precedent reading of “on sale” under the pre-AIA § 102,<sup>87</sup> the plain meaning of the term “on sale,”<sup>88</sup> the “clear language” canon,<sup>89</sup> the sole purpose intended by the catch-all phrase,<sup>90</sup> and the superfluous canon.<sup>91</sup> Teva emphasized that if Congress indeed intended to change the well-settled meaning of “on sale,” it would have acted expressly instead of vaguely.<sup>92</sup> Teva argued that the term “on sale” was a “term of art” with a well-settled judicial interpretation, and the fact that Congress left the term intact in the new AIA suggested that it intended to keep the same meaning, especially when there are many alternative terms that Congress could have used if such a change was intended.<sup>93</sup> In reply to Helsinn’s argument that the catch-all phrase changed the meaning of “on sale,” Teva argued that the Congress added the catch-all phrase for only one purpose: to cover prior art that would not be qualified under the pre-AIA § 102, such as oral presentations.<sup>94</sup>

Many groups also submitted *amicus* briefs for Respondent, including Congresswoman Zoe Lofgren,<sup>95</sup> who argued that the text “on sale” meant when it was offered for sale and that such

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sale’ when it sold the invention for \$11 million and disclosed every element of the invention to the buyer.”).

87. *See id.* at 18 (“[T]his Court has long held – from *Pennock* through *Pfaff* – that a sale or offer for sale to even *one* buyer, . . . triggers the on-sale bar regardless of what is disclosed to the public.”).

88. *See id.* (relying on the dictionary meaning of “on sale”).

89. *See id.* (“Had Congress intended to change the ordinary and settled meaning of ‘on sale,’ it would have done so directly and expressly.”).

90. *See id.* at 19 (arguing that the catch-all phrase was added for only one purpose to cover oral presentation and that the term “otherwise” does not mean that everything previously covered would fall into the catch-all).

91. *See id.* at 20 (explaining that the use of “disclosure” and “public disclosure” at the same time in Section 102 further evidenced that the “on sale” needs not to be “public”).

92. *See id.* at 26. (“But assertions that Congress changed the Court’s settled interpretation of statutory language must clear a high bar, especially when based on changes to *nearby* statutory language rather than the operative text.”).

93. *See id.* at 28 (“Had Congress meant to change its established meaning as Helsinn suggests, it had several obvious ways to do so that would have tracked the surrounding bars (“*patented*,” “described in a printed *publication*,” or in “*public use*”).”).

94. *See id.* at 30; *see supra* note 90 and its accompanying text.

95. *See generally* Brief for Congresswoman Zoe Lofgren as Amicus Curiae Supporting Respondent, *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 139 S. Ct. 628 (2019) (No. 17-1229).

interpretation was supported by precedents,<sup>96</sup> and the phrase “or otherwise available to the public” was to broaden but not to restrict the range of conduct.<sup>97</sup> The brief further questioned the reliability of the legislative history provided by Helsinn,<sup>98</sup> arguing that Congress explicitly rejected proposals that would have a sweeping change to the on-sale bar,<sup>99</sup> and purposely preserved the old terms under the new AIA.<sup>100</sup>

Additionally, a group called “Forty-Five Intellectual Property Professors” also submitted its *amicus* brief,<sup>101</sup> arguing that, as to the legislative history, the fact that Congress adopted the same terms: “public use” and “on sale”, in the new AIA instead of eliminating both from the new statute suggested Congress did not intend to remove secret sales from prior art.<sup>102</sup> It further noted that, as also noted by Congresswoman Lofgren, the legislative history provided by Helsinn was not reliable because it was a colloquy, or individual senator statement, but not the Committee as a whole.<sup>103</sup> The Brief further stressed that Helsinn’s interpretation of the AIA § 102(a)(1) would “radically

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96. *See id.* at 3–4 (“Though old, these cases are hardly relics, as their holdings have continued to be applied in more recent decisions.”).

97. *See id.* at 7–8 (“Congress added the phrase ‘or otherwise available to the public’ to broaden the range of conduct that could invalidate a patent, not to restrict it.”).

98. *See id.* at 10–11 (“The AIA’s legislative history provides no justification for departing from the plain language of the on-sale bar . . . . No one understands the legislative history behind reenacting the on-sale bar better than Rep. Lofgren, who championed retaining the ‘on-sale’ language that ultimately remained in the AIA against vocal opposition in Congress.”).

99. *See id.* at 11–12 (“Congress was aware of concrete proposals that would have enacted just such a sweeping change. Yet Congress *did not adopt* these proposals.”).

100. *See id.* at 12–14 (“Instead of adopting language that would have replaced the on-sale bar with a publicity-based standard, Congress preserved the on-sale bar in the AIA. . . .”).

101. Brief for 45 Intellectual Property Professors as Amicus Curiae Supporting Respondent, *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 139 S. Ct. 628 (2019) (No. 17-1229), 2018 WL 4941710.

102. *See id.* at 7–8 (“The history of the drafting of the AIA suggests that it did not intend to narrow the universe of prior art to exclude commercial uses and sales that were not disclosed to the public.”).

103. *See id.* at 9–10 (arguing that the “official reports written by the Committee that advanced the legislation to the floor” is a stronger form of legislative history than a “colloquy”); *see also* Brief for Congresswoman Zoe Lofgen as Amicus Curiae Supporting Respondent, *supra* note 95.

rewrite the law of prior art.”<sup>104</sup> The Brief cautioned that the “very old and very much relied-upon body of law” should not be changed so radically with an ambiguous phrase in the new statute, and it was “highly unlikely” Congress intended such change.<sup>105</sup>

On November 8, 2018, Helsinn filed a reply.<sup>106</sup> After reminding the Supreme Court that the AIA “worked a sea change in American patent law,”<sup>107</sup> the reply went on to point out that the Teva failed to recognize the clear plain meaning of the catch-all term in § 102(a)(1),<sup>108</sup> that Teva’s reliance on the doctrine of congressional ratification lacked merit,<sup>109</sup> and that the “publicly disclose” language in § 102(b)(1) did not render the meaning of “disclose” in § 102(a)(1) superfluous.<sup>110</sup> In addition, Helsinn argued that Teva failed to recognize the importance of the committee report in legislative history but to look at a “general recognition.”<sup>111</sup> Finally, Helsinn argued that the plain-

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104. *See id.* at 11 (“Petitioner’s reading . . . attributes a quite radical intent and effect to the new prior art provision in the AIA: it would sweep away scores of cases, accumulated over two centuries, defining in great detail each of the specific categories of prior art listed in AIA § 102(a). Opinions by giants in the patent field, from Joseph Story to Learned Hand to Giles Rich – gone, by virtue of one added word in the new statute.”).

105. *Id.*

106. Reply Brief for Petitioner, *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 139 S. Ct. 628 (2019) (No. 17-1229), 2018 WL 5876912.

107. *Id.* at 1.

108. *See id.* at 2–7 (arguing that the “otherwise” has been interpreted as a catch-all term modifying the precedent terms consistently by the Supreme Court and that Teva misunderstood the structure of the statute).

109. *See id.* at 8–12 (explaining that “[t]he doctrine of congressional ratification has two elements: (1) Congress must ‘reenact the relevant statutory language without change,’ and (2) the ‘supposed judicial consensus must be so broad and unquestioned that the Court must presume Congress knew of and endorsed it.’ (citation omitted). Respondents cannot satisfy either element.”). Most interestingly, Helsinn cited *Pfaff* to explain that the Court always stressed the critical “public domain.” *Id.* at 10 (citing to *Pfaff* in which the Court reiterated that the on-sale bar prevents an inventor from ‘removing existing knowledge from public use.’”).

110. *See id.* at 12–13. By criticizing Teva’s argument under the “superfluous” doctrine “both confusing and incorrect,” Helsinn once again explained in its Reply that the word “publicly” in § 102(b)(1)(B) clarifies that “the subject matter disclosed” falls within the ambit of the provision only if the earlier disclosure of the subject matter is itself public in order to avoid potential absurd results which are illustrated in the hypothetical examples given by Helsinn. *Id.*

111. *See id.* at 13 (“Respondents largely ignore the authoritative committee reports that manifest that [congressional] intention. Instead, they invoke a ‘general recognition,’ pieced together from the drafting history of bills that



language interpretation served better the purposes of the AIA and the patent system.<sup>112</sup>

On December 4, 2018, the Supreme Court heard the oral argument. The argument suggested that the court would resolve the problem from the perspective of statutory language.<sup>113</sup> The parties focused mainly on two issues.<sup>114</sup> The first issue was the function of the new language “otherwise available to the public.”<sup>115</sup> That is, whether the phrase was intended to modify and clarify the preceding terms,<sup>116</sup> or it was simply added to include items that were not covered by the pre-AIA § 102,<sup>117</sup> or both.<sup>118</sup> The second issue was the meaning of the term “on sale.”<sup>119</sup> Petitioner Helsinn argued that “on sale” was distinguishable from “sale” because only a “sale” that was open to public can constitute an item “on sale.”<sup>120</sup> Helsinn further argued that “on sale” would not apply when products were sold to distributors only.<sup>121</sup> Majority of the Justices who spoke at the hearing seemed to take the position that the catch-all phrase was not intended to modify the preceding terms and the term “on sale” included both public and private sale.<sup>122</sup> Chief Justice

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Congress abandoned, that Congress did not intend to require that all prior-art sales make a claimed invention publicly available . . . .That is the epitome of ‘entering a crowded cocktail party and looking over the heads of the guests for one’s friend.’”). Helsinn in its Reply reminded the Supreme Court that it has repeatedly noted that Committee reports are the most reliable source for legislative history. *Id.* at 15.

112. *See id.* 18–20 (“[S]uch a requirement preserves the fundamental quid pro quo of patent law, promotes predictability in the patent system, and ensures that small inventors are on equal footing with their larger counterparts.”).

113. *See* Ronald Mann, *Argument Analysis: Justices Debate Revised Language in Patent-Priority Statute*, SCOTUSBLOG (Dec. 4, 2018, 7:50 PM), <http://www.scotusblog.com/2018/12/argument-analysis-justices-debate-revised-language-in-patent-priority-statute/>.

114. *See generally* Oral Argument, *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 139 S. Ct. 628 (2019) (No. 17-1229), [https://www.supremecourt.gov/oral\\_arguments/argument\\_transcripts/2018/17-1229\\_p702.pdf](https://www.supremecourt.gov/oral_arguments/argument_transcripts/2018/17-1229_p702.pdf).

115. *See generally id.*

116. *Id.* at 26, ¶¶ 1–5.

117. *Id.* at 36, ¶¶ 5–13.

118. *Id.* at 13, ¶¶ 4–12.

119. *See generally id.* at 3–7.

120. *Id.* at 4, ¶¶ 11–16.

121. *Id.* at 22–24.

122. *Id.* Chief Justice Roberts noted that Helsinn’s interpretation that on sale requires public accessibility “might not be consistent with the actual meaning of the word ‘sale.’” *Id.* at 4, ¶¶ 2–4. Justice Kavanaugh questioned that

Roberts noted that the word “sale,” by its plain meaning, included both public and private sales.<sup>123</sup> Newly appointed Justice Kavanaugh, in response to Helsinn’s hypothetical regarding a private sale, stated that “it’s pretty hard to say something that has been sold was not on sale.”<sup>124</sup> Justice Ginsburg implied that the on-sale bar rule under the pre-AIA § 102(b) was a well-settled one including secret sale, and further noted that Helsinn’s argument would have suggested that “on sale” never included the secret sale.<sup>125</sup> While Helsinn replied that the AIA was intended to clarify the proper understanding of the phrase “on sale,” Justice Kavanaugh stated that such clarification was a “terrible” one.<sup>126</sup>

As to the new language of the AIA § 102(a)(1), Helsinn argued that this new provision was intended to achieve two objectives: to expand the scope of prior art and also to restrict it.<sup>127</sup> Helsinn further argued that the reason why Congress retained the terms “public use” and “on sale” was to abrogate the outlier cases involving the public use bar or on-sale bar where there was no public availability but retain the general jurisprudence concerning these terms.<sup>128</sup> Justice Breyer expressed his concern about Helsinn’s argument that the Supreme Court had never ruled that the on-sale bar could be triggered without any public accessibility by citing *Bonito Boats*.<sup>129</sup> However, Justice Breyer, recognizing the existence of

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“[i]sn’t it always the case that if you offer it to even one person or to a small group of people, it’s on sale?” *Id.* at 5, ¶¶ 15–18. Justice Breyer noted that the precedent cases suggest that the on-sale rule includes private sales and its purpose is to prevent people from benefiting from their invention and extending the monopoly. *Id.* at 6, ¶¶ 14–24.

123. *Id.* at 4, ¶¶ 6–10.

124. *Id.* at 5, ¶¶ 1–2.

125. *Id.* at 11, ¶¶ 1–5.

126. *Id.* at ¶ 23. (“[I]f that was a clarification, it was a terrible clarification because there were a lot of efforts, as you well know, to actually change the ‘on sale’ language, and those all failed.”)

127. *Id.* at 13, ¶¶ 4–12. (“ . . . the catch-all provision . . . was to achieve two objectives: to make sure that they reached all forms of prior art, such as oral presentations, PowerPoint presentations, and the like, and also to clarify that any form of prior art must be publicly available.”)

128. *See id.* at 13 (“I do think that what Congress was doing was abrogating some of the outlying lower court decisions that had extended both the on-sale bar and the public use bar to cases where there was not public availability.”)

129. *Id.* at 17. Justice Breyer stated: “in *Bonito Boats*, this Court, while it isn’t necessary for the holding, does quote Learned Hand, and it does say it is a condition upon the inventor’s right to a patent that he shall not exploit his

“experimental exceptions” in patent law, proposed that the question at issue may be a question of what was on sale, and not what was public or private.<sup>130</sup> Although *Helsinn* and *Amicus* United State argued that the law was not settled as to whether public availability must be required for triggering on-sale bar, Justice Kagan seemed to disagree and implied that *Pfaff* had already settled the issue.<sup>131</sup> She further questioned *Amicus* United States whether the new AIA language was enough to unsettle the law which was presumed to be settled, and *Amicus* United States answered no.<sup>132</sup>

Respondent Teva argued that the catch-all phrase was to create a new category of prior art that was not covered by the pre-AIA § 102 and that was the only purpose of the catch-all phrase.<sup>133</sup> A few Justices seemed to disagree. In order to facilitate the understanding of the term “otherwise,” Justice Breyer provided a hypothetical string of “basketball, running, swimming, or otherwise, or games that otherwise involve a ball” and “Fiber One bran flakes, fruit, tea, and food that otherwise is . . . fiber heavy” and suggested that the use of “otherwise” in those examples was “awkward.”<sup>134</sup> Justice Kagan provided a “brownie” hypothetical and implied that, with the “otherwise contains nuts” phrase, nut-less brownie should be okay to buy, and maybe by analogy the secret sales (like nut-less brownie which was excluded by the qualifying “otherwise” phrase) should not be a prior art under the new AIA § 102(a)(1) language.<sup>135</sup>

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discovery competitively after it is ready for patenting. He has to go ahead and patent it or keep it a secret forever . . . That seemed to me the clear – pretty clear rationale of Learned Hand, of why the Court did that in *Bonito Boats*, of why Justice Story said what he said, and I think it’s that the Lemley brief was relying upon when they made that statement.”

130. *Id.* at 18, ¶¶ 15–19, 20–24.

131. *Id.* 25–26.

132. *Id.* at 28.

133. *Id.* 35–37. Teva explained that examples included in the new category are “oral presentation at a conference without slides,” “PowerPoint slides that get distributed,” “a collaboration app which is not on the Internet and is not indexed and would not count as a printed publication but ought to be the kind of disclosure.” *Id.* at 37. Teva further argued that the new category’s primary function was to create new invalidating prior art disclosures that were not invalidating under pre-AIA (i.e., expanding the scope of prior art), but it would be “strange” for Congress, at the same time, narrowing the scope of prior art by “the strangest implication.” *Id.*

134. *Id.* at 41–42.

135. *Id.* at 43–45.

Finally, Justice Kagan questioned whether third-party secret sales would trigger on-sale bar, and Teva answered yes.<sup>136</sup>

#### D. THE SUPREME COURT AFFIRMED FEDERAL CIRCUIT'S DECISION

On January 22, 2019, less than two months after the oral hearing, the Supreme Court unanimously affirmed the Federal Circuit's decision and Justice Thomas delivered the Supreme Court's opinion.<sup>137</sup> Justice Thomas cited *Pfaff* at the beginning of the opinion, and stated the *Pfaff* two elements to determine the "on sale" under the pre-AIA § 102(b).<sup>138</sup> He conceded that the precise question had never been addressed by the Supreme Court, but explained that the precedents suggested that there was no requirement of public availability to trigger the on-sale bar.<sup>139</sup> Justice Thomas seemed to give great deference to the Federal Circuit and agreed that "secret sales" could constitute prior art under the on-sale bar.<sup>140</sup> Based on both of the Supreme

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136. *Id.* at 57.

137. *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, *supra*. note 9.

138. *Id.* at 628. ("More than 20 years ago, this Court determined that an invention was 'on sale' within the meaning of an earlier version of § 102(a) when it was 'the subject of a commercial offer for sale' and 'ready for patenting.'")

139. *Id.* 633

Although this Court has never addressed the precise question presented in this case, our precedents suggest that a sale or offer of sale need not make an invention available to the public. For instance, we held in *Pfaff* that an offer for sale could cause an inventor to lose the right to patent, without regard to whether the offer discloses each detail of the invention.

Other cases focus on whether the invention had been sold, not whether the details of the invention had been made available to the public or whether the sale itself had been publicly disclosed. See *e.g.*, *Consolidated Fruit-Jar Co. v. Wright*, 94 U.S. 92, 94 (1877) ("[A] single instance of sale or of use by the patentee may, under the circumstances, be fatal to the patent . . ."); *cf.* *Smith & Griggs Mfg. Co. v. Sprague*, 123 U.S. 249, 257 (1887) ("A single sale to another . . . would certainly have defeated his right to a patent . . ."); *Elizabeth v. Pavement Co.*, 97 U.S. 126, 136 (1878) ("It is not a public knowledge of his invention that precludes the inventor from obtaining a patent for it, but a public use or sale of it.").

140. *Id.* Justice Thomas emphasized that the Federal Circuit "has 'exclusive jurisdiction' over patent appeals" and "has made explicit what was implicit in our precedents." Justice Thomas further explained that the Federal Circuit "has long held that 'secret sales' can invalidate a patent. *E.g.*, *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353, 1357 (2001) (invalidating patent claims based on 'sales for the purpose of the commercial stockpiling of an invention' that 'took place in secret')." *Id.* See *Woodland Trust v. Flowertree Nursery, Inc.*, 148 F. 3d 1368, 1370 (1998) ("Thus an inventor's own prior commercial use, albeit kept

Court and the Federal Circuit precedents, Justice Thomas concluded that the meaning of “on sale” was settled in the context of the pre-AIA § 102 and Congress adopted the same judicial construction of that phrase when reenacting the same language in the AIA.<sup>141</sup> Justice Thomas further noted that, “adding the phrase ‘or otherwise available to the public’ to the statute ‘would be a fairly oblique way of attempting to overturn’ that ‘settled body of law.’”<sup>142</sup> As to the statutory interpretation of the catch-all phrase, Justice Thomas disagreed with Helsinn and concluded that the catch-all phrase was “simply not enough” to make such a significant change of a term whose meaning has already been well settled.<sup>143</sup> Thus, the Court adopted Teva’s interpretation that the catch-all phrase was only intended to include qualified prior art that had not been covered by the pre-AIA § 102 such as oral presentations.<sup>144</sup>

### III. ANALYSIS

#### A. THE SUPREME COURT LIKELY REACHED THE CORRECT CONCLUSION ALTHOUGH IT FAILED TO DISCUSS SEVERAL CRITICAL ASPECTS.

The Supreme Court’s affirmation of the Federal Circuit’s holding is likely correct. The AIA § 102(a)(1) would not require the details of the invention to be made publicly available to trigger the on-sale bar. However, it seems that the Supreme

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secret, may constitute a public use or sale under §102(b), barring him from obtaining a patent.”).

141. *Helsinn Healthcare S.A.*, 139 S.Ct. at 633–34. (“In light of this settled pre-AIA precedent on the meaning of ‘on-sale,’ we presume that when Congress reenacted the same language in the AIA, it adopted the earlier judicial construction of that phrase.”); see *Shapiro v. United States*, 335 U.S. 1, 16 (1948) (“In adopting the language used in the 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.’”).

142. *Id.* 634.

143. *Id.* at 634

As an initial matter, neither of the cited decisions addresses the reenactment of terms that had acquired a well-settled judicial interpretation. And Helsinn’s argument places too much weight on §102’s catch-all phrase. Like other such phrases, ‘otherwise available to the public’ captures material that does not fit neatly into the statute’s enumerated categories but is nevertheless meant to be covered. Given that the phrase ‘on sale’ had acquired a well-settled meaning when the AIA was enacted, we decline to read the addition of a broad catch-all phrase to upset that body of precedent.

144. *Id.*

Court focused only on the weight of the precedents but failed to discuss many relevant aspects in its decision. These relevant aspects include the plain meaning of the statutory language of § 102(a)(1), the legislative history of § 102(a)(1), and the underlying policies of the AIA. In fact, it is doubtful that whether the Supreme Court relying on the Federal Circuit's precedents is merely a convenient way to achieve the end they prefer.<sup>145</sup> It is said that the Supreme Court's opinion was written so succinctly to carefully "avoid saying anything that might upset any apple carts unnecessarily."<sup>146</sup> Nevertheless, considering the inherent ambiguity of the statutory text in § 102(a)(1) and the potential "sweeping change" on the scope of prior art which was established for 200 years, the Supreme Court likely reached the correct decision.

i. Like the Federal Circuit's Opinion, the Supreme Court's Opinion Contains Minimal Discussion of Statutory Interpretation.

In its opinion, the Federal Circuit did not apply the plain meaning rule in its statutory interpretation. In fact, the Federal Circuit did not discuss the impact of the catch-all phrase "otherwise available to the public" on the interpretation of the AIA § 102(a)(1) at all. It merely cited the precedents and concluded that it would be impossible for Congress to promulgate such a "sweeping change" rule.<sup>147</sup> Similarly, the Supreme Court did not discuss too much about the plain meaning of the catch-all phrase but instead emphasized that the meaning of the "on sale" was a settled law which should not be upset by the catch-all phrase in the new statute.<sup>148</sup>

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145. See generally Gene Quinn, *Supreme Court Decides Helsinn v. Teva, Secret Sale Qualifies as Prior Art Under the AIA*, IPWATCHDOG (Jan. 22, 2019), <http://www.ipwatchdog.com/2019/01/22/helsinn-v-teva-secret-sale-prior-art-aiid=105492/>.

146. See Ronald Mann, *Opinion Analysis: Justices Affirm Ruling that Secret Sales of Invention Bar Later Patent*, SCOTUSBLOG (Jan. 22, 2019, 4:37 PM), <https://www.scotusblog.com/2019/01/opinion-analysis-justices-affirm-ruling-that-secret-sales-of-invention-bar-later-patent/>.

147. See *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.* *supra* note 1, at 1371.

148. *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, *supra* note 9, at 634.

In statutory interpretation, the language itself is the first thing to examine.<sup>149</sup> “Where the language is plain and admits of no more than one meaning the duty of interpretation does not arise.”<sup>150</sup> Further, “[i]n the absence of a specific indication to the contrary, words in the statutes will be given their common, ordinary and accepted meaning, and the plain language of the statute should be afforded its plain meaning.”<sup>151</sup> The focus of the statutory interpretation of the AIA § 102(a)(1) is the meaning of the term “otherwise.”

As mentioned earlier, under Helsinn’s reading, this term modifies all the preceding terms. However, as pointed out in one *Amicus* brief, the prominent and common definition of “otherwise” is in fact “different.”<sup>152</sup> In other words, the “otherwise” phrase suggests a “different circumstances” of prior art besides the preceding ones.<sup>153</sup> This reading is consistent with Teva’s position that the added phrase was intended to expand the covered prior art. However, as Helsinn pointed out during the Supreme Court oral hearing, the Court has a modifier to the preceding terms that share a specific characteristic.<sup>154</sup> One example given by Helsinn comes from *United States v. Standard Brewery*.<sup>155</sup>

At the hearing, the Supreme Court extensively questioned whether the catch-all phrase in the AIA “expanded or contracted the universe of prior art.”<sup>156</sup> As mentioned earlier, many creative

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149. See *Caminetti v. U.S.*, 242 U.S. 470, 485 (1917) (“... the meaning of the statute must, in the first instance, be sought in the language in which the act is framed, and if that is plain, ... the sole function of the courts is to enforce it according to its terms.”).

150. NORMAN SINGER, *SUTHERLAND STATUTE AND STATUTORY CONSTRUCTION* § 45:2 (7th ed. 2018).

151. See generally *U.S. v. Lehman*, 225 F.3d 426 (4th Cir. 2000).

152. Brief for SPCM S.A. and High Tech Inventors Alliance as Amicus Curiae Supporting Respondent at 24–25, *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA Inc.*, 138 S. Ct. 2678 (2018) (No. 17-1229).

153. *Id.*

154. Transcript of Oral Argument, *supra* note 114, at 58–59.

155. *Id.* In that case, the statute (i.e., the Wartime Prohibition Act) prohibited the use of grains to manufacture “beer, wine, or other intoxicating malt or vinous liquor for beverage purposes.” The Supreme held that the statute does not apply to non-intoxicating beer because the qualifying words “other intoxicating” modified the preceding words “beer” and “wine.” Other interpretation would render the qualifying words superfluous. *United States v. Standard Brewery, Inc.*, 251 U.S. 210, 217, 218 (1920).

156. Dennis Crouch, *Of Brownies and Other Nutty Desserts: Supreme Court Considers Whether the “On Sale” Bar Is Limited to Public Sales*, PATENTLYO

hypotheticals were given during the hearing in order to understand what the term “otherwise” meant in statutes and in daily life, including Justice Kagan’s “brownie” hypothetical.<sup>157</sup> In fact, when Justice Kagan proposed the “brownie” hypothetical to Teva, Teva “ha[d] the wrong answer,” according to Justice Kavanaugh,<sup>158</sup> because Teva’s answer implied that, with the qualifying phrase “otherwise contains nuts,” buying nutless brownie was permissible. In other words, Teva seemed to agree that, at least in the hypothetical, the catch-all phrase indeed modified and limited the preceding terms when the preceding terms could have more than one meaning.

However, Teva insisted that, both in its brief and during the oral hearing, that the function of the catch-all phrase was to create a new category of invalidating prior art, such as the oral presentation that had not been covered under the pre-AIA § 102, and the new category should have no impact on the preceding terms.<sup>159</sup> Many Justices expressed concerns about Teva’s interpretation of the term “otherwise.” For example, Justice Breyer used the word “awkward”<sup>160</sup> and Justice Alito used the word “nonsense”<sup>161</sup> to describe the situation by using “otherwise” in proposed examples according to Teva’s interpretation.

Nevertheless, both parties agreed that the catch-all phrase was added to at least cover the kind of prior art such as oral presentation which was not covered under the pre-AIA § 102.<sup>162</sup> Teva argued that this was the only purpose of the catchall phrase, but Helsinn disagreed and argued that the phrase had dual functions.<sup>163</sup> The Supreme Court’s opinion suggested that it agreed with Teva.<sup>164</sup> However, despite the extensive discussion of the catch-all phrase’s meaning and its effect on

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(Dec. 4, 2018), <https://patentlyo.com/patent/2018/12/brownies-desserts-considers.html>.

157. Transcript of Oral Argument 43–44, *supra* note 114. The hypothetical given by Justice Kagan during the oral hearing is: when one says don’t buy peanut butter cookies, pecan pie, brownies, or any dessert that otherwise contains nuts, does one violate the injunction if he/she buys nutless brownies?

158. *Id.* at 46.

159. *Id.* at 36.

160. *Id.* 41–42.

161. *Id.* at 33.

162. *Id.* at 56.

163. *Id.* at 12.

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



precedent terms in the AIA § 102(a) during the oral hearing, the opinion contained minimal discussion but rather rushed to its conclusion that Helsinn placed too much weight on § 102's catch-all phrase and the weight of the well-settled law mattered the most.<sup>165</sup> It seems that the Supreme Court at least conceded that an ordinary reading of the catch-all phrase would have changed the meaning of "on sale" in the AIA § 102(a)(1), but nevertheless concluded that the effect was not enough to overturn existing precedents.<sup>166</sup> This reasoning is somewhat surprising considering the Supreme Court's decisions in *Myriad*<sup>167</sup> and *Mayo*,<sup>168</sup> the Supreme Court showed no hesitation to change a "well-settled" law with numerous precedents.<sup>169</sup> In contrast, here, while the Supreme Court considered the weight of the precedents, it simply avoided to consider the weight of the statutory interpretation of the catch-all phrase, which had at least two plausible interpretations.<sup>170</sup> Instead, it reached its "not enough" conclusion without giving an explanation as how to balance the weight of the plain meaning of statutory text and the weight of judicial precedents.<sup>171</sup> Although this opinion is likely correct, the Court should have at least discussed why Helsinn's interpretation of the catch-all phrase cannot outweigh prior precedents, especially where, as here, a plain meaning of the catch-all phrase at least plausibly suggests a different meaning of "on sale" under the new AIA. This leaves little guidance to lower courts as to how to conduct a balancing analysis when facing a conflict between statutory text and related precedents.

ii. The Supreme Court Did Not Discuss the Legislative History of the AIA 102(a)(1) in Its Opinion

The Federal Circuit held that the cited legislative history was not reliable and even if the court took the legislative history into consideration, because the precedent was related to a

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165. *See id.* at 635.

166. *See id.*

167. *See generally* *Ass'n. for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013).

168. *See generally* *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012).

169. *See Supreme Court Decides Helsinn v. Teva, Secret Sale Qualifies as Prior Art Under the AIA*, *supra*. note 145.

170. *Id.*

171. *See Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 139 S.Ct. 628, 635 (2019).

“public use” issue, it was not applicable to Helsinn because the issue here was about a “secret sale.”<sup>172</sup> The Supreme Court seemed to agree. In the Supreme Court’s opinion, no discussion of legislative history could be found. At most, in determining the congressional intent, Justice Thomas merely cited *Shapiro v. United States* and concluded that it was presumed that Congress adopted the old meaning of “on sale” when the AIA was reenacted.<sup>173</sup> This “presumption” seems un-rebuttable. Or, at least, one could assume that a plain meaning of the statute coupled with legislative history materials that could support such reading cannot rebut that presumption.

In *A Guide to the Legislative History of the America Invents Act: Part I of II*, Joe Matal observed that Senator Leahy and Hatch stated that new §102(a) limited prior art to the ones that made the invention available to the public; that private offers for sale or private uses or secret processes would no longer be prior art; and that the public-availability standard was defined in terms of the Federal Circuit’s public-accessibility jurisprudence.<sup>174</sup> Joe Matal pointed out that two passages of the Leahy-Hatch colloquy were particularly relevant to the new § 102(a) and both suggested that the prior art under new § 102(a) must meet the public-availability standard.<sup>175</sup> The catch-all phrase was first adopted in July 2007 during the

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172. *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 855 F.3d 1356, 1368 (Fed. Cir. 2017), cert. granted, 138 S. Ct. 2678 (2018).

173. *Helsinn Healthcare S.A.*, 139 S.Ct. at 634.

174. See Joe Matal, *A Guide to the Legislative History of the America Invents Act: Part I of II*, 21 FED. CIR. BAR J. 435, 467 (2012).

175. *Id.* 467–68 (citing 157 CONG. REC. S1496 (daily ed. Mar. 9, 2011)). Statement of Senator Hatch: “the important point is that if an inventor’s disclosure triggers the 102(a) bar with respect to an invention, which can only be done by a disclosure that is both made available to the public and enabled . . . If a disclosure resulting from the inventor’s actions is not one that is enabled, or is not made available to the public, then such a disclosure would not constitute patent-defeating prior art under 102(a) in the first place.” *Id.* at 467. Statement of Senator Leahy: “[o]ne of the implications of the point we are making is that subsection 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. In effect, the new paragraph 102(a)(1) imposes an overarching requirement for availability to the public, that is a public disclosure, which will limit paragraph 102(a)(1) prior art to subject matter meeting the public accessibility standard that is well-settled in current law, especially case law of the Federal Circuit.” *Id.* at 467–68.

Senate Judiciary Committee's markup of a predecessor bill.<sup>176</sup> In the 2007 Senate Committee Report, § 102(a)(1)'s new definition of "prior art" was commented on in two places: the Report's legislative history section<sup>177</sup> and the background section,<sup>178</sup> and both suggested that public availability was a requisite for constituting a § 102(a)(1) prior art. Again on September 6, 2011, Senator Kyl readdressed the bill's definition of "prior art" as the Senate considered the House-passed bill and pointed out that under new § 102(a), a sale or offer for sale could constitute prior art only if the sale or the offer makes the invention publicly accessible, and the new definition of "prior art" would substantially reduce litigation discovery costs.<sup>179</sup> Joe Matal further pointed out that the new definition of "prior art" was also reflected in other parts of the AIA itself.<sup>180</sup>

In the final Committee Report for the AIA which was issued on June 1, 2011, Senator Kyl's March 8 remarks as to his statements on new § 102(a) were included, including, among other things, "(3) stated that the use of the word 'otherwise' in the final clause 'makes clear that the preceding clauses describe things that are of the same quality or nature as the final clause;'" "(4) discussed three cases—*Strom v. Goldman, Sachs & Co.*;

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176. See *id.* at 470.

177. *Id.* at 471 (citing S. REP. NO. 110-259, at 39 (2008) ("This Managers' Amendment also added the phrase 'otherwise available to the public' to § 102 to make clear that secret collaborative agreements, which are not available to the public, are not prior art.")).

178. *Id.* at 472 (citing S. REP. NO. 110-259, at 9). Matal also notes that section 2 of the bill would "also, and necessarily, modif[y] the prior art sections of the patent law . . . and the phrase 'available to the public' is added to clarify the broad scope of relevant prior art, as well as to emphasize the fact that it must be publicly available." *Id.* at 466.

179. *Id.* 472–73 (citing 157 CONG. REC. S5319–21 (daily ed. Sept. 6, 2011)). "Public uses and sales of an invention will remain prior art, but only if they make the invention available to the public. An inventor's confidential sale of his invention, his demonstration of its use to a private group, or a third party's unrestricted but private use of the invention will no longer constitute [prior] art." *Id.* As to litigation cost, "[u]nder current law, depositions and litigation discovery are required in order to identify all of the inventor's private dealings with third parties and determine whether those dealings constitute a secret offer for sale or third party use that invalidates the patent under the current law's forfeiture doctrine. The need for such discovery is eliminated once the definition of 'prior art' is limited to those activities that make the [invention] accessible to the public. This will greatly reduce the time and cost of patent litigation and allow the courts and the [USPTO] to operate much more efficiently." *Id.*,

180. See *id.* 473–75.

*Universal City Studios, Inc. v. Reimerdes*; and *Williamson v. Southern Regional Council, Inc.*—holding that when the words ‘or otherwise’ or ‘or other’ are used to add a modifier at the end of a string of clauses, the modifier thus added restricts the meaning of the preceding clauses”; “(7) stated that new § 102(a) would ‘limit[] and reconcile[] the various purposes that have been ascribed to § 102’s definition of prior art, ‘and in particular eliminate []encouragement of prompt filing and limits on commercialization of an invention as purposes that are served by the definition of ‘prior art.’”<sup>181</sup>

The Federal Circuit ignored the legislative history supportive of Helsinn’s interpretation and stated that floor statements are typically not reliable as indicators of congressional intent.<sup>182</sup> Additionally, the Federal Circuit explained that the precedents in the legislative history cited by the parties were restricted to “public use” and since the public use issue was not before the court, it would not be addressed by the court.<sup>183</sup> The court further explained that even if the floor statements were intended to overrule the secret or confidential sale cases, that would not affect the result because “those cases were concerned entirely with whether the existence of a sale or offer was public” and there was no doubt about the existence of the supply and purchase agreement between Helsinn and MGI.<sup>184</sup> Further, Federal Circuit expressed its concern that Helsinn’s interpretation would “work a foundational change in the theory of the statutory on-sale bar.”<sup>185</sup> The court cited numerous cases to suggest that there was an established rule of on-sale bar and there was no indication in the floor statements that the Congress intended to overrule all the cases.<sup>186</sup> The court

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181. *See id.* 468–70. The Guide further noted that the final Committee Report also include, among other things, “(9) noted that new § 102(a)(1) would abrogate *Egbert v. Lippman*, the infamous ‘corset clasp’ case; and (10) argued that preservation of the secret-sale-and-use forfeiture doctrines would be ‘fairly disastrous for the U.S. patent system,’ because it would render post-grant review unmanageable and, in combination with the elimination of the geographic restrictions on prior art, enable foreign theft of U.S. inventions.” *Id.* at 470.

182. *See Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 855 F.3d 1356, 1368 (Fed. Cir. 2017), cert. granted, 138 S. Ct. 2678 (2018).

183. *See id.* at 1368–69.

184. *Id.* at 1369.

185. *Id.*

186. *See id.* at 1371. The Federal Circuit explained that the meaning of “available to the public” is that “the public sale itself would put the patented

concluded that no floor statement suggested that the sale or the offer must themselves publicly disclosing the details of the invention, and if Congress intended to make such “a sweeping change,” it would do so with a clear language.<sup>187</sup>

The Federal Circuit likely erred in concluding that the precedent was only concerned with “public use.” As mentioned above, private or secret sale has been mentioned more than once in numerous floor statements and committee reports, not only limited to “public use.” Specifically, the precedent cited in the legislative history was for the purpose of clarifying how courts should proceed with the new public availability standard, which should be based on the “public accessibility” established by the cited “public use” precedents. Nevertheless, the Federal Circuit was likely right in its decision to decline considering the legislative history. Legislative history can be easily manipulated by parties to support their positions. For example, Teva also cited numerous drafting history documents of the AIA to show that Congress intended to preserve the on-sale bar’s meaning.<sup>188</sup> Arguing that Helsinn’s sources were a post hoc concoction of a statement made after the speaker had failed to change the statutory text, Teva cited sources to suggest that Senator Kyl was aware of the meaning of on-sale bar and tried to change the text to repeal that term in the new statute.<sup>189</sup> Only after he failed to change the text, he attempted to accomplish his goal through the Congressional Record.<sup>190</sup> As pointed out by one *Amicus* brief, the floor statement of members of Congress merely reflects their “personal intent, unexpressed in the statute, to overrule existing law” and should not be used to “change settled law.”<sup>191</sup>

With so many controversies and disputes regarding how the legislative history of the AIA affect the interpretation of the on-sale bar under the AIA, like the Federal Circuit, the Supreme Court chose not to discuss it at all. The Supreme Court seemed

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product in the hands of the public.” *Id.* Further, the court stated that Senator Kyl himself agreed with such proposition because he said “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.” *Id.* (citing 157 Cong. Rec. 3423 (2011) (remarks of Sen. Kyl)).

187. *See id.*

188. *See* Brief for Respondents, *supra* note 86, at 39.

189. *See id.* 39–40.

190. *See id.* at 40.

191. Brief for 45 Intellectual Property Professors as *Amicus Curiae* Supporting Respondent, *supra* note 101, at 8–9.

to agree with the Federal Circuit that legislative history was not reliable and thus carried little weight in statutory interpretation. Considering the complexity and manipulability of various sources of legislative history, the Supreme Court might be justified to choose to ignore the legislative history arguments from both sides.

iii. The Supreme Court Should Discuss Other Underlying Policies Besides the Weight of Precedents

Although the Supreme Court considered the importance of precedents in reaching its decision, it did not discuss other important policies such as the main purpose of the enactment of the AIA. However, as mentioned earlier, the Supreme Court may purposely avoid such discussion to keep the opinion short.<sup>192</sup>

First, as pointed out by Helsinn, the move from a first-to-invent system to a first-inventor-to-file system obviates the need for a forfeiture doctrine since an inventor who delays filing patent application runs the risk of losing his right to another who files or discloses first.<sup>193</sup> A confidential agreement could not guarantee that the invention would not be disclosed by others.<sup>194</sup> In fact, the more agreements one enters into, there are more risks of disclosing the invention to the public.<sup>195</sup> In other words, the "public availability" standard may effectively rein in the potential abuse of the system. Further, since no countries in the world besides the United States has the concept of an on-sale bar, Helsinn's interpretation of the new § 102(a)(1) would better serve Congress's goal of harmonizing United States patent law with other foreign patent systems and would foster innovation by affording small companies flexibility to form partnerships to develop inventions.<sup>196</sup> However, the United States patent system is not the exact same as the rest of the world. For example, the grace period in United States is one year before the official filing date, while other foreign patent systems, which are all strict "first-to-file" systems, do not generally have friendly grace

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192. See Mann, *supra* note 146.

193. See Michael Pomianek & Michelle Nyein, *A Firsthand Account of the Helsinn v. Teva Arguments*, LAW360 (Dec. 7, 2018), <https://www-law360-com.ezproxy.law.umn.edu/articles/1108997/a-firsthand-account-of-the-helsinn-v-teva-arguments>.

194. *Id.*

195. *Id.*

196. See *id.*

periods.<sup>197</sup> Most of the foreign patent systems do not have a grace period or put too many restrictions on the grace period.<sup>198</sup> The one-year grace period in the United States patent system is much broader, both in scope and duration, as compared with other patent systems.<sup>199</sup> Therefore, the United States. grace period gives inventors enough time to seek business partners and financial support before deciding to file a patent application. It is the inventor's responsibility to not miss the one-year deadline.

Another policy concern is the overlap between the on-sale bar cases and the "public use" cases. Under the pre-AIA § 102, a prior use must be a public use in order to invalidate a patent.<sup>200</sup> This serves better on the policy that a patent is a tradeoff between the inventor and the society. As explained by Justice Thomas in the Supreme Court's opinion,<sup>201</sup> the purpose of the statutory bar is to prevent taking back something that is already in the public domain. If the use is "in private," there is nothing in the public domain. The "on sale" bar may be used in a similar way.

Teva was worried that allowing secret sale would encourage inventors to unjustifiably extend the patent term by delaying filing applications. The "public use" bar would arguably encounter the same risk. An inventor would have the incentive to delay the filing and use their invention in private for patent term extension. Under the pre-AIA § 102, an inventor can maintain a use as "private" as long as they exercise enough "control" over the invention, for example, by providing confidentiality agreements.<sup>202</sup> Further, the switch from "first-to-

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197. See PAUL GOLDSTEIN & MARKETA TRIMBLE, INTERNATIONAL INTELLECTUAL PROPERTY LAW CASES AND MATERIALS 466 (4th ed. 2015).

198. *Id.*

199. *Id.*

200. See *AIR-vend, Inc. v. Thorne Industries, Inc.*, 625 F. Supp. 1123, 1131 (D. Minn. 1985), *aff'd*, 831 F.2d 306 (Fed. Cir. 1987). See also *Delano Farms Co. v. California Table Grape Commn.*, 778 F.3d 1243, 1247 (Fed. Cir. 2015).

201. See *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 139 S. Ct. 628, 632 (2019) ("Congress has imposed several conditions on the 'limited opportunity to obtain a property right in an idea,' (citation omitted). One such condition is the on-sale bar, which reflects Congress' 'reluctance to allow an inventor to remove existing knowledge from public use' by obtaining a patent covering that knowledge.").

202. See *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1266 (Fed. Cir. 1986) (stating that the presence of a confidentiality agreement is a factor to be considered in determining public use).

invent" to "first-inventor-to-file" system (or more specifically, "first-inventor-to-disclose") provides additional incentives for inventors to file or disclose early. Further, regarding the potential abuse of the secret sale to extend the legal monopoly term, maybe the main question, as noted by Helsinn, is whether the on-sale bar should pursue the purpose to prevent such abuse "at all costs,"<sup>203</sup> including any benefits that could be conferred to small business owners.

Based on the facts, the published redacted agreement did not disclose the critical low dosage that was the invention of Helsinn. Using the specific drug to treat the specific disease was already well known. The important invention was that the low dosage of the drug would still be effective. No one in the public, after reading the redacted agreement, would understand what the claimed invention in the later-filed application would be. Most importantly, the purchaser was obligated to keep the information confidential and to prevent it from being in the public domain. This is similar to the confidential agreement in the "public use" rule. Since there would be no "public availability," such sale should not be considered as prior art just like a "private use" would not be considered as prior art.

However, the Supreme Court disagreed. Although the opinion did not discuss when the invention becomes "public," it is likely that the Court was influenced by the argument of amicus curiae United States during the oral hearing regarding when a product became "on sale" and decided that when the product is in the hands of a distributor (here, MGI), the product would be deemed as "on sale."<sup>204</sup> Teva further noted that a sale to a distributor put the product on sale and the existence of a confidential agreement was irrelevant to whether an invention was in public.<sup>205</sup>

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203. See Transcript of Oral Argument, *supra* note 114, at 18.

204. See *id.* 22–23 (Speaking as to what constitutes a sale, Justice Sotomayor said "But if you ask in the industry to distributors, they'll say the moment that Apple was going to start shipping it to distributors.").

205. See Brief for Respondents, *supra* note 86, at 54–58. ("A single commercial sale has always sufficed to trigger the bar, no matter who buys the invention or what the buyer does with it . . . It follows that a single sale is no less invalidating even if the buyer signs a non-disclosure agreement."); *Id.* at 55. ("Notably, the government does not argue that the existence of a non-disclosure agreement, or the number of sales, is relevant to whether an invention is 'available to the public.'").



One of the precedents that influence the Supreme Court's decision is likely the *Metallizing* case where Judge Hand hold that a commercial use of an invention constitutes a "public use" under the pre-AIA § 102(b), even if the use was done in secret.<sup>206</sup> In reaching the holding, Justice Hand had to read "public" to mean "secret" in order to modify "use."<sup>207</sup> The major reason for such reading is to prevent the inventor to unlimitedly extend the period of his monopoly.<sup>208</sup> During the oral hearing, Justice Kavanaugh and Justice Breyer both hinted at the policy consideration raised in *Metallizing*.<sup>209</sup> Even Helsinn conceded that a commercial exploitation should prevent an inventor from filing an application after the critical date.<sup>210</sup> However, Helsinn argued that Justice Hand did not mean that every pre-patent commercialization should trigger the on-sale bar.<sup>211</sup> That argument obviously did not convince the Supreme Court.

Although the Supreme Court did not discuss the *Metallizing* case in its opinion, it emphasized the underlying policy that the patent system should both promote innovation and prevent monopolies.<sup>212</sup> The Supreme Court reached the correct conclusion given the weight of the 200-year settled law as well as the important underlying policy. If the AIA was intended to change the old meaning of the on-sale bar by requiring "public availability," not only would it overrule all the judicial precedents overnight, it would also encourage inventors to conceal their inventions for secret commercial exploitation and thus extend their monopolies, which would defeat the exact purpose of having a patent system.

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206. See generally *Metallizing Engr. Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516 (2d Cir. 1946).

207. See *id.* at 520.

208. See *id.* ("[F]or he is not then making use of his secret to gain a competitive advantage over others; he does not thereby extend the period of his monopoly.").

209. See Transcript of Oral Argument, *supra* note 114, 8-9.

210. See *id.* 9-10.

211. See *id.* at 10. ("But I don't think it's fair to say that what Judge Hand was doing was saying that the on-sale bar reaches all forms of pre-patent commercialization. I think that is an over-reading of the on-sale bar.")

212. See *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 139 S. Ct. 628, 632 (2019) ("To further the goal of 'motivating innovation and enlightenment' while also 'avoiding monopolies that unnecessarily stifle competition . . .").

B. RECOMMENDATIONS TO INVENTORS NOW: BUSINESS STRATEGIES AND PATENT FILING PRACTICES

Although the *Helsinn* decision is correct in prohibiting secret commercial exploitation, the decision will undoubtedly have a significant impact on the consequences of engaging in commercial transactions before filing patent applications, especially for small and midsize pharmaceutical and biotech companies, which often rely on early-stage development partnerships to defray the costs and risks of new drug development.<sup>213</sup> Without the flexibility of entering contracts with partners, these companies would be unable to obtain sufficient funding to advance products through R&D or clinical trials, just like *Helsinn*.<sup>214</sup>

However, there are a few steps that inventors could and should take to safeguard their confidential commercial activities from becoming patent-defeating prior art after the Supreme Court's final decision in *Helsinn*. It is noted that the Court reaffirmed the *Pfaff* decision. In other words, notwithstanding that *Pfaff* was a pre-AIA decision, *Pfaff*'s two-step framework for on-sale bar is still valid after *Helsinn*.<sup>215</sup> The first step in *Pfaff* is whether there is a commercial offer for sale and it is analyzed under commercial contract law principles.<sup>216</sup> Precautions under this step that an inventor can take include (1) not reducing an exchange to writing; (2) qualifying discussions as providing only general estimates; (3) declaring the terms discussed are merely preliminary which require managerial approval in order to bind parties in transaction; and (4) "renting out" rather than selling the invention so that the title remains in the inventor.<sup>217</sup> As to the second step, an inventor should file a patent application as soon as the invention is "ready for patenting."<sup>218</sup> These precautions, although not necessarily foolproof, may help reduce

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213. See Pomianek & Nyein, *supra* note 193.

214. See *id.* ("Other common pre-filing sale activities include manufacturing or engineering services contracts that involve payment for resulting products.").

215. See David Gornish, *Protecting Innovation While Justices Ponder Helsinn v. Teva*, LAW360 (Dec. 13, 2018), <https://www.law360.com/articles/1110927/protecting-innovation-while-justices-ponder-helsinn-v-teva>.

216. See *id.*

217. See *id.*

218. See *id.* Even if the invention is still "unfinished," it is prudent to file on the best information in a provisional application.

the likelihood of on-sale bar.<sup>219</sup> In addition, patent attorneys, especially in-house patent attorneys, should pay close attention to what their commercial team is doing and monitor the interactions among different departments to avoid the problem that *Helsinn* encountered.<sup>220</sup> Further, because the USPTO has already relied on its own interpretation of the on-sale bar under the AIA for many years (which now is overruled by the Supreme Court decision), it would be prudent for patent attorneys to examine and update the existing patent portfolios to prevent any surprise regarding the on-sale bar in future litigations.

### CONCLUSION

The Supreme Court's decision of *Helsinn* is likely correct even though its opinion did not discuss many aspects that might be relevant to its decision, including the statutory interpretation of the AIA § 102(a)(1), the relevant legislative history, and the underlying policies relating to the AIA and the on-sale bar. Nevertheless, given the weight of the pre-AIA precedents, the Supreme Court is correct in its decision.

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219. *See id.*

220. Matthew Bultman, "On Sale" Ruling Shows Need for Earlier Patent Applications, LAW360 (Jan. 22, 2019, 9:07 PM EST), <https://www.law360.com/articles/1120924/-on-sale-ruling-shows-need-for-earlier-patent-applications>.