

# SECRET SALES ARE NO FUN (FOR INVENTORS): RE-EVALUATING THE SCOPE OF THE ON-SALE BAR AS ADOPTED IN THE AMERICA INVENTS ACT

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“On sale” in the Patent Act has historically meant any commercial sale, but the adoption of the America Invents Act (AIA) has led some to assert that this meaning was abandoned—that “on sale” now only means certain sales.<sup>1</sup> Even though the AIA still categorizes inventions that have been “on sale” as prior art, some claim that a newly-added catch-all clause in the AIA should allow patents to issue even after the invention has been marketed and sold, as long as all of the parties to the sale are bound to keep the details of the invention secret.

In 2017, in *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.*, the Federal Circuit considered whether the AIA had changed the meaning of “on sale.”<sup>2</sup> After evaluating the text of the statute and legislative history, the court determined that Congress, when enacting the AIA, did not modify the meaning of “on sale” to require a public disclosure.<sup>3</sup> The court cited pre-AIA precedent to apply the on-sale bar to an invention that had been the subject of the so-called “secret sale,” i.e., a transaction where the fact of the sale was disclosed in regulatory filings, but no details about the claimed invention were publicized.<sup>4</sup> The Supreme Court has granted certiorari to review whether such a transaction is patent-invalidating under the AIA.

This comment argues that the text of the AIA cannot support a legislative repeal of the on-sale bar, and therefore the term’s historical

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<sup>1</sup> See *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 67 (1998); *City of Elizabeth v. Am. Nicholson Pavement Co.*, 97 U.S. 126, 134 (1877).

<sup>2</sup> *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 855 F.3d 1356, 1360 (Fed. Cir. 2017).

<sup>3</sup> *Id.* at 1369, 1371.

<sup>4</sup> *Id.* at 1370.

meaning should stand: “secret sales” outside of the one-year grace period should remain patent-invalidating. Viewing the AIA as a repeal would have serious knock-on effects in other areas of patent law. Additionally, this comment briefly addresses how the construction of the AIA adopted by the Federal Circuit further muddies the waters by evaluating the public disclosure of the sale itself rather than the disclosure of details of the invention. While the statutory text alone is sufficient to support the conclusion that the AIA did not modify the on-sale bar, this comment examines the legislative history of the AIA to show that Congress has had opportunities to impose a public disclosure requirement on the on-sale bar but did not. Finally, this comment demonstrates that the shift to first-to-file does not justify adding a publicity requirement to the on sale-bar.

### BACKGROUND

The AIA represents the largest overhaul of the United States (U.S.) patent system in a generation.<sup>5</sup> The AIA ended the U.S. system of awarding patents to the first inventor and harmonized the system with its global peers by awarding patents to the first inventor to file with the U.S. Patent and Trademark Office (USPTO).<sup>6</sup> In addition, the AIA made subtler changes to other elements of the U.S. patent system, including modifications to 35 U.S.C. § 102, which defines novelty.<sup>7</sup> However, the AIA also re-enacted language from the prior statute, including the bar on patenting inventions which were previously “on sale”—a phrase that is a term of art in the judicially-created common law of patents.<sup>8</sup> These changes to the statute have led some to wonder if the old understandings associated with these statutory terms still apply or if Congress intended to overhaul these longstanding definitions alongside the shift to first-to-file.<sup>9</sup>

While the AIA modified the definitions of novelty and prior art, the on-sale bar carries over from the previous statute.<sup>10</sup> Pre-AIA, 35 U.S.C. § 102(b) prohibited granting a patent for an invention that was “in public use or on sale in this country” more than one year before the

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<sup>5</sup> Nathan Hurst, *How the America Invents Act Will Change Patenting Forever*, WIRED (Mar. 15, 2013, 6:30 AM), <https://www.wired.com/2013/03/america-invents-act/> [<https://perma.cc/CKR8-JFFU>].

<sup>6</sup> *See id.*; 35 U.S.C. § 102(a)(2) (2012).

<sup>7</sup> *See* 35 U.S.C. § 102 (2012).

<sup>8</sup> *Compare* 35 U.S.C. § 102(a) (2012), *with* 35 U.S.C. § 102(b) (2006) (pre-AIA version of the statute).

<sup>9</sup> Mark Lemley, *Does “Public Use” Mean the Same Thing It Did Last Year?*, 93 TEX. L. REV. 1119, 1119 (2015).

<sup>10</sup> *Compare* 35 U.S.C. § 102(a)(1) (2012), *with* 35 U.S.C. § 102(b) (2006) (pre-AIA version of the statute).

application was filed.<sup>11</sup> After the AIA was enacted, the on-sale bar and other categories of prior art were listed in 35 U.S.C. § 102(a)(1), which reads in relevant part: “[a] person shall be entitled to a patent unless . . . the claimed invention was patented, described in a printed publication, or in public use, on sale or otherwise available to the public before the effective filing date of the claimed invention.”<sup>12</sup> The one-year grace period remains in the AIA as part of § 102(b)(1), specifying that a “disclosure” by the inventor or a third party who obtains the knowledge from the inventor will not count as prior art if the disclosure is made within a year of filing the application.<sup>13</sup>

The Court established a test for when the on-sale bar applies in *Pfaff v. Wells Electronics*.<sup>14</sup> Noting that the previous “substantially complete” test created uncertainty inconsistent with the underlying policy of the patent law to “fix a period of limitation which should be certain,” the Court announced a bright line rule.<sup>15</sup> Under *Pfaff*, the on-sale bar applies if the claimed invention is the subject of a commercial offer for sale and is “ready for patenting” outside of the statutory grace period.<sup>16</sup> “Ready for patenting” can be shown by evidence of actual reduction to practice (meaning the invention is embodied in a physical form) or by showing that the inventor prepared drawings or descriptions that were “sufficiently specific to enable a person skilled in the art to practice the invention.”<sup>17</sup>

#### STATEMENT OF FACTS AND PROCEDURAL HISTORY

This case stems from an Abbreviated New Drug Application filed by respondent (Teva), which petitioner (Helsinn) claims infringed four patents that it owned for an intravenous drug intended to reduce the likelihood of chemotherapy-induced nausea and vomiting.<sup>18</sup> Three of those patents were governed by the pre-AIA version of § 102, while one was governed by the AIA.<sup>19</sup> Respondent asserted that a license agreement and a supply and purchase agreement between petitioner and MGI Pharma

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<sup>11</sup> 35 U.S.C. § 102(b) (2006) (pre-AIA version of the statute).

<sup>12</sup> 35 U.S.C. § 102(a)(1) (2012).

<sup>13</sup> 35 U.S.C. § 102(b) (2012).

<sup>14</sup> *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 65 (1998).

<sup>15</sup> *Id.* at 66 (quoting *Andrews v. Hovey*, 123 U.S. 267, 274 (1887)).

<sup>16</sup> *Id.* at 67.

<sup>17</sup> *Id.* at 67–68.

<sup>18</sup> *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 855 F.3d 1356, 1360 (Fed. Cir. 2017).

<sup>19</sup> *Id.*

in 2001 invalidated all four of petitioner's patents.<sup>20</sup> Respondent argues that these were sales of the invention outside the one-year grace period for petitioner's 2003 provisional patent application.<sup>21</sup>

The district court found that the challenged agreements did not trigger the on-sale bar and did not invalidate any of the patents. As to the patent governed by the AIA, the district court ruled that the AIA required a "public sale or offer for sale of the claimed invention," and in order to be public, the sale must publicly disclose the details of the invention.<sup>22</sup> Because both parties to the agreement were bound by non-disclosure agreements, and MGI's public filing with the U.S. Securities and Exchange Commission (SEC) disclosed only the fact of the transaction without details of the underlying invention, the district court did not apply the on-sale bar.<sup>23</sup>

The Federal Circuit reversed the lower court's decision and declared all four patents invalid.<sup>24</sup> As to the AIA patent, the court determined that the AIA did not require the sale to disclose the details of the invention to the public.<sup>25</sup> The court reasoned that because the AIA enacted the same term "on sale," which had been given a particular meaning by the court's interpretation of prior statutes, Congress intended to adopt that meaning.<sup>26</sup> If Congress had intended to repeal the body of on-sale jurisprudence, the Federal Circuit reasoned that Congress would have done so by clear language and not through a catch-all clause (also called a "residual clause").<sup>27</sup>

The Court granted certiorari and will soon decide whether the AIA requires that a sale disclose the details of the invention in order to qualify as prior art under § 102.

#### SUMMARY OF ARGUMENTS

Petitioner argues that the plain text of § 102 requires the conclusion that a sale must publicly disclose the invention to count as prior art. It asserts that the catch-all provision, "or otherwise available to the public," should be read to color the other enumerated categories (inventions "in public use" and those "on sale") as having a public

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<sup>20</sup> *See id.* at 1360, 1362.

<sup>21</sup> *Id.* at 1360.

<sup>22</sup> *Id.* at 1363.

<sup>23</sup> *Id.*

<sup>24</sup> *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 855 F.3d 1356, 1360 (Fed. Cir. 2017).

<sup>25</sup> *Id.* at 1369–70.

<sup>26</sup> *Id.* at 1371.

<sup>27</sup> *Id.*

element.<sup>28</sup> Petitioner claims that legislative history supports this interpretation, citing several Senators' floor statements insisting that the AIA would prevent secret sales from constituting prior art.<sup>29</sup> In addition, petitioner claims that the on-sale bar is no longer required to induce prompt filing by inventors because the AIA eliminated priority of invention and now requires patentees to be the first to file at the USPTO.<sup>30</sup> If an inventor can have his monopoly rights seized by an earlier filer, there is no need for a further judicial inducement to file.

On the other hand, respondent argues that the plain text of the AIA confirms that Congress did not change the meaning of "on sale" as it has been used in prior cases.<sup>31</sup> Respondent cites the cardinal rule of construction that Congress adopts the settled meaning when employing a term of art unless it expresses a specific intent to modify that meaning.<sup>32</sup> Respondent insists that petitioner's textual argument is undone because reading "otherwise available to the public" as modifying the other elements of the list ("on sale" and "in public use") creates serious redundancies.<sup>33</sup> The clause cannot apply to all elements of the list in § 102(a)(1) because all of the elements save one, "on sale," are already labeled as public or are inherently public.<sup>34</sup> Instead, respondent proposes that the proper reading is that "to the public" modifies only the immediately preceding words, "otherwise available."<sup>35</sup> Respondent also directs the Court's attention to the exceptions subsection of § 102, which explicitly distinguishes between "disclosures" and "public disclosures."<sup>36</sup> If all prior art disclosures are already public, respondent asks why there is a need for the exceptions clause to specify "public disclosures."<sup>37</sup> Respondent also seeks to discredit petitioner's legislative history argument, pointing out that Congress had numerous opportunities to pass a bill totally omitting the on-sale bar and limiting the definition of prior art to include only public uses or disclosures.<sup>38</sup> However, Congress declined to do so, as it repeatedly amended the bill to add back provisions further defining prior art, including the on-sale bar, which was explicitly added

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<sup>28</sup> Brief for Petitioner at 14, *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 138 S. Ct. 2678 (2018) (No. 17-1229).

<sup>29</sup> *Id.* at 15, 27.

<sup>30</sup> *Id.* at 16.

<sup>31</sup> *Id.* at 18.

<sup>32</sup> *See id.* at 26–27.

<sup>33</sup> Brief for Respondents at 35–36, *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 138 S. Ct. 2678 (2018) (No. 17-1229).

<sup>34</sup> *Id.* at 35–36.

<sup>35</sup> *Id.* at 30–31; 35 U.S.C. § 102(b)(1) (2012).

<sup>36</sup> Brief for Respondents, *supra* note 34, at 37–38.

<sup>37</sup> *Id.*

<sup>38</sup> *Id.* at 39–40.

back to the bill in 2011.<sup>39</sup> Finally, respondents argue that the first-to-file system cannot satisfy all of the concerns historically addressed by the on-sale bar.<sup>40</sup> Specifically, while first-to-file creates a risk that a competing application will pre-empt an inventor's patent rights, without the on-sale bar inventors who can maintain their invention as a trade secret may find it more profitable to accept that risk and may choose to sell their product in secret for some indefinite time prior to securing the patent and twenty additional years of exclusive use.<sup>41</sup>

#### THE TEXT DOES NOT SUPPORT A LEGISLATIVE REPEAL OF THE ON-SALE BAR

Despite petitioners arguments to the contrary, the plain text of the AIA retains inventions that were previously “on sale” as a separate category of prior art. 35 U.S.C. §102(a)(1) as modified by the AIA reads in relevant part as follows: “[a] person shall be entitled to a patent unless . . . the claimed invention was patented, described in a printed publication, or in public use, on sale or otherwise available to the public before the effective filing date of the claimed invention.”<sup>42</sup> “On sale” is a term of art from the pre-AIA version of this statute—a term that courts have interpreted over time to include nearly any commercial sale or offer for sale, including single or one-time sales, secret sales, and even sales made by third parties but excluding sales made solely for experimental purposes.<sup>43</sup> When Congress re-adopts an existing term of art, courts often assume that it knew of and generally accepted the meaning that courts have placed upon the term.<sup>44</sup> If Congress did intend to modify the fundamental details of a regulatory scheme, it would not do so in “vague terms or ancillary provisions—[Congress] does not, one might say, hide elephants in mouseholes.”<sup>45</sup> However, petitioner cautions that *Holder v.*

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<sup>39</sup> *Id.* at 40.

<sup>40</sup> *Id.* at 50.

<sup>41</sup> *Id.* at 49.

<sup>42</sup> 35 U.S.C. § 102(a)(1) (2012).

<sup>43</sup> *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 67 (1998); *see* *Woodland Tr. v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1370 (Fed. Cir. 1998) (stating that an inventor's secret commercial use may bar him from a patent); *J.A. LaPorte, Inc. v. Norfolk Dredging Co.*, 787 F.2d 1577, 1581–83 (Fed. Cir. 1986) (stating that the on-sale bar may apply from actions of a third party); *EZ Dock v. Schafer*, 279 F.3d 1347, 1352 (Fed. Cir 2002) (recognizing an exemption to the on-sale bar for sales for experimental purpose, as where the inventor would continue to study his invention).

<sup>44</sup> *Air Wisconsin v. Hoeper*, 571 U.S. 237, 246–47 (2014).

<sup>45</sup> *Whitman v. Am. Trucking Ass'n*, 531 U.S. 457, 468 (2001).

*Martinez-Gutierrez* requires that this doctrine can apply only when Congress re-adopts a statute “without relevant change.”<sup>46</sup>

While the AIA represents a massive and relevant change to the U.S. patent system, the changes to the “on sale” provision were not sufficiently clear to support a fundamental change to that rule. In *Martinez-Gutierrez*, the Supreme Court rejected a congressional ratification argument because Congress had removed the word “domicile” from a statute, and that word was the very basis for the line of prior decisions that petitioner argued Congress had ratified by passing the new statute.<sup>47</sup> By contrast, in the AIA, the relevant term “on sale” has actually been re-adopted.<sup>48</sup> The only “relevant” changes are adjacent to the term. In the AIA, Congress eliminated geographic limitations and added the residual clause, “or otherwise available to the public.”<sup>49</sup> These changes are insufficient to overcome the assumption that Congress knew of and intended to adopt the established meaning of “on sale.”<sup>50</sup>

Petitioner insists that the addition of the residual clause “or otherwise available to the public” should be read to color the other defined categories of prior art.<sup>51</sup> It claims that the phrase, “to the public,” is as much applicable to “otherwise available” as it is to “in public use” and “on sale”; the phrase should be read to apply to each element equally.<sup>52</sup> However, “to the public” is not equally applicable to each element of the list. Adopting this view would be redundant, causing the first element on the list to read “[publicly] available to the public.”<sup>53</sup> This reading would also cause the term, “on sale,” to be rendered largely meaningless, as it is difficult to conceive of a public sale which is not also a public use. A “cardinal principle” of statutory construction is that courts have a duty “to give effect, if possible, to every clause and word of a statute.”<sup>54</sup> Therefore, if the on-sale bar is to have any practical meaning at all, the Court must maintain its authoritative interpretation that “on sale” means a commercial sale or offer for sale and must not create a new public disclosure requirement for the on-sale bar.

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<sup>46</sup> *Holder v. Martinez-Gutierrez*, 566 U.S. 583, 593 (2012).

<sup>47</sup> *Id.*

<sup>48</sup> 35 U.S.C. § 102(a)(1) (2012).

<sup>49</sup> Compare 35 U.S.C. § 102 (2006), with 35 U.S.C. § 102 (2012).

<sup>50</sup> See *McDermott Int’l, Inc. v. Wilander*, 498 U.S. 337, 342 (1991).

<sup>51</sup> Brief for Petitioner, *supra* note 29, at 16.

<sup>52</sup> *Id.* (citing *Paroline v. United States*, 572 U.S. 434, 447 (2014)).

<sup>53</sup> See Brief of Respondents Opposing Certiorari at 21, *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 138 S. Ct. 2678 (2018).

<sup>54</sup> *Williams v. Taylor*, 529 U.S. 363, 404 (2000); *Duncan v. Walker*, 533 U.S. 167, 174 (2001) (internal quotations omitted).

## PRACTICAL ISSUES WITH PETITIONER'S CONSTRUCTION

Petitioner's construction of the AIA would also create uncertainty about other areas of patent law. The on-sale bar is just one of several judge-made rules based on interpretations of "on sale" and "in public use" that go well beyond the plain meaning of those words but nevertheless present a coherent patent policy.<sup>55</sup> To hold that the "otherwise available" residual clause was intended to dispose of judicial interpretations of "on sale" would then cast doubt on the validity of interpretations of "public use" or "printed publication" and could do away with the judge-made doctrine of experimental use.<sup>56</sup> These doctrines form the foundation of the patent system. Congress knows this and was free to address concerns with these policies directly by explicitly adopting new language or providing a legislative definition of "on sale." However, Congress declined to do any of these things. Instead, it enacted the same terms of art that have defined the patent system for decades, and the Court should not undermine those understandings on the back of a residual clause—especially where neither the statute nor the present case is equipped to fill the ensuing vacuum.<sup>57</sup>

## ISSUES WITH THE FEDERAL CIRCUIT'S DECISION BELOW

While the Federal Circuit was correct to reject the statutory construction proposed by petitioner, its holding goes astray by evaluating the public disclosure of the sale. If the AIA is not a legislative repeal of existing jurisprudence regarding the on-sale bar, and if *Pfaff's* test for applying the on-sale bar remains, then the disclosure of the sale itself is in no way relevant. *Pfaff* bars the grant of a patent following any commercial sale or offer for sale of the claimed invention after it is ready for patenting *regardless* of the invention's disclosure to the public.<sup>58</sup> The Federal Circuit's consideration of the extent of the sale's disclosure serves only to further muddy the waters about the scope of the on-sale bar post-AIA. Adopting a rule based on the public disclosure of the fact of the sale would unfairly pressure companies that are subject to mandatory SEC filings or other regulatory disclosures without protecting prior art in the public domain. The Court should clarify that the on-sale bar retains its historical role and applies regardless of public knowledge of the sale.

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<sup>55</sup> See Lemley, *supra* note 9, at 1121–22.

<sup>56</sup> *Id.* at 1134–35; see *City of Elizabeth v. Am. Nicholson Pavement Co.*, 97 U.S. 126, 127 (1877).

<sup>57</sup> See Dmitry Karshedt, *The Riddle of Secret Public Use: A Response to Professor Lemley*, 93 TEX. L. REV. 159, 161 (2015).

<sup>58</sup> *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 67 (1998).

LEGISLATIVE HISTORY DOES NOT SUPPORT DEVIATING FROM HISTORICAL  
MEANING AND PLAIN TEXT

The drafting history of the AIA shows that Congress could have passed a bill that supports petitioner's interpretation but instead chose not to. The first draft introduced to Congress in 2005 barred granting a patent if "the claimed invention was patented, described in a printed publication, or otherwise publicly known."<sup>59</sup> Congress notably excluded both "public use" and "on sale" from the 2005 bill. Congress would go on to re-adopt both terms in the 2007 House version of the bill.<sup>60</sup> The committee report accompanying that bill indicated that the intent to re-adopt "public use" and "on sale" was driven by "how the terms in 'public use' and 'on sale' have been interpreted by the courts."<sup>61</sup> When the bill finally became law in 2011, "on sale" remained in the definition of prior art alongside "public use" and the added catch-all "or otherwise available to the public" clause.<sup>62</sup>

To support the view that "on sale" should be read to apply only to sales that make an invention available to the public, petitioner cites floor statements of some of the bill's proponents. However, floor statements are considered among "the least illuminating forms of legislative history."<sup>63</sup> Senator Kyl's floor statement from the day of the vote stating that the residual clause should be read to impose a public availability standard upon "on sale" and "public use" is similarly unenlightening.<sup>64</sup> His remarks are particularly unpersuasive because throughout the debate over the AIA, he personally sought to remove the language "on sale" and in "public use" by proposing two different bills that omitted these terms entirely.<sup>65</sup> In another floor statement, he objected to the bill as passed because it retained "patent-forfeiture provisions that apply only to non-public prior art."<sup>66</sup> Despite his statement to the contrary on the day of the floor vote, these records indicate that Senator Kyl understood that the legislative battle was over the inclusion or exclusion of the term "on sale" because if the term "on sale" was used, it would import with it the historical meaning created by decades of judicial interpretation. It was only after he and

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<sup>59</sup> H.R. 2795, 109th Cong. (2005); S. 3818, 109th Cong. (2006).

<sup>60</sup> H.R. 1908, 110th Cong. (2007).

<sup>61</sup> H.R. REP. NO. 110-314, at 57 (2007).

<sup>62</sup> Compare H.R. 1908, 110th Cong. (2007), with H.R. 1249, 112th Cong. (2011).

<sup>63</sup> *Advoc. Health Care Network v. Stapleton*, 137 S. Ct. 1652, 1661 (2017).

<sup>64</sup> Brief of Petitioner, *supra* note 29, at 27 (citing 157 CONG. REC S1370).

<sup>65</sup> S. 3600, 110th Cong. § 2(b)(1) ("[T]he claimed invention was patented, described in a printed publication, or otherwise made available to the public . . ."); S. 610, 111th Cong. § 2(b)(1) (same).

<sup>66</sup> S. REP. NO. 111-18, at 60.

others lost this battle that the issue of what “on sale” should mean became a topic of debate. That debate should not detract from the plain language of the statute discussed here, which supports retaining the historical meaning of “on sale,” barring the issuance of a patent after *any* sale, secret or otherwise.

#### THE ON-SALE BAR IS STILL NECESSARY IN A FIRST-TO-FILE SYSTEM

The on-sale bar, alongside the public-use bar, has historically been construed purposively in order to encourage prompt filing with the USPTO and protect specific public interests. As the Court has frequently explained, “the patent system represents a carefully crafted bargain that encourages” inventors to create and disclose their inventions to the public in exchange for an “exclusive monopoly for a limited period of time.”<sup>67</sup> Therefore, the public-use bar prevents the patenting of knowledge that would reasonably appear to have already passed into the public domain, while the on-sale bar prohibits the commercial exploitation of the invention beyond the statutorily prescribed time period.<sup>68</sup> This emphasis on the limited period of the patent monopoly has led the Court to hold that “any attempt to use [an invention] for a profit . . . would deprive the inventor of this right to a patent” and to quote Judge Learned Hand, who stated that an inventor “must content himself with either secrecy, or legal monopoly” but not both.<sup>69</sup>

Despite the on-sale bar’s historical emphasis on policing the patent term by ensuring prompt filing, and despite the fact that Congress re-enacted the term “on sale,” the U.S., as amicus, insists that the AIA’s first-to-file system is a sufficient “alternative disincentive to artificial delay in applying for patents,” which shows that Congress meant for “on sale” to apply only to public disclosures.<sup>70</sup> The on-sale bar was certainly a *more* necessary tool to police the patent term when the first inventor in fact could obtain a patent, but it has *not* been obviated by the transition to first-to-file.

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<sup>67</sup> *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 63 (1998).

<sup>68</sup> Shashank Upadye, *To Use or Not to Use: Reforming Patent Infringement, the Public Use Bar, and the Experimental Use Doctrine as Applied to Clinical Testing of Pharmaceutical and Medical Device Invention*, 4 MINN. INTELL. PROP. REV. 1, 6 (2002); see *Cont’ Plastic Containers v. Owens Brockway Plastic Prods.*, 141 F.3d 1073, 1079 (Fed. Cir. 1998).

<sup>69</sup> *Pfaff*, 525 U.S. at 65, 68 (first quoting *City of Elizabeth v. Am. Nicholson Pavement Co.*, 97 U.S. 126, 137 (1877); then quoting *Metalizing Eng’g Co. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516, 520 (2nd Cir. 1946)).

<sup>70</sup> Brief for the United States as Amicus Curiae Supporting Petitioner at 24, *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 138 S. Ct. 2678 (2018) (No. 17-1229).

The on-sale bar was needed in the old first-to-invent system because an inventor would otherwise be free to commercially benefit from his invention in secret until somebody else filed an application, at which time the first inventor could appear at the patent office and claim his twenty-year monopoly. Today, first-to-file creates a new risk that a competitor will file an application and secure the monopoly for herself while the first inventor markets his invention in secret, thus rendering the first inventor an infringer.<sup>71</sup> However, there still are likely to be some inventors who are so confident that nobody else will make the same discovery that they take the risk of another inventor filing in order to sell their invention in secret in order to maximize the duration of their monopoly profits by delaying the start of the patent term. By allowing patents to issue long after secret sales have taken place, the interpretation advanced by the United States' amicus brief would allow an inventor who makes sales subject to a non-disclosure agreement (NDA) to reap monopoly profits from the public in excess of twenty years after he began realizing the commercial benefits of his discovery. The inventor would need only to engage in a round of sales to customers who can be made subject to an NDA in order to profit handsomely from these customers for some unlimited time before ultimately filing for a patent and enjoying twenty years of exclusivity while selling to the public at large. Such a rule would induce every seller who can incorporate an NDA into his sales agreements to do so. The policy advanced by the government would encourage inventors to protect themselves through secrecy rather than disclosure, contrary to the purpose of the patent bargain.<sup>72</sup> The first-to-file system creates an additional incentive to file promptly. However, the creation of a new incentive to promote a public interest is not a sufficient reason for the Court to set aside an existing incentive where the plain text shows that Congress decided to re-adopt that incentive—especially when, as here, the new incentive does not fully address the same interest.

#### CONCLUSION

The on-sale bar should retain its historical meaning under the AIA and prevent patents from issuing after non-public sales. While the move to first-to-file was a major shift designed to harmonize the U.S. patent system with its international peers, some elements of the old system must remain. Despite structural changes that may be read to require that publication before a disclosure qualifies as prior art, the willful inclusion

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<sup>71</sup> However, a limited defense to infringement applies to prior users of a process or a machine used in manufacturing. *See* 35 U.S.C. § 273 (2012).

<sup>72</sup> *Pfaff*, 525 U.S. at 63.

of the term “on sale” suggests that Congress intended to adopt the longstanding meaning of that term. Abandoning this precedent is likely to cause confusion about the scope of not only the on-sale bar but also the public-use bar and the experimental-use exemption. The transition to first-to-file is no substitute for the role of the on-sale bar in preventing manipulations to extend the patent term. Accordingly, the Court should affirm the ruling of the Federal Circuit and clearly announce that the on-sale bar applies to any commercial sale or offer for sale regardless of whether the details of the invention are made available to the public.