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A TALE OF TWO SALES: HOW A SECRET SALE REMAINS A BAR TO PATENTABILITY UNDER THE AIA

Kris Schroder

I. INTRODUCTION

Innovation and entrepreneurship are embedded into the history and fabric of the United States.¹ It began with the founding fathers, some of whom were notable innovators, such as Benjamin Franklin² and Thomas Jefferson.³ This tradition of innovation and entrepreneurship continued with individuals from Henry Ford⁴ to Bill Gates⁵ spearheading new technologies that would lead to drastic transformations to the United States economy.⁶ Intellectual property rights are one of the major forces driving innovation and entrepreneurship.⁷ Indeed, the United States Patent and Trademark Office states that its fundamental purpose is to “foster innovation, competitiveness, and job growth by recognizing and securing IP rights through the delivery of high-quality and timely patent and trademark examination and review proceedings.”⁸

It is against this backdrop of innovation and economic growth that Congress passed a recent change to the patent law of the United States in

1. *Entrepreneurs: The Backbone of American Economy and Society*, RUTGERS UNIVERSITY (Nov. 29, 2018), <https://online.rutgers.edu/blog/entrepreneurs-backbone-american-economy-society/> [<https://perma.cc/6U3L-EPFH>].

2. Rex Hammock, *Benjamin Franklin Never Sought a Patent or Copyright*, SMALLBUSINESS.COM (July 1, 2014) (Benjamin Franklin had many inventions, such as bifocals, the lightning rod, and the Franklin stove), <https://smallbusiness.com/history-etcetera/benjamin-franklin-never-sought-a-patent-or-copyright/> [<https://perma.cc/4ZLY-GYSQ>].

3. Rex Hammock, *Thomas Jefferson's Views on Patents and Intellectual Property Rights*, SMALLBUSINESS.COM (July 4, 2014), <https://smallbusiness.com/legal/thomas-jeffersons-views-on-patents/> [<https://perma.cc/RC8E-BN23>]; see also Joe Kissel, *The Inventions of Thomas Jefferson*, INTERESTING THING OF THE DAY (Apr. 20, 2018), <https://itotd.com/articles/2385/the-inventions-of-thomas-jefferson/> [<https://perma.cc/L5P7-K95B>].

4. *Henry Ford*, PBS: THEY MADE AMERICA (June 30, 2004), https://www.pbs.org/wgbh/theymadeamerica/whomade/ford_hi.html [<https://perma.cc/3FVW-XQG9>].

5. *Bill Gates Biography*, BIOGRAPHY.COM (Apr. 2, 2014), <https://www.biography.com/people/bill-gates-9307520> [<https://perma.cc/8QB9-C9CC>].

6. James Titcomb, *Windows 95 at 20: how Bill Gates' software changed the world*, THE TELEGRAPH (Aug. 24, 2015, 3:47 PM), <https://www.telegraph.co.uk/technology/microsoft/windows/11817065/Twenty-years-ago-Microsoft-launched-Windows-95-changing-the-world.html> [<https://perma.cc/YXY5-YULA>].

7. Lorenzo Montanari, *IP Rights Promote Innovation and Prosperity*, FORBES (Apr. 26, 2017, 8:01 AM), <https://www.forbes.com/sites/lorenzomontanari/2017/04/26/ip-rights-promote-innovation-and-prosperity/> [<https://perma.cc/6UC5-5BZL>].

8. U.S. PATENT & TRADEMARK OFFICE, 2018–2022 STRATEGIC PLAN 3 (Nov. 29, 2018), https://www.uspto.gov/sites/default/files/documents/USPTO_2018-2022_Strategic_Plan.pdf [<https://perma.cc/P9N7-E7RK>].

the form of the America Invents Act.⁹ The America Invents Act was intended to help American entrepreneurs thrive by bringing their inventions to market faster.¹⁰ After its implementation into law, one issue involved the interpretation of a particular provision: does the addition of the phrase “otherwise available to the public” to 35 U.S.C. § 102 imply that the preceding collection of bars to patentability are public, or may those bars continue to stay private as the interpretations of the old statute had determined? This legal issue was argued in front of the Supreme Court of the United States in *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*¹¹

Part II of this note will discuss the background of the on-sale bar within patent law, the relevant statutes before and after the America Invents Act, the intent of Congress when writing the America Invents Act, and a case analysis of *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.* Part III of this note will argue that the Judiciary misread the intent of Congress and suggest a change to the statutory language. Part IV will summarize the note’s arguments and concludes that the proposed amendment will restore the intent of Congress.

II. BACKGROUND

The United States Constitution gives Congress the power to enact laws concerning the protection of intellectual property.¹² The four main types of intellectual property rights in the United States are copyrights, patents, trademarks and trade secrets.¹³ For patents and trademarks, Congress has delegated this duty to the United States Patent and Trademark Office (the “USPTO”).¹⁴ The patent system in the United States works in a *quid pro quo* fashion, in which the USPTO grants limited monopolies in the form of patents to inventors in exchange for a public disclosure of how the

9. Pub. L. No. 112-29, 125 Stat. 284 (2011).

10. Press Release, The White House, President Obama Signs America Invents Act, Overhauling the Patent System to Stimulate Economic Growth, and Announces New Steps to Help Entrepreneurs Create Jobs (Sep. 16, 2011), <https://obamawhitehouse.archives.gov/the-press-office/2011/09/16/president-obama-signs-america-invents-act-overhauling-patent-system-stim> [<https://perma.cc/H CZ3-NA82>].

11. 139 S. Ct. 628 (2019).

12. U.S. CONST. art. I, § 8, cl. 8 (granting Congress the power to “promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries”).

13. *Outline of the Legal and Regulatory Framework for Intellectual Property in the United States of America*, WORLD INTEL. PROP. ORG., <https://wipo.int/en/info/outline/US> [<https://perma.cc/J93X-58J6>].

14. 35 U.S.C. § 1.

invention works.¹⁵ The idea behind this exchange is to incentivize innovation that will benefit society.¹⁶ Patents convey strong property rights to a patent holder.¹⁷ They allow the patent holder to exclude others from making the invention, using the invention, selling the invention, and importing the invention within the United States.¹⁸ Nevertheless, not every invention deserves these strong property rights.¹⁹ The USPTO requires that an invention be a process, machine, manufacture, or composition of matter.²⁰ Additionally, the invention must be useful,²¹ novel,²² nonobvious,²³ and it must be disclosed in the patent application sufficiently such that a person with adequate technical background could make and use the invention.²⁴

The novelty requirement has bars that must be avoided in order to obtain a patent.²⁵ The statute for the novelty requirement, 35 U.S.C. § 102, was drastically changed when Congress updated the United States patent system with the adoption of the Leahy-Smith America Invents Act (the “AIA”) in 2011.²⁶ In Section A, the novelty requirements under 35 U.S.C. § 102 before the implementation of the AIA (“pre-AIA”) will be analyzed. In Section B, the novelty requirements will be analyzed under 35 U.S.C. § 102 after the implementation of the AIA (“post-AIA”). Section C will highlight case law interpreting the on-sale bar pre-AIA. Section D will analyze amicus briefs and Congressional floor statements regarding the adoption of the new language in the post-AIA 35 U.S.C. §

15. See *Bonito Boats v. Thunder Craft Boats*, 489 U.S. 141, 152 (1989) (“The tension between the desire to freely exploit the full potential of our inventive resources and the need to create an incentive to deploy those resources is constant.”).

16. James Evans, *Remembering the Real Purpose of Patents*, ACLU (Apr. 10, 2013, 10:44 AM), <https://www.aclu.org/blog/free-speech/internet-speech/remembering-real-purpose-patents> [<https://perma.cc/Z9NU-XGNV>].

17. 35 U.S.C. § 271.

18. *Id.*

19. See 35 U.S.C. §§ 101-103.

20. 35 U.S.C. § 101 (requiring that the invention be a new and useful process, machine, manufacture, or composition of matter).

21. *Id.*

22. 35 U.S.C. § 102 (requiring that the invention be novel and sets out various exceptions to prior art and bars to patentability).

23. 35 U.S.C. § 103 (stating that a patent 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).

24. 35 U.S.C. § 112 (requiring that a patent application “contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.”).

25. 35 U.S.C. § 102.

26. Pub. L. No. 112-29, 125 Stat. 284.

102. Section E will highlight the judiciary's reasoning in an on-sale bar dispute between two pharmaceutical companies that culminated in the Supreme Court Decision *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.*²⁷

A. Pre-America Invents Act 35 U.S.C. § 102

The pre-AIA 35 U.S.C. § 102 statute lists many requirements for novelty.²⁸ In pre-AIA 35 U.S.C. § 102(a), there are bars to patentability for any invention that was (1) known by others in this country before the invention by the applicant, (2) used by others in this country before the invention by the applicant, (3) patented or described in a printed publication in the United States before the invention by the applicant, or (4) patented or described in a printed publication in a foreign country before the invention by the applicant.²⁹

Pre-AIA 35 U.S.C. § 102(b) deals with bars to patentability by the inventor.³⁰ These bars to patentability are:

1. The invention was patented or described in a printed publication in the United States more than one year prior to the date of application,
2. The invention was patented or described in a printed publication in a foreign country more than one year prior to the date of application,
3. The invention was in public use in the United States more than one year prior to the date of application, and
4. The invention was on sale in the United States more than one year prior to the date of application.³¹

The language of this section is of particular importance for the public use and on-sale bar and has been the source of much litigation, which will be discussed in Section C.³² The pertinent language reads "... in public use or on sale in this country, more than one year prior to the date of

27. 139 S. Ct. 628 (2019).

28. See 35 U.S.C. § 102 (Lexis 2010).

29. 35 U.S.C. § 102(a) (Lexis 2010).

30. 35 U.S.C. § 102(b) (Lexis 2010) ("(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States . . .").

31. *Id.*

32. See *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353, 1354 (Fed. Cir. 2001) (Patent claims invalidated based on "sales for the purpose of the commercial stockpiling of an invention" that "took place in secret"); *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55 (1998) (each detail of invention does not need to be disclosed in order for a sale to act as a bar.); *Pennock v. Dialogue*, 27 U.S. 1 (1829); *Smith & Griggs Mfg. Co. v. Sprague*, 123 U.S. 249 (1887) ("A single sale to another . . . would certainly have defeated his right to a patent . . ."); *Woodland Trust v. Flowertree Nursery, Inc.*, 148 F. 3d 1368, 1370 (Fed. Cir. 1998) ("Thus an inventor's own prior commercial use, albeit kept secret, may constitute a public use or sale under §102(b), barring him from obtaining a patent.").

application for patent in the United States”³³

Pre-AIA 35 U.S.C. § 102(c) deals with abandonment of an invention.³⁴ Pre-AIA 35 U.S.C. § 102(d) lays out a bar to patentability if an inventor applied for a foreign patent more than one year prior to applying for the patent with the USPTO and that foreign patent was issued before the application to the USPTO was filed.³⁵ Pre-AIA 35 U.S.C. § 102(e) lays out a bar to patentability in a situation where another individual describes the invention in a published U.S. patent or patent application before the invention by the applicant.³⁶ Pre-AIA 35 U.S.C. § 102(f) deals with the instance in which the applicant for a patent did not himself invent the subject matter to be patented.³⁷ Finally, pre-AIA 35 U.S.C. § 102(f) describes interference proceedings, which occur in situations where there is a dispute between two applicants about who invented the subject matter first.³⁸

B. Post-America Invents Act 35 U.S.C. § 102

The adoption of the AIA represented a drastic change to the patent system in the United States, as the system moved from a “first to invent” system to a “first to file” system.³⁹ In a first to invent system, the law is more concerned with giving patent rights to the person who invented the subject matter first, as seen in the various provisions of the pre-AIA 35 U.S.C. § 102.⁴⁰ In a first to file system, the law is more concerned with granting benefits to those inventors who disclose their invention first, allowing the public to benefit from the *quid pro quo* nature of the patent system faster.⁴¹ The change to the first to file system brought the United States closer to harmony with most of the other patent systems in the

33. 35 U.S.C. § 102(b) (Lexis 2010).

34. 35 U.S.C. § 102(c) (Lexis 2010).

35. 35 U.S.C. § 102(d) (Lexis 2010).

36. 35 U.S.C. § 102(e) (Lexis 2010).

37. 35 U.S.C. § 102(f) (Lexis 2010).

38. 35 U.S.C. § 102(g) (Lexis 2010) (“In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.”).

39. John Villasenor, *March 16, 2013: The United States Transitions To A 'First-Inventor-To-File' Patent System*, FORBES (Mar. 11, 2013, 11:54 PM), <https://www.forbes.com/sites/johnvillasenor/2013/03/11/march-16-2013-america-transitions-to-a-first-inventor-to-file-patent-system/> [https://perma.cc/993N-58GX].

40. 35 U.S.C. § 102(b) (Lexis 2010).

41. Villasenor, *supra* note 39.

world, who also use a first to file system.⁴²

Post-AIA 35 U.S.C. § 102(a)(1) reads:

- (a) Novelty; prior art. A person shall be entitled to a patent unless--
- (1) the claimed invention was patented, described in a printed publication, or in public use, *on sale, or otherwise available to the public* before the effective filing date of the claimed invention;⁴³

Therefore, the current bars to patentability include:

1. The invention was patented or described in a printed publication before the filing date of the claimed invention,
2. The invention was in public use before the effective filing date, and
3. The invention was on sale or otherwise available to the public before the effective filing date of the claimed invention.⁴⁴

Post-AIA 35 U.S.C. § 102(a)(2) describes a bar to patentability in which the claimed invention is described in a patent or published patent application that was filed before the filing date of the claimed invention.⁴⁵

Post-AIA 35 U.S.C. § 102(b) describes the exceptions to these bars.⁴⁶ These exceptions include disclosures made within one year before the filing date by the inventor or by a third party who obtained the disclosed information from the inventor directly or indirectly.⁴⁷ Additionally, when an inventor makes a public disclosure, that disclosure prevents subsequent third party disclosures from acting as bars to patentability of the invention.⁴⁸

When viewing the comparable sections in the post-AIA 35 U.S.C. § 102 statute to the pre-AIA 35 U.S.C. § 102 statute, Congress added the phrase “otherwise available to the public” to the public use and on-sale bars to patentability.⁴⁹ It is up for debate whether Congress intended this additional language to cover unforeseen circumstances by which the claimed invention become available to the public, or if this was a clarification that the rest of the statute only applies when the claimed invention becomes available to the public. The question is then whether it is or is not implied that the on-sale bar should be for public sales only.⁵⁰

42. Toshiko Takenaka, *Harmony with the Rest of the World? The America Invents Act*, 7 J. OF INTELL. PROP. LAW & PRACTICE 4 (Nov. 11, 2011), <https://academic.oup.com/jiplp/article/7/1/4/870662> [<https://perma.cc/ZCY9-Z6AP>].

43. 35 U.S.C. § 102(a)(1) (emphasis added).

44. *Id.*

45. 35 U.S.C. § 102(a)(2).

46. 35 U.S.C. § 102(b).

47. *Id.*

48. *Id.*

49. *See* 35 U.S.C. § 102 (Lexis 2010); 35 U.S.C. § 102 (2018).

50. The statute would then be read as, “or in public use, on sale [to the public], or otherwise available to the public”

C. The on-sale bar provision of 35 U.S.C. § 102

The idea of an on-sale bar provision began to appear early in the history of the patent system in the United States.⁵¹ In *Pennock v. Dialogue*, the Supreme Court tackled an issue around the public use and sale of an invention before it was patented.⁵² The Court explained that “it would materially retard the progress of science and the useful arts” to allow an inventor to “sell his invention publicly” and later “take out a patent” and “exclude the public from any farther use than what should be derived under it.”⁵³ In *Elizabeth v. Pavement Co.*, the Supreme Court explained that “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.”⁵⁴ Only a single sale is needed to defeat the right of an inventor to a patent.⁵⁵

In *Woodland Trust v. Flowertree Nursery, Inc.*, the Federal Circuit reasoned that the policy behind pre-AIA 35 U.S.C. § 102(b) was to encourage an inventor to enter the patent system promptly.⁵⁶ Building on this reasoning, the court held that an inventor’s own prior commercial use, even if kept secret, constitutes a public use or sale and acts as a bar to patentability.⁵⁷

Pfaff v. Wells Electronics, Inc. described a situation in which an individual was marketing a computer chip that he had sketched out more than a year before he filed for a patent application.⁵⁸ The Supreme Court held the patent invalid because the on-sale bar applied.⁵⁹ The Court described two conditions needed for the on-sale bar to apply.⁶⁰ First, a product must be subject to a commercial offer of sale.⁶¹ Second, the product must be ready to be patented.⁶² A product can be ready to be patented either by 1) having been reduced to practice in the form of a prototype or by 2) having prepared drawings or descriptions detailed enough such that a person having ordinary skill in the art would be enabled to practice the invention.⁶³

In *Special Devices, Inc. v. OEA, Inc.*, the Federal Circuit invalidated a

51. *Pennock v. Dialogue*, 27 U.S. 1 (1829).

52. *Id.*

53. *Id.* at 19.

54. 97 U.S. 126, 136 (1877).

55. *Smith & Griggs Mfg. Co. v. Sprague*, 123 U.S. 249, 257 (1887).

56. 148 F.3d 1368, 1370 (Fed. Cir. 1998).

57. *Id.*

58. 525 U.S. 55 (1998).

59. *Id.* at 68-69.

60. *Id.* at 67-68.

61. *Id.*

62. *Id.*

63. *Id.*

patent due to the on-sale bar because the inventor had contracted with a supplier to mass produce and stockpile the product in secret more than one year before the patent application.⁶⁴ It is important to note that in this instance the supplier and the inventor were not the same entity because if they were the same entity, the on-sale bar would not have applied.⁶⁵

The on-sale bar clearly applied to secret sales prior to the adoption of the AIA.⁶⁶ However, the addition of the phrase “otherwise available to the public” into 35 U.S.C. § 102 has complicated the interpretation.⁶⁷ Supreme Court case-law provides guidance when interpreting statutory revisions. In *Shapiro v. United States*, the Supreme Court held that when Congress adopted language in a new legislative act that was used in a prior legislative act, Congress also adopted the judicial interpretation of such language and made it a part of the new legislative act.⁶⁸ The Court in *Holder v. Martinez Gutierrez* held that “the doctrine of congressional ratification applies only when Congress reenacts a statute without relevant change.”⁶⁹ In *Paroline v. United States*, the Supreme Court, in a 5-4 decision, refused to extend the protection of a statute that had been reenacted without “language expressly suggesting Congress intended that approach.”⁷⁰ The dissenting opinion by Justice Sotomayor reasoned that textual and contextual reasoning was enough to conclude Congressional intent in this instance.⁷¹ In *Federal Maritime Comm’n v. Seatrain Lines, Inc.*, the Supreme Court refused to extend a statute that had changed due to the context provided by the legislative history.⁷²

D. Congressional intent in the post-America Invents Act 35 U.S.C. § 102

There are differing opinions in the legal world about how much weight legislative history should be given when interpreting a statute.⁷³ On one hand, some attorneys worry that “a legislative history can allow for manipulation, meaning a judge can find what he or she is looking for

64. *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353, 1354 (Fed. Cir. 2001).

65. *Id.* at 1357.

66. *See Woodland Trust v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1370 (Fed. Cir. 1998).

67. 35 U.S.C. § 102.

68. 335 U.S. 1, 15-16 (1948).

69. 566 U.S. 583, 592-593 (2012).

70. 572 U.S. 434 453 (2014).

71. *Id.* at 477.

72. 411 U.S. 726, 735 (1973).

73. Lauren Mattiuzzo, *Legislative Intent and Statutory Interpretation*, HEINONLINE: BLOG (Mar. 22, 2018), <https://home.heinonline.org/blog/2018/03/legislative-intent-and-statutory-interpretation/> [<https://perma.cc/RJ67-QJZ6>].

within the documents.”⁷⁴ Other attorneys, however, feel that “sifting through a legislative history will provide clarity to the original intent of the legislation.”⁷⁵ Additionally, proposed legislation undergoes many amendments such that the final language may not adequately describe the intent of the legislators when there is disagreement.⁷⁶ Here, the interpretation of the new statute was explicitly laid out in the legislative history.⁷⁷ As such, the legislative history should be given more weight.

In the legislative history of the AIA, there are many interesting comments by members of Congress involved in drafting and amending the legislation.⁷⁸ Senator Orrin Hatch and Senator Patrick Leahy were both quoted on the floor during an AIA clarification session.⁷⁹ Senator Hatch was quoted as stating: “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.”⁸⁰ Senator Leahy further clarified:

One 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.⁸¹

The on-sale bar further appeared in other floor hearings discussing the AIA. Senator Jon Kyl from Arizona said:

Another one of the bill’s clear improvements over current law is its streamlined definition of the term “prior art.” 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

74. *Id.* (citing Kenneth W. Starr, *Observations about the Use of Legislative History*, 1987 DUKE L.J. 371, 379 (1987), <https://heinonline.org/HOL/Page?handle=hein.journals/duklr1987&id=387&collection=journals>).

75. *Id.* (citing Matthew B. Todd, *Avoiding Judicial In-Activism: The Use of Legislative History to Determine Legislative Intent in Statutory Interpretation*, 46 WASHBURN L.J. 189, 222 (2006), <https://heinonline.org/HOL/Page?handle=hein.journals/wasbur46&id=195&collection=journals>).

76. *Id.*

77. 157 CONG. REC. S1496 (2011).

78. *See generally* 157 CONG. REC. S1496 (2011); 157 CONG. REC. S5319 (2011); 157 CONG. REC. S5431 (2011); 157 CONG. REC. H4429 (2011).

79. 157 CONG. REC. S1496 (2011).

80. *Id.*

81. *Id.*

demonstration of its use to a private group, or a third party's unrestricted but private use of the invention will no longer constitute private art. Only the sale or offer for sale of the invention to the relevant public or its use in a way that makes it publicly accessible will constitute prior art. The main benefit of the AIA public availability standard of prior art is that it is relatively inexpensive to establish the existence of events that make an invention available to the public. Under 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 doctrines. 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 PTO to operate much more efficiently.⁸²

After the bill was passed to the House of Representatives and back in the ordinary legislative process, Senator Kyl, being involved in negotiations with the House of Representatives, also made clarifications about the final form of the AIA that relates to the on-sale bar provision:

As Chairman SMITH most recently explained in his June 22 remarks, "contrary to current precedent, in order to trigger the bar in new 102(a) in our legislation, an action must make the patented subject matter 'available to the public' before the effective filing date." Therefore, "[i]f an inventor's action is such that it triggers one of the bars under 102(a), then it inherently triggers the grace period in section 102(b)." When the committee included the words "or otherwise available to the public" in section 102(a), the word "otherwise" made clear that the preceding items are things that are of the same quality or nature. As a result, the preceding events and things are limited to those that make the invention "available to the public." The public use or sale of an invention remains prior art, thus making clear that an invention embodied in a product that has been sold to the public more than a year before an application was filed, for example, can no longer be patented. Once an invention has entered the public domain, by any means, it can no longer be withdrawn by anyone. But public uses and sales are prior art only if they make the invention available to the public. In my own remarks last March, I cited judicial opinions that have construed comparable legislative language in the same way. Since that time, no opponent of the first-to-file transition has identified any caselaw that reads this legislative language any other way, nor am I aware of any such cases. I would hope that even those opponents of first to file who believe that supporters of the bill cannot rely on committee reports and sponsors' statements would at least concede that Congress is entitled

82. 157 CONG. REC. S5319 (2011). Senator Kyl was one of the main proponents of the AIA, as such his interpretation that prior art should be limited to activities that make the invention available to the public is important.

to rely on the consistent judicial construction of legislative language. Finally, I would note that the interpretation of 102 that some opponents appear to advance—that nondisclosing uses and sales would remain prior art, and would fall outside the 102(b) grace period—is utterly irrational. Why would Congress create a grace period that allows an invention that has been disclosed to the world in a printed publication, or sold and used around the world, for up to a year, to be withdrawn from the public domain and patented, but not allow an inventor to patent an invention that, by definition, has not been made available to the public? Such an interpretation of section 102 simply makes no sense, and should be rejected for that reason alone.⁸³

In the House, there have also been discussions about the on-sale bar, such as the comments by Congressman Lamar Smith referenced by Senator Kyl above.⁸⁴

However, not all of the representatives in Congress agree with the interpretation. In her Amicus Brief for *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*,⁸⁵ Representative Zoe Lofgren from California summarized the secret on-sale bar’s opposition statement as:

When Congress retained the phrase “on sale” without alteration in the Leahy-Smith America Invents Act of 2011 (“AIA”), Congress clearly intended to preserve the meaning of the on-sale bar as it had long been judicially interpreted, including in many of this Court’s own cases. All of the ordinary tools of statutory interpretation point to that result, including the plain language of the on-sale bar and established canons of statutory construction. The legislative history surrounding the AIA does not undermine this result—it supports it. Congress considered several alternative bills to the AIA that would have achieved the result for which Petitioner now advocates: replacing the on-sale bar with a pure publicity standard. Yet Congress did not adopt the language of those proposals and chose instead to preserve the on-sale bar as it had previously existed. Both advocates and opponents of the on-sale bar contemporaneously acknowledged that retaining the bar also meant retaining its judicially-defined meaning. It was only after opponents of the on-sale bar lost their bid to change the AIA’s text that individual members of Congress delivered floor statements (notoriously the least reliable form of legislative history) pressing a creative interpretation of the AIA’s ultimately-enacted language that would accomplish the very thing Congress had declined to do. Petitioner’s legislative history arguments rely on these isolated floor statements, ignoring the overall weight of legislative history and the traditional canons of statutory construction, all of which strongly favor

83. 157 Cong. Rec. S5431 (2011). Senator Kyl highlights that any contrary interpretation to the new 35 U.S.C. § 102 to the interpretation put forth by himself and Representative Smith would not make sense when the intent of the statute is considered.

84. See 157 Cong. Rec. H4429 (2011).

85. 139 S. Ct. 628 (2019).

Respondent's position in this case.⁸⁶

Representative Lofgren argues that the addition of “otherwise available to the public” broadens the conduct that invalidates a patent and does not constrict the range of conduct that invalidates a patent.⁸⁷ Going into further detail, Representative Lofgren states:

[R]eading “or otherwise available to the public” to modify the list of established terms preceding it would be inconsistent with the canon of statutory interpretation that applies when determining whether Congress has changed the meaning of a term this Court has previously defined. *Supra*, at 5-7. As explained, this Court expects that Congress will “provide[] a relatively clear indication of its intent” to change a statute’s meaning and disfavors “modification by implication.” *TC Heartland*, 137 S. Ct. at 1520 (quoting in part *Madigan*, 300 U.S. at 506). Yet “modification by implication” is precisely what Petitioner thinks Congress did. Petitioner would have this Court imply from the addition of the “or otherwise” language that Congress intended to modify the meaning of every judicially-interpreted term of art preceding it, essentially a clandestine way of making sweeping changes to existing caselaw. That is flatly inconsistent with how this Court expects Congress to act when it legislates around its precedential decisions.⁸⁸

Later in the brief, Representative Lofgren alleges:

Simply put, Rep. Lofgren offered her amendment to retain not only the words “on sale,” but also the meaning associated with those words, as they had been interpreted by this Court and the lower courts—indeed, that was the entire point of her amendment. Following her statement, Rep. Smith announced his support for Rep. Lofgren’s amendment and encouraged his colleagues to join him. Markup 102 (statement of Rep. Smith). Rep. Lofgren’s amendment passed, thus blocking the attempt to remove the on-sale bar from the bill in Committee.⁸⁹

However, when going back to the markup, a different story appears:

However, the related change in the manager's amendment goes beyond revising the grace period and also amends the definition of prior art in subsection 102(a). I have now heard strenuous concerns about the broader change from a wide range of stakeholders. In particular, they are concerned about the deletion of specific categories of prior art with well established meanings in case law and replacing those terms with a more ambiguous term otherwise disclosed to the public. Now, I understand that the chairman may be prepared to accept this amendment, and I would welcome that

86. Brief for Congresswoman Zoe Lofgren as Amicus Curiae Supporting Respondents, at 2, *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 139 S. Ct. 628 (2019) (No. 17-1229).

87. *Id.* at 3.

88. *Id.* at 8.

89. *Id.* at 13-14.

without further debate. *I am not offering an amendment to replace the section today because as we struggled to write something, it became clear in discussion with leg counsel that this is too complicated to draft in this time frame.*⁹⁰

The amendment that was agreed to by Representative Smith was an early amendment that automatically triggered the 35 U.S.C. § 102(b) grace period when a 35 U.S.C. § 102(a) bar was triggered, not an amendment dealing with the “otherwise available to the public” phrasing.⁹¹ Additionally, the manager’s amendment that Representative Lofgren was concerned about subsequently passed.⁹² Furthermore, nearly two months after the Representative Smith’s alleged agreement to Representative Lofgren’s interpretation of the on-sale bar provision, Representative Smith authored a report and stated: “Thus, in section 102 the ‘in this country’ limitation as applied to ‘public use’ and ‘on sale’ is removed, 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 accessible.”⁹³ Representative Smith has been consistent in this interpretation, stating in his Amicus Brief that “Most significantly, the term ‘available to the public’ in new § 102(a)(1) now functions as a terminal qualifier limiting prior art arising from ‘in public use’ or ‘on sale’ activities to what renders the subject matter defined by the patent claims available to the public.”⁹⁴

E. Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc. on-sale bar dispute

The determination of whether the secret on-sale bar provision had been removed or retained came to a head in *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*⁹⁵ In *Helsinn*, a Swiss pharmaceutical company, Helsinn

90. *America Invents Act of 2011: Markup of H.R. 1249 Before the H. Comm. on the Judiciary*, 112 Cong. 101 (2011) [hereinafter *Markup*] (statement of Rep. Zoe Lofgren) (emphasis added), https://www.uspto.gov/sites/default/files/aia_implementation/20110414-house_judiciary_markup_transcript.pdf [<https://perma.cc/T5A8-2L2M>].

91. *Markup*, supra note 91, 102 (statement of Rep. Lamar Smith). (“In that colloquy, the Senators discussed the scope of the grace period in the bill. Senator Leahy expressed his intent that, quote, if an inventor’s actions are such as to constitute prior art under subsection 102(a), then those actions necessarily trigger subsection 102(b)’s protections for the inventor, and what would have been section 102(a) as prior art would be excluded as prior art by the grace period provided by section 102(b).”).

92. *Markup*, supra note 91, 108 (statement of Rep. Lamar Smith and Ms. Kish). (“Ms. Kish: ‘Mr. Chairman, 29 members voted aye; 2 members voted nay.’ Chairman Smith. ‘The majority having voted in favor of the manager’s amendment, it is agreed to’”).

93. *Markup*, supra note 91, 42 (statement of Rep. Lamar Smith).

94. Brief for Congresswoman Zoe Lofgren as Amicus Curiae Supporting Respondents, at 3, *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 139 S. Ct. 628 (2019) (No. 17-1229).

95. 139 S. Ct. 628 (2019).

Healthcare S.A. (“Helsinn”), entered into a license agreement and a supply and purchase agreement with a Minnesota based company, MGI Pharma, Inc.⁹⁶ The two agreements included the dosage information, but required MGI Pharma, Inc. to keep proprietary information confidential.⁹⁷ The agreements were announced publicly, but did not disclose the dosage information.⁹⁸ Helsinn filed multiple patents relating back to the initial drug, the fourth patent being effective in May 2013.⁹⁹ Teva Pharmaceutical Industries, Ltd. is an Israeli company and Teva Pharmaceuticals USA, Inc. is its American affiliate (“Teva”).¹⁰⁰ They both manufacture generic drugs.¹⁰¹ Helsinn sued Teva for infringing the fourth patent relating to its drug.¹⁰² Teva claimed that the patent was invalid because the dosage was on-sale more than one year before the application was filed.¹⁰³

The District Court reasoned that the on-sale bar did not apply because “under the AIA, an invention is not ‘on sale’ unless the sale or offer in question made the claimed invention available to the public.”¹⁰⁴ Since the public disclosure of the sale did not include the dosage, the court reasoned that the invention was not on sale.¹⁰⁵

The Federal Circuit reversed and explained that “if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms of sale” to come under the on-sale bar of the AIA.¹⁰⁶ Therefore, the on-sale bar applied according to the Federal Circuit because the sale of the drug was public.¹⁰⁷ The Federal Circuit relied on *Medicines Co. v. Hospira, Inc.*¹⁰⁸ to make its decision.¹⁰⁹ The court reasoned that the question of whether there was an offer for sale must be “‘analyzed under the law of contracts as generally understood’ and ‘must focus on those activities that would be understood to be commercial sales and offers for sale ‘in the commercial community.’”¹¹⁰ The court then looked to the Uniform Commercial Code and determined that “A sale

96. *Id.* at 631.

97. *Id.*

98. *Id.*

99. *Id.*

100. *Id.*

101. *Id.*

102. *Id.*

103. *Id.*

104. *Id.* at 632 (citing *Helsinn Healthcare S. A. v. Dr. Reddy’s Labs. Ltd.*, 387 F. Supp. 3d 439, 2016 U.S. Dist. LEXIS 27477, 2016 WL 832089, *45, *51 (D.N.J., Mar. 3, 2016)).

105. *Id.*

106. *Id.*

107. *Id.*

108. 827 F.3d 1363 (Fed. Cir. 2016).

109. *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 855 F.3d 1356, 1364 (Fed. Cir. 2017).

110. *Id.*

occurs when there is a ‘contract between parties to give and to pass rights of property for consideration which the buyer pays or promises to pay the seller for the thing bought or sold.’”¹¹¹

Other factors from *Medicines* that the court looked at include passage of title, the confidential nature of a transaction, and the presence of commercial marketing of the invention.¹¹² In this case, those factors weighed against applying the on-sale bar.¹¹³ The absence of regulatory approval for a product in a sale does not preclude the on-sale bar from being triggered.¹¹⁴ Helsinn argued that the floor statements of Congress should be analyzed to determine the post-AIA 35 USC § 102(a).¹¹⁵ The Federal Circuit rejected this argument and declined to decide the case more broadly than necessary.¹¹⁶ The court reasoned that no cases were identified by the floor statements that would be overturned by the amendments.¹¹⁷ The court further explained: “Even if the floor statements were intended to overrule those secret or confidential sale cases discussed above . . . that would have no effect here since those cases were concerned entirely with whether the existence of a sale or offer was public.”¹¹⁸

Helsinn additionally argued that the “otherwise available to the public” language requires that details of the claimed invention be disclosed before the on-sale bar is triggered.¹¹⁹ The court relied on a case from the early 19th century, *Pennock v. Dialogue*,¹²⁰ to determine that the on-sale bar still applies when the secrets of the invention are withheld from the public.¹²¹ The court reasoned that the floor statements must have intended for the public sale to put the patented product in the hands of the public.¹²² The court cited a statement by Senator Kyl, in which he stated “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.”¹²³ The court further stated that there are no floor statements suggesting that the sale must publicly disclose the details of the claimed invention in order for the on-sale bar to apply.¹²⁴ The court concluded by stating that if Congress

111. *Id.*

112. *Id.*

113. *Id.*

114. *Id.* at 1365.

115. *Id.*

116. *Id.*

117. *Id.*

118. *Id.* at 1369.

119. *Id.*

120. 27 U.S. 1 (1829).

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

122. *Id.* at 1371.

123. *Id.* (citing 157 CONG. REC. 3423 (2011) (remarks of Sen. Kyl)).

124. *Id.*

wanted to make a drastic change to the on-sale bar, they would have done so by using clear language.¹²⁵

The Supreme Court affirmed the Federal Circuit's judgment.¹²⁶ The Court reasoned that "The new §102 retained the exact language used in its predecessor statute ('on sale') and, as relevant here, added only a new catch all clause ('or otherwise available to the public')." ¹²⁷ The Court did not consider the addition of "or otherwise available to the public" a strong enough reason to conclude Congress' actual intention.¹²⁸ The Court refused to read the addition as a modifier because the phrase "on sale" had acquired a well-settled meaning when the AIA was enacted.¹²⁹ Therefore, the court determined that *Pfaff v. Wells Electronics, Inc.*¹³⁰ was still controlling.¹³¹ This ruling therefore meant that "on sale" was to be interpreted the same as the pre-AIA 35 U.S.C. § 102(a), which required that the invention was "the subject of a commercial offer for sale" and "ready for patenting."¹³² Under *Pfaff*, each detail of invention does not need to be disclosed in order for a sale to act as a bar.¹³³ The Court relied on *Shapiro v. United States*¹³⁴ to adopt the presumption that "when Congress reenacted the same language in the AIA, it adopted the earlier judicial construction of that phrase."¹³⁵

III. DISCUSSION

The Supreme Court's interpretation of the post-AIA 35 USC § 102(a) is seemingly at odds with the explicit intent of the main congressional supporters of the AIA.¹³⁶ The Supreme Court reasons that the phrase "otherwise available to the public" did not affect the meaning of the post-

125. *Id.* (citing *Dir., OWCP v. Perini N. River Assocs.*, 459 U.S. 297, 321, 103 S. Ct. 634, 74 L. Ed. 2d 465 (1983)).

126. *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 139 S. Ct. 628, 632 (2019).

127. *Id.* at 634.

128. *Id.*

129. *Id.*

130. 525 U.S. 55 (1998).

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

132. *Id.* The invention can be shown to be ready for patenting by proof of reduction to practice or drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention.

133. *Id.* at 633.

134. 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.'").

135. *Helsinn Healthcare S.A.*, 139 S. Ct. at 633-34 (2019).

136. See *Helsinn Healthcare S.A.*, 139 S. Ct. 628; 157 CONG. REC. S5431 (2011); 157 CONG. REC. S1496 (2011).

AIA 35 USC § 102(a).¹³⁷ However, Senator Kyl, Senator Leahy, and Representative Smith have argued that the addition of the phrase “otherwise available to the public” had the purpose of removing secret sales from the equation when considering the on-sale bar of the post-AIA 35 USC § 102(a).¹³⁸ This section argues that the Supreme Court was incorrect in its interpretation of the post-AIA 35 USC § 102(a) and suggests language that Congress could add to make its intent clear enough for the Supreme Court so that the interpretation is in line with the original Congressional intent of the AIA.

A. The Supreme Court incorrectly interpreted post-AIA 35 USC § 102

The Supreme Court declined to read the addition of “otherwise available to the public” as a modifier because the phrase “on sale” had acquired a well-settled meaning when the AIA was enacted.¹³⁹ The Court also determined that the language of the post-AIA 35 USC § 102(a) had the same judicial construction as the earlier pre-AIA 35 USC § 102.¹⁴⁰

However, the primary sponsors of the Leahy-Smith America Invents Act had a different interpretation. When discussing the addition of “otherwise available to the public” and its effect on the on-sale bar, Senator Leahy stated on the record that one of the goals of the revisions of 35 USC § 102(a) was “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.”¹⁴¹ Similarly, Representative Smith has been quoted in Congressional records as saying “contrary to current precedent, in order to trigger the bar in new 102(a) in our legislation, an action must make the patented subject matter ‘available to the public’ before the effective filing date.”¹⁴² The intent of the authors of the AIA were made clear on the floor of Congress in both chambers prior to voting. If a disagreement in this interpretation was present, it could have been addressed in the form of an amendment by another Congressman. While Congresswoman Lofgren did raise concerns and suggest an amendment, that amendment was never passed. Therefore, the intent of Congress was that “otherwise available to the public” lined up with the interpretation of the cosponsors of the bill.

On one side, the Supreme Court alleges that Congressional addition of

137. *Helsinn Healthcare S.A.*, 139 S. Ct. at 633-34.

138. 157 CONG. REC. S5431 (2011); 157 CONG. REC. S1496 (2011).

139. *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 139 S. Ct. 628, 632 (2019).

140. *Id.* at 634.

141. 157 CONG. REC. S1496 (2011).

142. 157 CONG. REC. S5320 (2011).

“otherwise available to the public” does not modify the preceding language in 35 USC § 102(a) and that the statute’s construction is the same as before the AIA. On the other side, Senator Leahy explicitly states that the draft of the new 35 USC § 102(a) was done in such a way as to “do away with precedent under current law” that private offers for sale act as part of the on-sale bar. Further supporting Senator Leahy is Representative Smith’s quote saying “contrary to current precedent” an action must be available to the public to trigger the new on-sale bar. These facts are in direct conflict with one another.

It is clear that the main cosponsors of the AIA agreed that the addition of “otherwise available to the public” did away with the precedent of the pre-AIA 35 USC § 102(a) on-sale bar construction. This amounts to an overreach by the Supreme Court. The Court essentially ignores the intent of Congress and instead opts to replace the interpretation of the new law with the interpretation of the old law. The Supreme Court relied on precedent that suggested “a sale or offer of sale need not make an invention available to the public.”¹⁴³ A sale or offer of sale that does not make the invention available to the public is a private sale. Congressional intent was to get rid of the private sale as a bar to patentability. Therefore, the precedent that the Supreme Court relied upon to make their interpretation was not valid.

This leads to an analysis of what the Supreme Court thought the addition of “otherwise available to the public” was meant to do. The Court stated that the addition of “otherwise available to the public” was meant to capture “material that does not fit neatly into the statute’s enumerated categories but is nevertheless meant to be covered.”¹⁴⁴ This interpretation is both broad and vague. Material that does not fit neatly into the statute’s enumerated categories is not discussed by Congress. This interpretation essentially gives the Judiciary free reign to decide whether material was “meant to be covered” or not. Essentially, the Judiciary has given itself the power to erase Congressional intent and replace it with Judicial intent.

The Supreme Court claimed that “otherwise available to the public” was a broad catchall phrase. If the intent of Congress when authoring the statute was considered, it is clear that the interpretation of “otherwise available to the public” is actually narrowing, as it is meant to narrow “on sale” to only sales that are public.

143. *Helsinn Healthcare S.A.*, 139 S. Ct. at 633.

144. *Id.* at 634.

B. A proposed change to 35 USC § 102(a) that removes private sales as a bar.

As discussed above, the Supreme Court's interpretation of 35 USC § 102(a) and Congressional interpretation of 35 USC § 102(a) are at odds with one another. Since it is unlikely that the Supreme Court reverses its own opinion, the way to align the state of the law with the original Congressional intent is for Congress to amend the statute. This note recommends removing "otherwise available to the public" altogether to remove the apparent ambiguity and replace it with "to public" immediately after "on sale". The statute would read like this:

- (a) Novelty; prior art. A person shall be entitled to a patent unless--
- (1) the claimed invention was patented, described in a printed publication, or in public use, or on sale to the public before the effective filing date of the claimed invention;

This change would unquestionably bring the meaning of the statute within the original intent of the AIA by removing secret or private sales from the bar to patentability under 35 USC § 102(a). This amendment would result in a phrase that is clear in its meaning.

IV. CONCLUSION

Obtaining a patent is an expensive process, especially for a small business or entrepreneur that is dealing with a limited budget and limited cash flow. The AIA was intended to help entrepreneurs and small businesses. One way it was intended to accomplish this was by allowing flexibility in the form of allowing secret sales. Allowing secret sales would allow small businesses and entrepreneurs to increase their budgets and cash flows in anticipation of patenting. Large Fortune 500 companies have plenty of cash, so they can play it safe and file patents when there is an invention ready for patenting.

Even more expensive than obtaining a patent is patent litigation. A patent owner will bring infringement claims to court with hopes of obtaining large amount of damages that will make their litigation costs worth it. When faced with a claim of patent infringement, a common strategy is to argue that the patent is invalid and should not have been granted in the first place. One way to do this is by applying one of the novelty bars described in 35 USC § 102. When Congress tried to narrow the on-sale bar to only encompass sales available to the public, it was essentially strengthening patents and making them harder to invalidate. As innovation powers forward in all fields of technology within the United States, many large companies have run into many patent litigation issues with smaller patent holders. Thus, there was an incentive for the

large companies to push forward questions regarding the on-sale bar after the implementation of the AIA in the Judiciary, as the old interpretation of the statute was more beneficial to them.

The Supreme Court ultimately decided the interpretation of 35 USC § 102(a) in *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, where it decided that the addition of “otherwise available to the public” was not intended to change the meaning of the statute. However, records from the floor of both chambers of Congress suggest that Congress did in fact intend for the addition of “otherwise available to the public” to remove private or secret sales from the on-sale bar. When considering these statements, it becomes clear that the Supreme Court incorrectly interpreted the statute. A simple Congressional amendment to the statute by changing “on sale” to “on sale to the public” could harmonize the interpretation of the statute with the intent of Congress, but this time in a clear manner that would not be up to the discretion of the Supreme Court.