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Helsinn v. Teva: A Big Blow to Small Pharma

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HEL SINN V. TEVA: A BIG BLOW TO SMALL PHARMA

Anureet Sandhu*

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In Helsinn v. Teva, the Supreme Court held that Congress did not alter the meaning of “on sale” when it enacted the Leahy-Smith America Invents Act and, therefore, an inventor’s sale of an invention to a third party who is obligated to keep the invention confidential may qualify as prior art. The Court relied upon precedent which suggested that a sale or offer of sale need not make an invention available to the public to qualify as prior art. Instead, the on-sale bar only required that the invention be the subject of a commercial offer for sale and ready for patenting.

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Unfortunately, the Court's nine-page opinion fell short of expectations. Not only was the Court's decision at odds with the legislative history of the Leahy-Smith America Invents Act, it will undoubtedly create unnecessary confusion regarding the proper implementation of the on-sale bar. Further, this decision interferes with Congressional intent to harmonize the United States patent system with those of other countries. Most importantly, this decision will have a particularly detrimental effect on small and midsize pharmaceutical companies who frequently rely on partnerships with larger, more profitable entities in order to continue with their research and development of new drugs.

INTRODUCTION

When *Helsinn v. Teva* finally reached the Supreme Court, there was anticipation that this case could offer some much-needed clarification on the true interpretation of the on-sale bar in the wake of the passage of the Leahy-Smith America Invents Act ("AIA").¹ Congress had significantly changed patent laws under the AIA including some minor yet noteworthy changes to the on-sale bar.² Not only was the on-sale bar no longer limited to commercial activity within the United States, but the new catchall provision suggested that in order to constitute prior art a sale must make the claimed invention "available to the public."³ Such changes were implemented with the intent to improve the United States patent system and harmonize it with the patent laws of other countries.⁴

Unfortunately, the Federal Circuit's decision in *Helsinn* appeared to contradict such intentions.⁵ The Federal Circuit held that any sale, whether public or private, may render a patent

¹ Hans Sauer, *Why Helsinn v. Teva Creates Inscrutable Uncertainty About the Scope of Prior Art Instead of Confirming Longstanding Law*, IP WATCHDOG (Feb. 5, 2019), <https://www.ipwatchdog.com/2019/02/05/helsinn-v-teva-creates-inscrutable-uncertainty-scope-prior-art-instead-confirming-longstanding-law/id=105953/> (noting the need for clarity regarding the implementation of the on-sale bar for business and patent owners under current AIA law).

² Brief for Petitioner at 3-4, *Helsinn Healthcare S.A. v. Teva Pharm. USA Inc.*, 139 S. Ct. 628 (2019) (No. 17-1229) (describing how Congress modified the on-sale bar with the removal of the geographical requirement as well as the addition of the phrase "or otherwise available to the public").

³ *Id.*

⁴ *Id.*

⁵ *Helsinn*, 855 F.3d 1356, 1371 (Fed. Cir. 2017) (holding 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").

invalid.⁶ However, the Federal Circuit refrained from answering whether the AIA had changed the meaning of the on-sale bar.⁷ The Federal Circuit's hesitation in answering this question only increased the confusion surrounding the true interpretation of the on-sale bar in light of the AIA. In particular, the Federal Circuit's holding created a great deal of uncertainty for small and midsize pharmaceutical companies who often rely on confidential deals with business partners to finance the research and development of new drugs.⁸

Thus, when the Supreme Court granted certiorari on the single issue of whether a confidential sale of an invention to a third party would qualify as prior art under the AIA, there was hope that the Supreme Court could shed some light on questions left unanswered by the Federal Circuit.⁹ Unfortunately, the Court's holding further exacerbated the problem created by the Federal Circuit's decision.¹⁰ The Court's unanimous yet relatively short opinion hardly delved into the drafting history of the AIA.¹¹ By failing to adequately consider the drafting history, which led to significant changes in the language of the on-sale bar, the Supreme Court thwarted efforts to streamline patent laws in the United States and potentially jeopardized the research and development of innovative drugs fueled by the efforts of small and midsize pharmaceutical companies.

Part I of this Note describes the history and development of the AIA. In particular, Part I will examine the status of the on-sale

⁶ *Id.*

⁷ *Helsinn*, 855 F. 3d at 1368.

⁸ Brief for Massachusetts Biotechnology Council ("MassBio") as Amicus Curiae Supporting Petitioner at 13, *Helsinn*, 139 S. Ct. 628 (explaining how the high cost of drug development and limited resources leads many small and midsize biotechnology companies to rely on partnerships with business partners to support their research and development).

⁹ Sauer, *supra* note 1 (noting that the Supreme Court granted *Helsinn* certiorari on the sole issue of whether confidential sales by inventors to third parties may constitute prior art); see also *Helsinn*, 855 F. 3d at 1368 (refraining from answering whether the AIA had changed the meaning of the on-sale bar and therefore deciding the case "more broadly than necessary").

¹⁰ *Id.* (lamenting the "host of problems" that *Helsinn* would create which were "never the law before or after the AIA").

¹¹ *Helsinn*, 139 S. Ct. at 634 (limiting discussion of Congressional intent in enacting the on-sale bar language of the AIA by stating that "the addition of 'otherwise made available to the public' is simply not enough of a change for us to conclude that Congress intended to alter the meaning of the reenacted term 'on sale'").

bar before and after the passage of the AIA. Part II discusses the factual and procedural history of *Helsinn* and the Supreme Court's decision. Part III argues that the Court's decision runs contrary to the drafting history of the AIA and ignores Congressional intent. Finally, Part IV explains the potential negative implications of this decision for research and development efforts by small and midsize pharmaceutical companies. Part V offers a brief conclusion.

I. THE HISTORY AND DEVELOPMENT OF THE ON-SALE BAR

Congress is authorized by the Constitution “[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.”¹² The United States patent system is therefore a delicate balance between rewarding inventors while preventing monopolization.¹³ In the interest of striking this balance, Congress has included some version of the on-sale bar in “every patent statute since 1836.”¹⁴ The on-sale bar was created with the intention of preventing situations wherein an inventor may profit from his or her invention and only remove it from the public domain when threatened by competition.¹⁵

Patent law was dramatically changed in 2011 when Congress enacted the AIA in order to “replace the existing first-to-invent patent system with a first-to-file system.”¹⁶ This was done with the intention of bringing the United States patent system in harmony with other major patent systems around the world.¹⁷ A major development in the law included changes to the definition of prior art.¹⁸ The AIA altered the definition of prior art in three

¹² Art. 1, §8, cl. 8.

¹³ *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55, 63 (1998) (explaining that “the patent system represents a carefully crafted bargain that encourages both the creation and the public disclosure of new and useful advances in technology, in return for an exclusive monopoly for a limited period of time.”).

¹⁴ *Id.* at 65 (noting that the Patent Act of 1836 was the first statute to include an on-sale bar).

¹⁵ *Pennock v. Dialogue*, 27 U.S. 1, 13 (1829) (describing how it would be unfair to allow an inventor to exclude knowledge previously available to the public even though he has already made and sold his invention publicly for many years).

¹⁶ Brief for Petitioner at 5, *Helsinn*, 139 S. Ct. 628 (noting that the AIA “transformed the Nation’s patent laws”).

¹⁷ *Id.* (discussing how the AIA altered the definition of prior art).

¹⁸ *Id.* at 6.

major ways including: (1) the addition of the catchall phrase “or otherwise available to the public,” (2) removal of the geographical limitations for patent invalidity and (3) replacing the term “invention” with the phrase “claimed invention.”¹⁹ This Part will discuss the implementation of the on-sale bar before and after the passage of the AIA.

A. The State of the On-sale Bar Prior to the America Invents Act

Prior to the passage of the Patent Act of 1836 which was the first federal Patent Act to include some form of an on-sale bar, *Pennock v. Dialogue* was decided.²⁰ The *Pennock* opinion included an important discussion of the negative consequences of an inventor’s decision to commercially exploit his or her invention prior to applying for a patent.²¹ In *Pennock*, the Court reasoned that an inventor may not “acquire good title to a patent, if he suffers the thing invented to go into public use, or to be publicly sold for use, before he makes application for a patent.”²² The Court repeatedly emphasized that it is the fact that an invention has been made *publicly* available which invalidates the patent.²³

Under the Patent Act of 1952, the on-sale bar stated that a patent may be invalid if an “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.”²⁴ The language of the on-sale bar in the Patent Act of 1952 therefore remained true to the goal of rewarding innovation while “avoiding monopolies that unnecessarily stifle competition.”²⁵ The Supreme Court analyzed the implications of this overarching goal of patent law in *Bonita Boats, Inc. v. Thunder Craft Boats, Inc.*²⁶ The Court

¹⁹ *Id.*

²⁰ *See Pfaff*, 525 U.S. at 65; *see also Pennock*, 27 U.S. at 13.

²¹ *See Pennock*, 27 U.S. at 8 (noting that it is “directly contrary” to the purposes of patent law when an inventor attempts to withdraw his invention from the common stock after the public has already had full possession of it).

²² *Id.* at 10.

²³ *Id.* at 20 (describing how under the common law of England, letters patent were unavailable for the protection of articles in public commerce at the time of the application and this embodied in the patent laws passed in this country).

²⁴ 35 U.S.C 102(b) (2006).

²⁵ *See Pfaff*, 525 U.S. at 63.

²⁶ *Bonita Boat, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 156-157 (1989) (holding that “a state law that substantially interferes with the enjoyment

reiterated the reasoning in *Penncock* that “the public sale of an unpatented article has acted as a complete bar to federal protection of the idea embodied in the article thus placed in public commerce.”²⁷ Again, the Court emphasized that a key disqualifying factor for patentability was the *public* nature of the sale.

When the Supreme Court decided *Pfaff v. Wells Electronics, Inc.* in 1998, however, it shifted the focus of the on-sale bar analysis.²⁸ The Court held that the on-sale bar applied when an invention was “the subject of a commercial offer for sale” and “ready for patenting” for more than one year before the inventor filed his or her patent application.²⁹ Notably, this standard is completely devoid of any discussion of whether the sale must disclose the claimed invention to the public as was the case in *Pennock* and *Bonita Boats*.³⁰ Nevertheless, this has been the standard for the pre-AIA on-sale bar since its inception.³¹ The Court later clarified in *Medicines Company v. Hospira* that mere preparations for commercial sales did not invalidate a patent under the pre-AIA on-sale bar.³²

B. The Development and Implementation of the America Invents Act

While the AIA was enacted in 2011, efforts to bring about these major changes to the United States patent system began as early as 1982.³³ A “nationwide consensus” had been developing

of an unpatented utilitarian or design conception which has been freely disclosed by its author to the public at large impermissibly contravenes the ultimate goal of public disclosure and use which is the centerpiece of federal patent policy”).

²⁷ *Id.* at 149.

²⁸ See Brief for Petitioner at 5, *Helsinn*, 139 S. Ct. 628 (noting that the holding in *Pfaff* “was in tension with this Court’s repeated statements that the on-sale bar reached the ‘public sale of an unpatented article’ that placed the article ‘in public commerce’”).

²⁹ See *Pfaff*, 525 U.S. at 67.

³⁰ *Id.* at 68 (finding that the plaintiff’s patent was invalid under the on-sale bar because his invention was ready for patenting prior to the critical date without considering whether the sale made the invention available to the public).

³¹ See *Helsinn*, 139 S. Ct. at 634 (clarifying that the Court had not previously addressed whether a sale must disclose the claimed invention to public in order to invalidate a patent under the on-sale bar).

³² *Medicines Co. v. Hospira, Inc.*, 827 F.3d 1363, 1377 (holding that “the mere stockpiling of a patented invention by the purchaser of manufacturing services does not constitute a ‘commercial sale’ under §102(b)”).

³³ Brief for The Intellectual Property Law Association of Chicago

amongst the patent community for the United States to “move to a first-inventor-to file patent system.”³⁴ Therefore, the Senate created an Intellectual Property Subcommittee of the Senate Judiciary Committee in 2005.³⁵ Congress consulted those in the patent community as well as the United States Patent and Trademark Office (“USPTO”) in reforming the United States patent system.³⁶

Alongside other significant changes, the Patent Reform Act of 2007 specifically altered the scope of prior art.³⁷ The Act clarified that prior art must be “available to the public.”³⁸ The Patent Reform Act of 2009 reiterated this idea as well.³⁹ The Senate bill finally passed in 2011.⁴⁰ In its consideration of the AIA, the House Report stated that the Act “simplifies how prior art is determined, provides more certainty, and reduces the cost associated with filing and litigating patents.”⁴¹ The House and Senate subsequently passed the AIA.⁴²

Prior to the passage of the bill, members of Congress debated the particular language of the on-sale bar at great length.⁴³ The final Committee Report for the AIA cited floor remarks from Senator Jon Kyl who explained the Congressional intent behind changing the language of the on-sale bar.⁴⁴ He stated that Congress wished to do away with the “secret-sale and private use forfeiture doctrines” which served as “traps for unwary inventors” imposing “extreme results to no real purpose.”⁴⁵ Therefore, the new §102(a)(1) purposely limited the scope of non-patent prior art to that which is “available to the public.”⁴⁶

Furthermore, the addition of the catchall provision aligned

(“IPLAC”) as Amicus Curiae Supporting Petitioner at 6, *Helsinn*, 139 S. Ct. 628.

³⁴ *Id.* at 7.

³⁵ *Id.* at 8.

³⁶ *Id.*

³⁷ *Id.* at 9.

³⁸ *Id.*

³⁹ *Id.*

⁴⁰ *Id.* at 11.

⁴¹ *Id.*

⁴² *Id.*

⁴³ See Brief for Petitioner at 7, *Helsinn*, 139 S. Ct. 628 (explaining that the phrase “or otherwise made available to the public” originated in the Senate Judiciary Committee and was included in the House Bill as well).

⁴⁴ Joe Matal, *A Guide to the Legislative History of the America Invents Act: Part 1 of II*, 21 FED. CIR. B.J. 435, 466-469.

⁴⁵ *Id.*

⁴⁶ *Id.*

with Congressional intent to harmonize the United States patent system with that of its international counterparts.⁴⁷ Prior to the passage of the AIA, the United States was the only patent system which did not abide by the first-inventor-to-file principle.⁴⁸ Moreover, most other patent systems outside of the United States required that a claimed invention be made public in order to constitute prior art.⁴⁹ Thus, by switching to a first-inventor-to-file system and adding the phrase “or otherwise available to the public,” Congress made United States patent law consistent with the laws of other major patent systems around the world.

Additionally, the USPTO issued revised guidelines for examining patent applications after the passage of the AIA.⁵⁰ The USPTO instructed examiners that a sale under the AIA “must make the invention available to the public” to qualify as prior art.⁵¹ This interpretation was later included in the Manual of Patent Examining Procedures.⁵² Therefore, the USPTO respected Congressional intent in its application of the post-AIA on-sale bar.

II. *HEL SINN V. TEVA*

The drafting history of the AIA strongly suggests that Congress intentionally and thoughtfully included this catchall provision in the on-sale bar of the AIA. Yet, despite the addition of this new language in the on-sale bar of the AIA, neither the Federal Circuit nor the Supreme Court interpreted the new statutory language prior to *Helsinn*.⁵³ When *Helsinn* filed a writ of certiorari in February 2018, the Supreme Court finally had the

⁴⁷ See Brief for Petitioner at 6, *Helsinn*, 139 S. Ct. 628 (noting that “the AIA’s fundamental innovation was to replace the existing first-to-invent patent system with a first-inventor-to-file system which would bring “the American patent system in line with the world’s other major patent systems”).

⁴⁸ *Id.*

⁴⁹ Brief for Congressman Lamar Smith as Amicus Curiae Supporting Petitioner at 6, *Helsinn*, 139 S. Ct. 628 (clarifying that other countries have long interpreted “available to the public” to “preclude subject matter that remains confidential or otherwise secret from constituting prior art and being used to invalidate a patent”).

⁵⁰ See Brief for Petitioner at 8, *Helsinn*, 139 S. Ct. 628.

⁵¹ *Id.*

⁵² *Id.*

⁵³ Joseph A. Herndon & James L. Korenchan, *Pre-AIA and Post AIA Issues Presented By The On-Sale Bar*, LAW360 (Aug. 11, 2016, 12:13 PM), <https://www.law360.com/articles/825887/pre-ai-a-and-post-ai-a-issues-presented-by-the-on-sale-bar>; see also *Helsinn*, 139 S. Ct. at 634.

opportunity to offer some insight into the true interpretation of the new language.⁵⁴

The Supreme Court granted certiorari in June 2018 on the sole issue of whether a confidential sale by an inventor to a third party places the invention “on sale” within the meaning of §102(a).⁵⁵ This Part will describe the facts and procedural history of the case and conclude with a discussion of the Court’s opinion.

A. Facts and Procedural History in the Lower Courts

The patents at issue in this case cover dosages of palonosetron which is used in treating chemotherapy-induced nausea and vomiting.⁵⁶ Scientists working under a company named Syntex (U.S.A), Inc. (“Syntex”) in California began the original research into the usage of palonosetron for preventing nausea and vomiting.⁵⁷ Syntex was later acquired by Roche, a Swiss pharmaceutical company.⁵⁸ Petitioner Helsinn Healthcare S.A. (“Helsinn”) is also a Swiss pharmaceutical company and when it became aware that Roche had decided to terminate its palonosetron development project, it entered into a license agreement with Roche and continued the development of palonosetron into a pharmaceutical product.⁵⁹ In order to proceed with development of the product, Helsinn partnered with Oread, Inc. (“Oread”).⁶⁰ However, Oread went out of business in the middle of Phase III trials of the drug.⁶¹

Helsinn then found a commercial partner in MGI Pharma, Inc. (“MGI”), a Minnesota company.⁶² They entered into a license agreement and a supply and purchase agreement with MGI.⁶³ MGI was not buying a product but rather the rights to participate in the development effort to potentially have a product in the future.⁶⁴ MGI is a publicly traded company required to file SEC disclosures

⁵⁴ Petition for Writ of Certiorari, *Helsinn*, 139 S. Ct. 628 (2019) (No. 17-1229).

⁵⁵ Sauer, *supra* note 1.

⁵⁶ *Helsinn Healthcare S.A. v. Dr. Reddy’s Laboratories Ltd.*, No. 11-3962, 2016 WL 832089, at *1 (D.N.J 2016).

⁵⁷ *Id.* at 5.

⁵⁸ *Id.* at 8.

⁵⁹ *Id.* at 10-12.

⁶⁰ *Id.* at 14-15.

⁶¹ *Id.*

⁶² *Id.* at 27.

⁶³ *Id.*

⁶⁴ *Id.* at 28.

and so in its published SEC Form 8-K it reported these agreements with Helsinn.⁶⁵ Palonosetron was mentioned in the public disclosures but the exact dosage was redacted.⁶⁶

Helsinn brought suit against respondents Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA, Inc. ("Teva") alleging infringement of its patents including the '219 patent.⁶⁷ In response, Teva argued that the '219 patent was invalid under the on-sale bar.⁶⁸ The District Court held that under the AIA the claimed invention must be made available to the public in order to trigger the on-sale bar.⁶⁹ In making this determination, the court considered the statutory language, UPSTO guidelines, the legislative history of the AIA, and public policy implications.⁷⁰ Thus, the Court found that because the public disclosure of the agreements between Helsinn and MGI did not disclose exact dosage of palonosetron, the invention was not "on sale" prior to the critical date.⁷¹

The Federal Circuit reversed the District Court's holding and held that there was a sale under the standard set by *Pfaff* given that invention was ready for patenting.⁷² However, the Federal Circuit refrained from engaging in a discussion as to whether the AIA had altered the meaning of the on-sale bar.⁷³ The Supreme Court granted certiorari on this issue alone.⁷⁴

B. The Court's Opinion

The Court delivered a unanimous opinion holding that a confidential sale of an invention to a third party places the invention "on sale" within the meaning of §102(a).⁷⁵ The Court's

⁶⁵ *Id.* at 29.

⁶⁶ *Id.*

⁶⁷ *Id.* at 1.

⁶⁸ *Id.*

⁶⁹ *Id.* at 45.

⁷⁰ *Id.*

⁷¹ *Id.* at 52.

⁷² *See Helsinn*, 855 F. 3d at 1371 (holding the invention was ready for patenting as it was reduced to practice prior to the critical date).

⁷³ *Id.* at 1368 (refraining from deciding the case "more broadly than necessary").

⁷⁴ Sauer, *supra* note 1.

⁷⁵ *See Helsinn*, 139 S. Ct. at 634 (holding that Congress had not altered the meaning of "on sale" with the passage of the AIA and therefore an inventor's confidential sale constitutes prior art under §102(a)).

reasoning began with a discussion of the standard set by *Pfaff*.⁷⁶ While the Court acknowledged that it had never before attempted to answer “the precise question presented in this case,” it was guided by its precedents in holding that a sale or offer of sale need not make an invention available to the public.⁷⁷ The Court emphasized that in prior cases public disclosure was not relevant in analyzing whether or not an offer for a sale had occurred.⁷⁸ Furthermore, the Court noted that the Federal Circuit had previously held that a confidential sale may invalidate a patent.⁷⁹

In the Court’s opinion, the “well settled pre-AIA precedent” suggested that Congress had not altered the meaning of the AIA when it reenacted the same language regarding sales and offers for sale as prior art.⁸⁰ The Court reasoned that if Congress had intended to alter the meaning of what kinds of sales qualified as prior art, this would not have been accomplished with the subtle addition of the phrase “or otherwise available to the public.”⁸¹ Therefore, the Court affirmed the judgment of the Federal Circuit.⁸²

III. THE HOLDING OF *HEL SINN* RUNS CONTRARY TO THE DRAFTING HISTORY OF THE AMERICA INVENTS ACT

The Court’s relatively short opinion in *Helsinn* overstepped its authority when it largely ignored the plain-text interpretation of the on-sale bar of the AIA, as well as the drafting history and Congressional intent behind the language of the on-sale bar.⁸³ Congress, not the Supreme Court, was granted the authority by the Constitution to regulate patent law.⁸⁴ The duties of the Supreme

⁷⁶ *Id.* at 632.

⁷⁷ *Id.* at 633.

⁷⁸ *Id.*

⁷⁹ *Id.*

⁸⁰ *Id.* at 633-634.

⁸¹ *Id.* at 634.

⁸² *Id.*

⁸³ Eileen McDermott, *Industry Insiders: Opinions Mixed in the Aftermath of Supreme Court Holding in Helsinn*, IP WATCHDOG (Jan. 23, 2019), <http://www.ipwatchdog.com/2019/01/23/industry-insiders-aftermath-supreme-court-helsinn/id=105527/> (quoting the opinion of retired Chief Judge Paul Michel of the United States Court of Appeals for the Federal Circuit that the Supreme Court as the tendency “treat patent law as if it were largely common law” and therefore “legislate patent law from the bench”).

⁸⁴ *Id.* (clarifying that patent law is a “wholly statutory regime” and the

Court are limited to the interpretation of the statutory language enacted by Congress.⁸⁵ Thus, the Court's decision does little more than "legislate patent law from the bench" and instead further muddles the true interpretation of the on-sale bar.⁸⁶

A. The Court's Decision is Inconsistent with the Plain-text Interpretation of the Post-AIA On-sale Bar Language

The current language of on-sale bar states that "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."⁸⁷ Every category of prior art within the current language of the on-sale bar "intrinsically" shares the characteristic of disclosing the claimed invention to the public in some manner.⁸⁸ In this way, "the *noscitur a sociis* canon confirms the petitioner's interpretation of Section 102(a)(1)."⁸⁹ This canon holds that the meaning of ambiguous words in a statute may be informed by the language which surrounds them.⁹⁰ Moreover, the Supreme Court has held that "otherwise" and other analogous linking terms may "relate and define" the language which precede them.⁹¹ Therefore, the true purpose of the catchall provision "or otherwise available to the public" is to clarify that the categories of prior art directly preceding the catchall provision share the "key characteristic" of disclosing the claimed invention to the public.⁹²

The Supreme Court's holdings in *Seatrain Lines* and *Paroline* strengthen this interpretation of the catchall provision.⁹³ In *Seatrain Lines*, the Court held that every enumerated category within the statutory language at issue should "be read in light of the final, comprehensive category" which was intended to be a "catchall provision."⁹⁴ Additionally, in *Paroline*, the Court again

Supreme Court "should be limited to interpreting any ambiguous term in the Patent Act").

⁸⁵ *Id.*

⁸⁶ *Id.*

⁸⁷ 35 U.S.C. 102(a)(1).

⁸⁸ See Brief for Petitioner at 18, *Helsinn*, 139 S. Ct. 628.

⁸⁹ *Id.* at 20

⁹⁰ *Id.*

⁹¹ *Id.* at 19.

⁹² *Id.*

⁹³ *Id.* at 21.

⁹⁴ *Federal Maritime Commission v. Seatrain Lines*, 411 U.S. 726, 734 (1973).

emphasized the idea that “enumerated provisions in a statute must be read in light of a catchall provision that follows them.”⁹⁵

Teva argued that the *noscitur a sociis* doctrine may not apply where no ambiguity exists in the statutory language.⁹⁶ It further argued that Helsinn’s reliance on *Seatrain* and *Paroline* was misplaced given that the catchall provision within §102(a) did not “apply as much to the first and other words as to the last.”⁹⁷ However, both of these arguments are without merits. First, given that each category of prior art shares the characteristic of public disclosure in the post-AIA on-sale bar, the catchall provision does apply equally to all the terms which precede it.⁹⁸ Second, the Supreme Court itself conceded in the *Helsinn* opinion that it had not previously explored the effect of confidential sales on a patent’s validity under the AIA.⁹⁹ Furthermore, the Federal Circuit refrained from addressing this issue in its brief as well.¹⁰⁰ The hesitancy of both the Supreme Court and Federal Circuit in analyzing the language of the post-AIA on-sale bar suggests that Teva was incorrect in asserting that there was no ambiguity in the statutory language. The language of the post-AIA on-sale bar needed to be informed by the preceding language as Helsinn correctly asserted. Unfortunately, the Supreme Court refrained from analyzing the statutory language in this way and therefore their decision was inconsistent with the plain-text interpretation of the post-AIA on-sale bar language.

B. The Court Ignored Congressional Intent Behind the Post-AIA On-sale Bar Language

The most disappointing aspect of the Court’s decision in *Helsinn* was its refusal to thoroughly discuss the Congressional intent behind the post-AIA on-sale bar language.¹⁰¹ The Court merely stated that if Congress had intended to change the meaning of the on-sale bar they would have done so explicitly.¹⁰² However, by ignoring the drafting history of the AIA completely, the Court fails to realize that Congress did indeed clarify that the purpose of the catchall provision was to inform the meaning of the preceding

⁹⁵ *Paroline v. United States*, 572 U.S. 434, 477 (2014).

⁹⁶ Brief for Respondent at 19, *Helsinn*, 139 S. Ct. 628.

⁹⁷ *Id.* at 35.

⁹⁸ See Brief for Petitioner at 18, *Helsinn*, 139 S. Ct. 628.

⁹⁹ See *Helsinn*, 139 S. Ct. at 634.

¹⁰⁰ See *Helsinn*, 855 F. 3d at 1368.

¹⁰¹ See *Helsinn*, 139 S. Ct. at 634.

¹⁰² *Id.*

categories of prior art. Congress never intended for confidential sales to qualify as prior art under the post-AIA on-sale bar.

In enacting the AIA, Congress consulted with prominent members of the patent community as well as the USPTO.¹⁰³ The Act went through many revisions before passing in 2011.¹⁰⁴ Congress consistently reiterated its belief that sales or offers for sales must be made public to qualify as prior art in every version of the Act.¹⁰⁵ The House Judiciary Committee stated in its “favorable report of the AIA” that the catchall provision, “or otherwise available to the public,” was included “to emphasize the fact that [prior art] must be publicly accessible.”¹⁰⁶ Moreover, the final Committee Report for the AIA cited floor remarks from Senator Jon Kyl and Senator Patrick Leahy, one of the bill’s sponsors, which noted that it was Congress’s intent that the meaning of prior art under the AIA must necessarily include public disclosure.¹⁰⁷ This point was also strongly conveyed by Congressman Lamar Smith, another one of the bill’s sponsors, in his *amicus curiae* brief in support of the petitioner.¹⁰⁸

The Supreme Court echoed the argument made by Teva that if Congress had intended to change the meaning of the on-sale bar it would not have left the “on sale” language unchanged.¹⁰⁹ However, Congressman Smith noted in his brief that language such as “prior art” was reused from the previous statute and this did not mean that “prior art” had the same definition as it did before the passage of the AIA.¹¹⁰ Congressional intent to preserve the meaning of a term may not be construed from the reuse of the term from the repealed statute alone.¹¹¹ The on-sale bar “must be construed in its new statutory context.”¹¹²

Lastly, in holding that confidential sales qualify as prior art

¹⁰³ See Brief for The Intellectual Property Law Association of Chicago (“IPLAC”) as Amicus Curiae Supporting Petitioner at 7, *Helsinn*, 139 S. Ct. 628.

¹⁰⁴ *Id.* at 9.

¹⁰⁵ *Id.*

¹⁰⁶ Brief for United States as Amicus Curiae Supporting Petitioner at 24, *Helsinn*, 139 S. Ct. 628.

¹⁰⁷ See Matal, *supra* note 44.

¹⁰⁸ See Brief for Congressman Lamar Smith as Amicus Curiae Supporting Petitioner at 2, *Helsinn*, 139 S. Ct. 628.

¹⁰⁹ See *Helsinn*, 139 S. Ct. at 634; see also Brief for Respondent at 26, *Helsinn*, 139 S. Ct. 628.

¹¹⁰ See Brief for Congressman Lamar Smith as Amicus Curiae Supporting Petitioner at 29, *Helsinn*, 139 S. Ct. 628.

¹¹¹ *Id.*

¹¹² *Id.* at 30.

under the AIA, the Supreme Court interfered with one of Congress's primary goals in enacting the legislation. Congress hoped to synchronize the United States patent system with the enactment of the AIA.¹¹³ Patent systems which have adopted the "first-inventor-to-file" system hold that prior art must make a claimed invention available to the public.¹¹⁴ Therefore, the Supreme Court's interpretation that prior art need not be publically disclosed under the AIA directly conflicts with Congressional intent to synchronize the United States patent system with those of other nations.

IV. THE CHILLING EFFECT OF *HEL SINN* ON RESEARCH AND DEVELOPMENT EFFORTS BY SMALL AND MIDSIZE PHARMACEUTICAL COMPANIES

Helsinn will undoubtedly have many negative implications for inventors of all kinds but its effect on small and midsize pharmaceutical companies will be particularly detrimental.¹¹⁵ The development of many drugs often begins with small and midsize pharmaceutical companies.¹¹⁶ It may take "10 to 15 years and approximately \$2.6 billion to successfully bring a new drug to the market."¹¹⁷ Due to high costs and limited resources, these small and midsize pharmaceutical companies often rely on business partners to continue with the research and development of their drugs.¹¹⁸ Furthermore, when the business partner is a publicly traded company, they "may be required to disclose the existence of any such transactions under federal statutes such as the Securities Exchange Act of 1934."¹¹⁹

In fact, *Helsinn* is illustrative of this business model. Palonosetron was first created by researchers in California.¹²⁰ It was then acquired by Roche and next by *Helsinn*.¹²¹ *Helsinn* later

¹¹³ See Brief for Petitioner at 3-4, *Helsinn*, 139 S. Ct. 628.

¹¹⁴ *Id.* at 33.

¹¹⁵ See Brief for Massachusetts Biotechnology Council ("MassBio") as Amicus Curiae Supporting Petitioner at 11-12, *Helsinn*, 139 S. Ct. 628.

¹¹⁶ *Id.*

¹¹⁷ *Id.*

¹¹⁸ *Id.* at 13.

¹¹⁹ *Id.* at 14.

¹²⁰ See *Helsinn Healthcare S.A. v. Dr. Reddy's Laboratories Ltd.*, No. 11-3962; 2016 WL 832089, at *5 (D.N.J. 2016).

¹²¹ *Id.* at 8, 10-12.

teamed up with Oread to continue developing the product.¹²² Finally, Helsinn had to partner with MGI to continue with Phase III of the project when Oread suddenly went out of business.¹²³ Given the fact that MGI was a publicly traded company, it had to disclose the agreements it had entered into with Helsinn.¹²⁴ In this way, the invention was passed from entity to entity. This is the reality of drug development in the United States. Thus, the reliance on confidential sales by small and midsize pharmaceutical companies is not an attempt to bypass patent laws. It is often the only way in which an inventor can continue to finance the research and development of their new drug product. As such, “63% of new drugs approved between 2013 and 2018 and more than three-quarters of the new molecular entities approved in 2017 originated in small and midsize companies.”¹²⁵

The decision in *Helsinn* therefore unfairly targets the research and innovation of these small and midsize pharmaceutical companies. The Federal Circuit held in *Medicines Co.* that the on-sale bar should not be applied differently to inventors “depending on whether their business model is to outsource manufacturing or to manufacture in-house.”¹²⁶ This is precisely what has occurred in the decisions rendered by the Federal Circuit and the Supreme Court in *Helsinn*. The holdings of these Courts will have a “chilling effect that disproportionately harms small and midsize biotechnology companies.”¹²⁷

Finally, not only will the decision in *Helsinn* affect future research and development of drugs, it will also call into question “the validity of many pending and granted patents.”¹²⁸ The USPTO interpreted the on-sale bar of the AIA to exclude confidential sales and included this interpretation in guidelines to patent examiners.¹²⁹ Many small and midsize pharmaceutical companies may be dragged into unnecessary litigation for patents which were previously understood as being valid.

¹²² *Id.* at 14-15.

¹²³ *Id.* at 27.

¹²⁴ *Id.* at 28.

¹²⁵ Adam Houldsworth, *SCOTUS ruling is a blow to small companies on the frontline of life sciences innovation*, IAM, <https://www.iam-media.com/law-policy/scotus-ruling-blow-small-companies-frontline-life-sciences-innovation>.

¹²⁶ *See Medicines*, 827 F. 3d at 1378-1379.

¹²⁷ *See* Brief for Massachusetts Biotechnology Council (“MassBio”) as Amicus Curiae Supporting Petitioner at 14, *Helsinn*, 139 S. Ct. 628.

¹²⁸ *See* Houldsworth, *supra* note 125.

¹²⁹ *See* Brief for Petitioner at 8, *Helsinn*, 139 S. Ct. 628.

CONCLUSION

Patent law in the United States is a fine balance between promoting innovation and preventing monopolization. The on-sale bar is one of the ways in which Congress strikes this balance. Congress thoughtfully and purposefully added the catchall provision in the on-sale bar of the AIA. It was done with the intention of doing away with unnecessary “traps” for inventors in the form of needless litigation due to confidential sales.¹³⁰ However, the Court’s decision in *Helsinn* seriously contradicts this intention and the repercussions of this decision will be felt most strongly by small and midsize pharmaceutical companies. In overstepping its authority and ignoring Congressional intent, the Court has interfered with Congress’s goal to streamline American patent laws and threatened the research and development of many potentially valuable drugs.

¹³⁰ See Matal, *supra* note 44.