Giving Meaning to "Otherwise Available to the Public": How *Helsinn* Perpetuates a Version of the On-Sale Bar to Patentability that Disproportionately Burdens Small Inventors

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This Note argues that the Federal Circuit's holding in Helsinn Healthcare v. Teva*—that sales that are publicly known but that do not disclose the invention trigger the on-sale bar to patentability—perpetuates an interpretation of the on-sale bar that disproportionately burdens small inventors by limiting their ability to engage in pre-commercialization transactions with third parties. The addition of the language "otherwise available to the public" to 35 U.S.C. § 102 provided the Federal Circuit with the opportunity to narrow the on-sale bar to include only sales that make the invention publicly available, but the Federal Circuit did not apply such an interpretation in* Helsinn*. Furthermore, this Note argues that the interpretation of the on-sale bar adhered to in* Helsinn *is undesirable as a matter of policy because it obstructs innovation by small firms and individuals. A narrow on-sale bar that does not cover pre-commercialization transactions would better serve to drive innovation. An exploration of the policy implications of the Federal Circuit's decision is particularly timely since the Supreme Court granted Helsinn's petition for a writ of certiorari on June 25, 2018.*

I. Introduction

What types of business agreements made in the course of getting an invention to market should bar an inventor from patent protection? Is it fair or wise to have a bar to patentability that is most easily avoided simply by having sufficient resources to work around it? Consider for a moment two hypothetical companies:

> Big Bucks, Inc. is a large, vertically integrated pharmaceutical company. It has extensive internal marketing and distribution divisions. It also has a large, well-staffed legal team. Big Bucks develops an innovative drug and is able to manufacture, stockpile, develop a marketing plan for, and put in place distribution channels for its new drug—all before ever applying for a patent.
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> Underdog Pharmaceuticals is a much smaller pharmaceutical company. It has no internal marketing and distribution at all. Its legal

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> department is small and it lacks the funds to pay an outside firm. Underdog also develops an innovative drug. However, because Underdog lacks internal resources, it must form an agreement with an outside company to establish marketing and distribution channels to get the product to market as well as to afford the FDA approval process. Just like Big Bucks, Underdog waits until a marketing strategy and distribution channels are in place, which takes just over a year, before filing for a patent.

Which company succeeds in acquiring a patent for its drug: Big Bucks, Underdog, both? Under U.S. patent law, Big Bucks will get a patent on its drug but Underdog, the smaller company, will be barred from receiving a patent because the invention was "on sale" to its marketing and distribution partner one year before the priority date. Is this outcome fair? More importantly, is this outcome good for innovation? The answer to both questions is no.

On May 1, 2017, the United States Court of Appeals for the Federal Circuit decided the case *Helsinn Healthcare v. Teva Pharmaceuticals*[1] and, in doing so, perpetuated the longstanding power disparity that makes it easier for large companies to avoid the pitfalls of the on-sale bar to patentability than for small companies to do the same. In *Helsinn*, the Federal Circuit held that a sale triggers the on-sale bar to patentability, even if the sale does not disclose to the public the details of invention, so long as the existence of the sale itself is public.[2] While this holding may seem narrow, the policy implications of the decision are far-reaching. This Note takes the position that the passage of the Leahy–Smith America Invents Act (AIA) presented an opportunity to develop a more nuanced view of the on-sale bar that would make it easier for small companies to benefit from the patent system, but the *Helsinn* decision did not take advantage of that opportunity. This Note's analysis of the policy benefits that would arise from reinterpreting the on-sale bar's statutory language is particularly timely since the Supreme Court granted Helsinn's petition for a writ of certiorari on June 25, 2018.[3]

Under the AIA, the text of § 102(a) states that one is barred from patenting an invention if "the claimed invention was patented, described in a printed publication, or in public use, on sale, *or otherwise available to the public* before the effective filing date."[4] The addition of the language, "or otherwise available to the public," sparked intense debate amongst legal scholars as to whether the public-use and on-sale bars were now narrowed to only bar patentability in cases in which the public had access to the invention.[5] This change in the language of § 102 provided the Federal Circuit

1. 855 F.3d 1356 (Fed. Cir. 2017).
2. *Id.* at 1371.
3. Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc., 138 S. Ct. 2678 (2018).
4. 35 U.S.C. § 102(a) (2012) (emphasis added).
5. *See, e.g.*, Robert A. Armitage, *Understanding the America Invents Act and Its Implications*

an opportunity to develop a more narrow interpretation of both the public-use and the on-sale bars. The narrower interpretation would have made it so that only sales to the public, not secret private sales, would render an invention unpatentable.[6] Such an interpretation of the on-sale bar would better incentivize innovation and would level the playing field of the market by enabling small companies to better avoid accidental disclosure under § 102(a).

This Note will argue that the *Helsinn* decision, holding that publicly known sales that nonetheless keep the details of the invention secret trigger the on-sale bar, perpetuates negative policy impacts arising from the power disparity between large and small companies and, further, that this was a missed opportunity to positively change the law in light of the new statutory language introduced to § 102 by the AIA. Part II of this Note will detail the changes made by the AIA and explain how those changes provided the Federal Circuit with an opportunity to interpret the law in a way that would better incentivize innovation. Part III will examine *Helsinn* in greater detail as well as contrast its holding with the outcome of *Medicines Co. v. Hospira, Inc.*[7] Finally, Part IV will explain how the outcome in *Helsinn* disproportionately harms small companies and argue that such a disproportionate impact is undesirable as a matter of public policy.

II. The AIA Presented an Opportunity to Improve the On-Sale Bar so that Small Companies Would No Longer Be Disproportionately Affected

The AIA streamlined and consolidated the novelty requirements (and the exceptions) in § 102.[8] Before the passage of the AIA, an invention could not be patented if "the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States."[9] Post-AIA, the novelty requirement states that:

> (a) NOVELTY; PRIOR ART.—A person shall be entitled to a patent unless—
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> (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;

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for Patenting, 40 AIPLA Q.J. 1, 53 (2012) (arguing that "the terms 'in public use or on sale' have been further modified and qualified by" the new "otherwise available to the public" language and that Congress did this "to impose an overarching requirement for availability to the public in order for a prior disclosure to constitute prior art"); Robert P. Merges, *Priority and Novelty Under the AIA*, 27 BERKELEY TECH. L.J. 1023, 1031 n.23 (2012) (arguing that the "otherwise available" language introduced by the AIA "does not imply that the other categories must now be interpreted so as to include only widely accessible references").

6. Armitage, *supra* note 5, at 54.
7. 827 F.3d 1363 (Fed. Cir. 2016).
8. Merges, *supra* note 5, at 1025.
9. 35 U.S.C. § 102(b) (2012).

or . . . .[10]

The changes to the novelty provisions were numerous, some of the most noticeable being the elimination of geographic distinctions for all categories of prior art[11] and a shift from a "first-to-invent" to a "first-inventor-to-file" system of priority.[12] However, one of the most controversial changes to § 102 was the addition of a prior-art category, "or otherwise available to the public," in the list after "public use" and "on sale."[13] It is this additional language, "or otherwise available to the public," that provided the Federal Circuit with the opportunity to narrow the on-sale bar and make it easier for small companies to avoid inadvertently sacrificing their patent rights. A brief examination of the arguments on both sides of the debate about the meaning of this new language is important to put the *Helsinn* decision in context and explain why it was a missed opportunity.

A. Background Details Regarding the On-Sale Bar

The legal framework of the on-sale bar, as with any law, is shaped by the policy concerns that the law is intended to address. The Court of Claims (which predates the formation of the Federal Circuit) stated in *General Electric Co. v. United States*[14] that there are four policy considerations underlying the on-sale bar:

> First, there is a policy against removing inventions from the public which the public has justifiably come to believe are freely available to all as a consequence of prolonged sales activity. Next, there is a policy favoring prompt and widespread disclosure of new inventions to the public. The inventor is forced to file promptly or risk possible forfeiture of his invention rights due to prior sales. A third policy is to prevent the inventor from commercially exploiting the exclusivity of his invention substantially beyond the statutorily authorized 17-year period. The "on sale" bar forces the inventor to choose between seeking patent protection promptly following sales activity or taking his chances with his competitors without the benefit of patent protection. The fourth and final identifiable policy is to give the inventor a reasonable amount of time following sales activity (set by statute as 1 year) to determine whether a patent is a worthwhile investment.[15]

These underlying policy concerns are critical because the Federal

10. *Id.* § 102(a).

11. Merges, *supra* note 5, at 1027. Under the old rule, an invention sold abroad would not constitute invalidating prior art, but post-AIA, a sale of the invention anywhere in the world constitutes prior art. *Id.*

12. Daniel Taskalos, Note, Metallizing Engineering*'s Forfeiture Doctrine After the America Invents Act*, 16 STAN. TECH. L. REV. 657, 685 (2013).

13. *See supra* note 5.

14. 654 F.2d 55 (Ct. Cl. 1981).

15. *Id.* at 61 (citations omitted).

Circuit has stated numerous times that the on-sale bar is not simply informed by—but is effectively defined by—these policy concerns.[16]

While the on-sale bar to patentability was first explicitly laid out by Congress in the Patent Act of 1836 and has changed over time since then,[17] the modern test for what triggers the on-sale bar was laid out by the Supreme Court in *Pfaff v. Wells Electronics, Inc.*[18] According to the Court, the on-sale bar is triggered if, before the critical date (1) the invention is the subject of a "commercial offer for sale" and (2) the invention is ready for patenting.[19] The Court stated that the requirement of a "commercial offer for sale" was not subject to concerns of indefiniteness because "[a]n inventor can both understand and control the timing of the first commercial marketing of his invention."[20] The second requirement, that the invention be "ready for patenting," has also generated extensive debate and litigation; however, those issues lie outside the scope of this Note.[21] While the Court presented the requirement of a "commercial offer for sale" as being an easily applied and definite rule, it did not lay out precisely what constitutes a "commercial offer for sale."[22]

The Federal Circuit grappled with, and attempted to clarify, what interactions would rise to the level of a "commercial offer for sale" and trigger the on-sale bar in *Group One, Ltd. v. Hallmark Cards, Inc.*[23] The court held that "whether an invention is the subject of a commercial offer for sale is a matter of Federal Circuit law, to be analyzed under the law of contracts as generally understood."[24] Further, the Federal Circuit stated that it "will look to the Uniform Commercial Code ('UCC') to define whether . . . a communication or series of communications rises to the level of a commercial offer for sale."[25]

Undermining the Supreme Court's claim that the "commercial offer for sale" standard was not subject to concerns of indefiniteness, the Federal Circuit acknowledged the difficulty of clearly determining whether an interaction constituted a sale in *Group One*, explaining that they "do not

16. RCA Corp. v. Data Gen. Corp., 887 F.2d 1056, 1062 (Fed. Cir. 1989); J.A. LaPorte, Inc. v. Norfolk Dredging Co., 787 F.2d 1577, 1582 (Fed. Cir. 1986); W. Marine Elecs., Inc. v. Furuno Elec. Co., 764 F.2d 840, 844 (Fed. Cir. 1985).

17. Mark Levy, *An Analysis of the On Sale Bar and Its Impact on the Structure and Negotiation of Development Agreements*, 30 U. DAYTON L. REV. 181, 183 (2004).

18. 525 U.S. 55 (1998).

19. *Id.* at 67.

20. *Id.*

21. For an overview of issues and cases relating to the requirement that the invention be "ready for patenting" in order to trigger the on-sale bar, see Levy, *supra* note 17, at 187–92.

22. *Pfaff*, 525 U.S. at 67.

23. 254 F.3d 1041 (Fed. Cir. 2001).

24. *Id.* at 1047.

25. *Id.* The Federal Circuit views the UCC as representing the general understanding of contract law. *See* Enercon GmbH v. Int'l Trade Comm., 151 F.3d 1376, 1382 (Fed. Cir. 1998) ("The U.C.C. has been recognized as the general law governing the sale of goods.").

mean to suggest that it will always be easy to ascertain whether a set of interactions between parties constitutes a commercial offer to sell" and that they do not "propose to offer rules or even binding guidance for making such determinations."[26] Further adding to the confusion, the Federal Circuit has stated that, while it looks to the UCC to decide such matters, the UCC is a "useful, though not authoritative, source" in determining what constitutes a sale.[27] This uncertainty of what may constitute a "commercial offer for sale" adds risk of inadvertent disclosure of any communications made by an inventor to another partner. This additional source of uncertainty about the validity of a patent may exacerbate the issue of "probabilistic patents," where the value of a patent remains in question even after it has been granted.[28] The Federal Circuit's inability to provide clear guidelines about what is or is not an offer for sale that could invalidate a patent is central to the disparity in the ability of small and large companies to successfully commercialize their products, since large companies can evade this uncertainty by keeping things in-house while small companies lack such a luxury.

B. Debate over the Meaning of "Otherwise Available to the Public"

After the passage of the AIA, several different ways of construing "otherwise available to the public" were put forward. Three different ways that the new language could be understood follow: (1) it represents a separate catch-all category that supplements the preexisting categories of public use and on sale; (2) it modifies the other terms listed in § 102(a), requiring that a public use or sale be available to the public in order to constitute disqualifying prior art; and (3) it was meant to align with the meaning of the "available to the public" language of the European Patent Convention.[29] This Note, and most of the existing academic literature, focuses on the first and second possible interpretations (these were also the positions taken by the parties in *Helsinn*). It is worth reiterating that this debate is extensive and can be (and has been) the subject of notes unto themselves.[30] This Note merely provides a brief overview in order to frame the issue and illustrate the positions of the parties in *Helsinn*.

The position taken by Helsinn, as well as by the United States government, was that the language "otherwise available to the public" modified the meaning of the preceding terms: "on sale" and "public use" such that public availability was an aspect of both.[31] The government wrote in

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26. *Group One*, 254 F.3d at 1048.

27. *Enercon*, 151 F.3d at 1382.

28. Mark A. Lemley & Carl Shapiro, *Probabilistic Patents*, J. ECON. PERSP., Spring 2005, at 75, 76 (examining the ways in which litigation uncertainty regarding patent validity affects the economic value of patents).

29. Caroline Schneider, Note, *The New Novelty: Defining the Content of Otherwise Available to the Public*, 41 J. LEGIS. 151, 171 (2014).

30. *See supra* note 5 and accompanying text.

31. Principal Brief of Plaintiffs–Appellees Helsinn Healthcare S.A. & Roche Palo Alto LLC at

support of Helsinn because the Patent and Trademark Office (PTO) had adopted as its formal rule that secret sales did not trigger the on-sale bar because they did not involve public availability.[32] The textual argument put forward by the government and Helsinn was quite simple: interpreting "otherwise available to the public" in any way that did not modify the preceding terms would deprive "otherwise" of any meaning, and the courts are supposed to interpret statutory language based on its "plain meaning."[33] Essentially, they argued that the language cannot be viewed as merely aesthetic or superfluous but instead must be given the weight of its grammatical meaning—that it modifies the earlier terms in the list.[34]

Helsinn further supported its argument that the new statutory language was meant to require that the on-sale bar have an element of public availability by referring to the legislative history of the AIA.[35] The House Judiciary Committee report on the bill stated that "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*."[36] Furthermore, no member of the House Judiciary Committee dissented with regards to how the new language in § 102(a) was to be interpreted.[37] Helsinn also pointed to a statement made during the floor debates by Representative Lamar Smith (House sponsor of the AIA bill): "[C]ontrary to current precedent, in order to trigger the bar in the new 102(a) in our legislation, an action must make the patented subject matter 'available to the public' before the effective filing date."[38] Helsinn also referred to similar statements made by Senators Leahy and Kyl.[39]

On the other side, Teva argued that the "otherwise available to the public" language was merely a catch-all category to include things not explicitly listed and that "otherwise available to the public" was not meant to

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34, Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc., 855 F.3d 1356 (Fed. Cir. 2017) (Nos. 2016-1284, -1787); Brief for the United States as Amicus Curiae in Support of Appellees at 4, Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc., 855 F.3d 1356 (Fed. Cir. 2017) (Nos. 2016-1284, -1787).

32. Brief for the United States as Amicus Curiae in Support of Appellees at 5, Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc., 855 F.3d 1356 (Fed. Cir. 2017) (Nos. 2016-1284, -1787).

33. *Id.* at 4.

34. Principal Brief of Plaintiffs–Appellees Helsinn Healthcare S.A. & Roche Palo Alto LLC at 38, Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc., 855 F.3d 1356 (Fed. Cir. 2017) (Nos. 2016-1284, -1787).

35. *Id.* at 49–54.

36. H.R. REP. NO. 112-98, at 43 (2011), *as reprinted in* 2011 U.S.C.C.A.N. 67, 73 (emphasis added).

37. Principal Brief of Plaintiffs–Appellees Helsinn Healthcare S.A. & Roche Palo Alto LLC at 49, Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc., 855 F.3d 1356 (Fed. Cir. 2017) (Nos. 2016-1284, -1787).

38. *Id.* at 52 (emphasis omitted).

39. *Id.* at 51–52.

modify the preceding list but rather to define the scope of the catch-all.[40] Teva argued that interpreting "otherwise available to the public" as modifying the preceding items would read unnecessary redundancy into the statute since all of the prior items in the list, aside from "on-sale," already have an implicit modifier of "public availability."[41] Teva's logic suggests that the plain meaning of the new language is not to modify the preceding listed items because no modification of the entire list is necessary due to the preexisting limitations on each term. Teva argues that if the statutory language was meant to add a public-availability requirement to the on-sale bar, Congress would have changed the language to "publicly on sale."[42]

Teva made two responses to Helsinn's arguments regarding the legislative history of the AIA. First, Teva argued that reliance on legislative history is inappropriate when the meaning of the statutory language is not unclear, and Teva argued that there is no ambiguity because "otherwise available" is not a modifier but instead defines the scope of the catch-all category.[43] Additionally, Teva argued that the Legislature is presumed to know and adopt the preexisting legal meanings of terms of art that it utilizes, and thus, the prior case law holding that secret sales can be prior art is still good law, regardless of legislative statements to the contrary.[44]

As stated before, this Note's summary of the debate simplifies the issue and focuses on the arguments put forward by two specific parties. There have been numerous different arguments made about how and why the new statutory language should be interpreted, but many lie outside the scope of this Note's argument. Furthermore, this Note does not suggest that Helsinn's argument is necessarily correct (though it aligns with the policy advocated by this Note). The mere existence of the debate alone is of great significance because it provided the Federal Circuit an opportunity to reinterpret the meaning of the on-sale bar free from the constraints of its prior decisions.

III. *Helsinn*: Case Review and Relation to *Medicines*

A. Helsinn v. Teva

Analyzing *Helsinn* presents several interesting points of contradiction. It is a case in which the holding appears and is stated to be quite narrow but implicates a large swath of important business transactions; it is a case in which the court does not explicitly issue a broad rule but seems to do so by implication. And it is a case that seems, yet claims not, to contradict the

40. Reply Brief for Defendants–Appellants Teva Pharmaceuticals USA, Inc., Teva Pharmaceuticals Industries, Ltd. at 16, Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc., 855 F.3d 1356 (Fed. Cir. 2017) (Nos. 2016-1284, -1787).

41. *Id.* at 17.

42. *Id.*

43. *Id.* at 16, 26.

44. *Id.* at 22.

Federal Circuit's earlier decision in *Medicines*. These peculiarities of the case illustrate the difficulty of identifying what the exact boundaries of the on-sale bar are or should be.

The allegedly disqualifying sale at the center of *Helsinn* was a "Supply and Purchase Agreement," made a little under two years before the critical date, between Helsinn Healthcare and MGI Pharma, Inc. (MGI).[45] Under a separate license agreement, MGI agreed to pay Helsinn an initial $11 million and future royalties on distribution of the invention that consisted of the 0.25 and 0.75 milligram doses of the drug.[46] These agreements were publicly announced via a joint press release as well as via MGI's Form 8-K filing with the Securities and Exchange Commission; however, neither the price nor the specific dosage formulations were publicly disclosed in either release.[47] Furthermore, the supply and purchase agreement (made before FDA approval) obligated Helsinn to sell and MGI to buy whichever, if either, of the doses (0.25 or 0.75 mg) received FDA approval.[48] Ultimately, the Federal Circuit held that this agreement, consisting of a future sale agreement that was publicly announced but that kept the details of the invention secret (a semi-secret sale), was a commercial offer for sale that triggered the on-sale bar to patentability under § 102(a).[49]

In its brief, Helsinn presented three core arguments as to why its patents were not invalidated by the on-sale bar: (1) the invention was not ready for patenting before the critical date and thus did not trigger the on-sale bar; (2) the supply and purchase agreement with MGI was not an offer for sale of the invention; and (3) the new "otherwise available for sale" language means that secret sales, in which the details of the invention are not available to the public, do not trigger the on-sale bar.[50] For the purposes of this Note, which is focused on narrowing the on-sale bar to exclude pre-commercialization sales that keep the details of the invention secret, the third argument is the most important and where analysis will be focused. The details of both sides' arguments regarding statutory interpretation can be found in Part II's discussion of the statutory debate itself.

While both sides argued extensively about how "otherwise available to the public" should be interpreted, the Federal Circuit failed to provide an explicit answer to the question of how, if at all, the new language affected the meaning of "public use" or "on sale." Instead, the Federal Circuit stated that it "decline[d] the invitation by the parties to decide this case more broadly

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

46. *Id.*

47. *Id.* at 1361–62.

48. *Id.* at 1364.

49. *Id.* at 1371. The court held that the supply and purchase agreement would trigger the on-sale bar under both pre- and post-AIA law. *Id.*

50. Principal Brief of Plaintiffs–Appellees Helsinn Healthcare S.A. and Roche Palo Alto LLC at 8–10, Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc., 855 F.3d 1356 (Fed. Cir. 2017) (Nos. 2016-1284, -1787).

than necessary"[51] and that its holding would not extend to the "secret sale cases" that the legislative history suggests the statute meant to overturn.[52] Despite this statement of the court's intent not to resolve the issue of statutory interpretation, its strong rejection of Helsinn's argument that the focus of the public-use and on-sale bars be on disclosure of the details of the invention itself to the public strongly suggests that the Federal Circuit does not view the new AIA language to be particularly transformative. In response to Helsinn's argument that Congress intended the new § 102(a) language to limit the on-sale bar to instances in which the details of the invention were disclosed to the public, the court stated, "Our cases explicitly rejected a requirement that the details of the invention be disclosed in the terms of sale."[53] However, the case to which the Federal Circuit cites in support of this proposition, *RCA Corp. v. Data General Corp.*[54] was decided in 1989, twenty-four years before the effective date of the relevant portions of the AIA. Reliance on pre-AIA case law to rebut this argument implicitly suggests that the court sees no difference in the standards of what constitutes an invalidating sale before and after the passage of the AIA.

The *Helsinn* court further justified its holding on this matter by stating that requiring a sale to disclose the details of the invention to the public in order to trigger the on-sale bar would be inconsistent with "[a] primary rationale of the on-sale bar . . . that publicly offering a product for sale that embodies the claimed invention places it in the public domain, regardless of when or whether actual delivery occurs."[55] However, this articulation mistakenly conflates the past rule with the policy justification for that rule. The statement that offering an invention for sale puts it into the public domain, regardless of whether delivery occurs, is a rule—not a "rationale." Why does offering to sell an invention put that invention into the public domain, regardless of whether delivery occurs? The answer to that question is the policy consideration. In conflating the policy for the rule that arises from the policy, the court circularly avoids the question of whether the policies that effectively define the on-sale bar[56] would be better served by adopting the statutory construction put forward by Helsinn. Additionally, while the court appears to be referring to the policy of not allowing inventors to remove from the public domain that which the public expects to have access to due to past sales,[57] the court fails to explicitly address the other three central policy concerns, as laid out in *General Electric*,[58] that help define the on-sale bar. In Part IV, this Note will argue that weighing all four of these

51. *Helsinn*, 855 F.3d at 1368.
52. *Id.* at 1369.
53. *Id.* at 1370.
54. 887 F.2d 1056 (Fed. Cir. 1989).
55. *Helsinn*, 855 F.3d at 1370.
56. *See supra* notes 15–16 and accompanying text.
57. *See supra* note 15 and accompanying text.
58. *See supra* note 15 and accompanying text.

policy concerns together leads to the conclusion that the on-sale bar should not be triggered by sales, like that in *Helsinn*, that are pre-commercialization transactions that do not reveal the invention to the public.

Finally, the court offered a relatively meager response to Helsinn's argument that applying the on-sale bar to distribution agreements (like the supply and purchase agreement at issue) would unfairly advantage larger, vertically integrated companies with the in-house resources to unilaterally get their invention to market. Helsinn cited to *Medicines* (holding that a contract for manufacturing services to produce the invention, and the subsequent stockpiling of the product by the inventor, did not constitute a "commercial sale" that triggered the on-sale bar)[59] to support its argument that activities that could, with the proper resources, be conducted in-house should not, for policy reasons, trigger the on-sale bar. In response to this argument, the court simply claims that "[s]uch a broad principle would largely eviscerate the on-sale bar provision except as to sales to end users."[60] Despite the court's claims that the concerns that drove the *Medicines* case are not present in *Helsinn*,[61] it is worth examining the connection raised by Helsinn more closely to better understand why applying the on-sale bar to pre-commercialization transactions is undesirable as a matter of policy.

B. Reconciling Helsinn *with* Medicines

Medicines provides an interesting foil to *Helsinn*. Both cases dealt with an agreement made by a small pharmaceutical company with a third-party company to ensure that they could get their invention to market; however, one company, MedCo (aka Medicines), got to keep its patent rights while the other, Helsinn, lost its patent rights. What explains the difference in outcome for these two similarly situated companies? According to the Federal Circuit, this difference stems from, and is justified by, the fact that MedCo's agreement was a confidential manufacturing contract to stockpile the product in preparation for commercialization while Helsinn's agreement was a sale of future goods to a distribution partner in preparation for marketization.[62] A closer evaluation of both cases reveals that, from a policy perspective, it is difficult to reconcile the two. The rationale underlying the *Medicines* decision appears to apply with equal force to situations like that of *Helsinn* (albeit in a slightly different manner), and *Medicines* provides a compelling case for why the new "otherwise available to the public" language should be read to narrow the on-sale bar to only apply if the invention, or details of the invention, are available to the public.

One important distinction between *Medicines* and *Helsinn* is that *Medicines* was governed entirely by pre-AIA law while *Helsinn* involved a

59. Meds. Co. v. Hospira, Inc., 827 F.3d 1363, 1377 (Fed. Cir. 2016).
60. *Helsinn*, 855 F.3d at 1367.
61. *Id.*
62. *See id.* (discussing Helsinn's contract).

patent (though not all patents at issue) that was governed by post-AIA novelty law. This means that the holding of *Medicines* was reached without any need to refer to the newly introduced "otherwise available to the public" language. It is the contention of this Note, however, that this new statutory language gave the *Helsinn* court a prime opportunity to expand on the ideas articulated in *Medicines* in order to best equalize power between large and small companies as well as to best incentivize future innovation.

The alleged invalidating sale in *Medicines* was a transaction between MedCo (the patentee) and Ben Venue Laboratories (hereinafter "Ben Venue") under which Ben Venue manufactured three commercially sized batches of bivalirudin (the invention) in exchange for $347,500 in payment from MedCo.[63] There was no transfer of title to the invention, and the agreement between MedCo and Ben Venue was confidential in nature.[64] Once produced, the batches were stockpiled with MedCo's distributor, Integrated Commercialization Solutions (ICS), pending FDA approval.[65]

The Federal Circuit held that MedCo's transactions with Ben Venue, the confidential manufacturer, did not constitute a "commercial sale" that would trigger the on-sale bar and that the stockpiling was "mere pre-commercial activity in preparation for future sale."[66] The court focused on the absence of a transfer of title, the confidential nature of the relationship, and the pre-commercial nature of the transactions in concluding that the on-sale bar was not implicated. Furthermore, the court expressed its disdain for the idea of "penalizing a company for relying, by choice or by necessity, on the confidential services of a contract manufacturer."[67] Critically, the court specifically stated that "[t]he on-sale bar is triggered by actual *commercial marketing* of the invention, not preparation for potential or eventual marketing."[68] Essentially, *Medicines* stands for the proposition that transactions, such as manufacturing agreements, that are made in preparation for full commercialization of the invention should not constitute sales that trigger the on-sale bar.

It seems incongruous that the same court that expressed concerns about unfairly harming a company incapable of manufacturing its invention in-house did not, in a case just one year later, show similar concern to a company incapable of putting into place a marketing and distribution strategy without outside help. Manufacturing and the development of a commercialization strategy are two steps in the same process—getting the invention into the

63. *Meds. Co.*, 827 F.3d at 1367. There was also a distribution agreement with ICS, which provided that ICS would be the exclusive distributor of the drug in the United States and would make weekly orders to Medco, but this agreement was not reviewed by the appellate court. *Id.*

64. *Id.* at 1376.

65. *Id.* at 1367.

66. *Id.* at 1377.

67. *Id.* at 1378.

68. *Id.* at 1377 (emphasis added).

marketplace. In manufacturing, the inventor pays a third party to make the product for them, and in the case of commercialization strategy, the inventor pays a third party to institute distribution and marketing logistics. Both processes must occur before the product (such as a new drug) can get to the market (those who need the drug). The same concerns about "penalizing a company" that is incapable of manufacturing in-house should apply with equal force to a company that is incapable of putting into place marketing and distribution infrastructure in-house.

It is true that the supply and purchase agreement of *Helsinn* contemplated a transfer of title[69] and the manufacturing agreement of *Medicines* did not.[70] It is also true that the agreement in *Medicines* was technically a sale of manufacturing services, rather than a sale of the product to the inventor.[71] Read formalistically, these distinctions do lead to the conclusion that the agreement in *Helsinn* was probably an offer for sale for the purposes of the *Pfaff* test of whether the on-sale bar applies. However, this formalism ignores the fact that the statutory language of § 102 *changed* with the passage of the AIA. This change gave the Federal Circuit the opportunity to focus on the policy similarities between the two situations rather than on their technical differences under the old language.

This Note does not contend that *Helsinn* was determined in a technically incorrect manner. Rather, it argues that the unsettled nature of the new statutory language and the compelling arguments (both linguistically and policy-wise) provided by *Helsinn*, legal academics, and interested third parties should have led the Federal Circuit to adopt a narrower view of the on-sale bar—a view that would enable inventors to engage in pre-commercialization transactions to establish distribution channels and marketing strategies. Such a change would reduce the unjust disparity in power between large and small companies as well as more effectively incentivize future innovation.

IV. The Current, Strict On-Sale Bar Disproportionately Burdens Small Companies and Negatively Affects Innovation

The most effective way to demonstrate that a broad on-sale bar, which encompasses pre-commercialization transactions that are known to the public but do not disclose the details of the invention, is undesirable is to analyze such a bar through the lens of the core underlying policy concerns that "define"[72] the bar. The four central policy concerns that shape the meaning of the on-sale bar are:

(1) A policy against removing inventions from the public domain that the public has a reliance interest in;

69. Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc., 855 F.3d 1356, 1364 (Fed. Cir. 2017).
70. *Meds. Co.*, 827 F.3d at 1369.
71. *Id.* at 1374.
72. *See supra* note 16 and accompanying text.

(2) A policy favoring prompt and widespread disclosure of inventions;

(3) A policy of preventing inventors from having the ability to exclusively commercially exploit their invention for longer than the duration of the patent term; and

(4) A policy of giving inventors a reasonable amount of time after the first sale to decide if it is worth pursuing patent rights.[73]

To this list of policies specific to the on-sale bar itself, it is critical to add a fifth, overarching policy concern that is the constitutionally stated purpose of the patent system itself: "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."[74] Evaluating whether, and to what extent, the on-sale bar furthers or undermines these five policy objectives in cases involving semi-secret, pre-commercialization transactions provides the clearest means of determining how the on-sale bar should be read. The on-sale bar was not established to punish inventors but instead serves to prevent negative policy outcomes; thus, the bar should be interpreted in the way that most successfully serves its policy purpose.[75] Part II illustrated how the new statutory language of the AIA presents an opportunity to reinterpret the on-sale bar, and this Part will illustrate why such a reinterpretation is socially valuable.

A. Policy Against Removing Inventions from the Public Domain Once the Public Has a Reliance Interest

The *Helsinn* court appears to have attempted to invoke this policy rationale to justify its ruling that sales do not have to disclose the nature of the invention to trigger the on-sale bar.[76] As previously argued, the court's argument on this point is unclear because it states a rule arising from the policy of protecting the public's reliance interest but then refers to that rule as a "primary rationale" of the on-sale bar. Assuming arguendo that the court did intend to argue that permitting patents on inventions that had been the subject of pre-commercialization sales that did not disclose the nature of the invention would compromise the public's reliance interest, the key question to ask is: Did the "public" have access to the invention?

Looking to the analogous pre-commercialization transaction of outsourcing manufacturing to a third party (which, under *Medicines*, does not trigger the on-sale bar), in this instance, the only people who have access to

73. This list is a paraphrased recounting of the four policy concerns laid out by the United States Court of Claims in *General Electric Co. v. United States*. *See supra* notes 14–15 and accompanying text.

74. U.S. CONST. art. I, § 8, cl. 8.

75. Winslow B. Taub, *Blunt Instrument: The Inevitable Inaccuracy of an All-or-Nothing On-Sale Bar*, 92 CALIF. L. REV. 1479, 1482 (2004).

76. *See supra* notes 52–55 and accompanying text.

the invention are the inventor and the manufacturer.[77] Furthermore, neither the manufacturer nor the manufacturer's employees have an expectation of reliance on unencumbered use of the invention arising from that relationship.[78] Additionally, the terms of the manufacturing agreement almost certainly require that the details of the invention be kept confidential. Thus, in the case of pre-commercialization manufacturing agreements, the public has no reliance interest to protect, so the policy against removing from the public domain is inapplicable since the invention never truly entered the public domain.

A pre-commercialization transaction outsourcing distribution organization and marketing-strategy development, like the one in *Helsinn*, similarly does not implicate the public's reliance interest. In cases involving this type of transaction: Does the public have access to the invention? The Federal Circuit, in its argument regarding the policy against removing inventions from the public domain, simply stated: "[O]ur prior cases have applied the on-sale bar even when there is no delivery, when delivery is set after the critical date, or, even when, upon delivery, members of the public could not ascertain the claimed invention."[79] In purely relying on its pre-AIA case law, the court again misses the opportunity to evaluate the policy implications on their own merits.

Just as in the case of the manufacturing agreement, the only parties with access to the invention when this type of transaction occurs are the inventor and the marketing/distribution partner. Until the product has been introduced to a third party, outside the scope of the private relationship, the invention has not properly entered the public domain and the public has no reliance interest. Furthermore, the fact that the existence of the sale itself is public knowledge has no bearing on whether the public has a reliance interest. How can the public have reliance in an invention when its only knowledge of it comes from a press release that discloses "insufficient technical and financial details to apprise a third-party of what exactly was sold"?[80] Thus, the policy against removing from the public domain inventions that the public has a reliance interest in is inapplicable to pre-commercialization transactions that, while not themselves secret, keep the details of the invention secret, and the policy does not weigh against a narrower reading of the on-sale bar that excludes such sales.

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77. Leah C. Fletcher, *Equal Treatment Under Patent Law: A Proposed Exception to the On-Sale Bar*, 13 TEX. INTELL. PROP. L.J. 209, 238 (2005).

78. *Id.*

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

80. The Biotechnology Innovation Organization (BIO) as Amicus Curiae Supporting Rehearing En Banc at 3, Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc., 855 F.3d 1356 (Fed. Cir. 2017) (Nos. 2016-1284, -1787).

B. Policy Favoring Prompt and Widespread Disclosure

The *Helsinn* court also argued that excluding semi-secret sales from the on-sale bar would undermine the policy in favor of encouraging prompt and widespread disclosure.[81] This is the policy consideration that most strongly weighs against the proposition that the on-sale bar should be narrowed. It is presumably true that excluding pre-commercialization sales that keep the details of the invention secret would result in more delays between invention and disclosure. However, that delay is less problematic than the Federal Circuit argues for two reasons: (1) the delay is not indefinite, disclosure will still occur in a reasonable time and (2) large companies are already able to exploit this delay due to their greater internal resources.

The first reason that concerns over delays in disclosure are overstated is that any additional delay created by reinterpreting the on-sale bar will not be indefinite. Because the benefit to the inventor stems from the ultimate commercialization of the product and the likelihood of another inventor developing the same idea increases every passing day, inventors still have an incentive to get their product to market (and thus properly trigger the on-sale bar) as quickly as possible. This additional delay is only the amount of time necessary for the inventor to ensure that she is properly positioned to leverage her invention. What is more, this delay already occurs in many cases, which is the basis of the second mitigating factor.

A second consideration that mitigates concerns of delayed disclosure is the fact that delay of disclosure until pre-commercial activities are completed already occurs; it is simply accessible to only large, vertically integrated companies. Small companies may effectively have shorter patent terms than large companies because they are unable to delay disclosure in the same manner. This same inequality when disclosure is required was observed with regard to outsourcing manufacturing services prior to the creation of the manufacturing services exception in *Medicines*.[82]

Looking to the hypothetical presented at the start of this Note, the large company (Big Bucks) with internal distribution and marketing divisions is able to delay its patent application until its marketization strategy is in place while the small company (Underdog), which is no less inventive, must disclose immediately or risk losing its patent, thus reducing the effective length of Underdog's patent relative to Big Bucks's patent. What justifies this disparity? As will be shown, the benefits of rectifying this disparity more than make up for any additional delay in disclosures from small companies.

C. Policy of Preventing Inventors from Exclusively Exploiting Their

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81. *Helsinn*, 855 F.3d at 1369.

82. Fletcher, *see supra* note 77, at 234–35 ("The court's first policy argument ignores the fact that it treats companies differently based on manufacturing capacity, unfairly requiring *more prompt* filing from companies that outsource manufacturing (most likely smaller companies). To decline to create an exception for sales to inventors does of course encourage prompt patent application, but it does so at the expense of a manifest inequality in its treatment of inventors.").

Invention for Longer than the Duration of the Patent

The court in *Helsinn* seems concerned that permitting transactions that keep the nature of the invention secret will enable inventors to sell their inventions to the public without a patent for as long as they can keep the nature of the invention secret and then later patent it once they can no longer keep the secret, essentially monopolizing the invention for longer than the patent term. They refer to the foundational case, *Pennock v. Dialogue*,[83] in which Justice Story concluded that

> [i]f an inventor should be permitted to hold back from the knowledge of the public the secrets of his invention; if he should for a long period of years retain the monopoly, and make, and sell his invention publicly, and thus gather the whole profits of it, relying upon his superior skill and knowledge of the structure; and then, and then only, when the danger of competition should force him to secure the exclusive right, he should be allowed to take out a patent, and thus exclude the public from any farther use than what should be derived under it during his fourteen years; it would materially retard the progress of science and the useful arts, and give a premium to those who should be least prompt to communicate their discoveries.[84]

However, again, the new statutory language of the AIA provides an opportunity to more simply avoid such a scenario. Pre-commercialization transactions, be they manufacturing or logistical in nature, are conducted in preparation for future sale to the public. This Note does not call for a requirement that the public actually be able to ascertain the details of the invention once they have obtained it. "Otherwise *available* to the public" leads to the simple inference that mere possession, or the ability to obtain possession, is what matters, not specific knowledge of how the invention works. Knowledge of the details of the invention, as would have been available had the press release in *Helsinn* specified the exact drug formulation, is simply one way of the public obtaining constructive possession of the invention.

Under the standard proposed by this Note, an invention would enter the public domain for purposes of the on-sale bar if it were sold in such a way that disclosed the invention (even if the sale was for pre-commercialization purposes) or when the first commercial sale to the public occurred. The public, in this case, would be the users who first derive benefit from the inventive concept of the invention. For example, a sale to the public would occur when the drug is made available to those who are ill and need it, a manufacturing machine would be available to the public when sold to the manufacturer (regardless of when the product it manufactures is sold), and a small component in a larger product would be available to the public when first sold to the party that combines it (not when the final product is sold). In

83. 27 U.S. (2 Pet.) 1 (1829).
84. *Id.* at 19.

this way, public availability depends to some degree on the nature of the invention; commercial exploitation sufficient to trigger the on-sale bar occurs when the invention is sold to someone who will derive benefit from the inventive concept. Pre-commercialization activity necessarily implies that commercialization is to occur. The delay in disclosure lasts only until the inventor is best situated to take full advantage of the patent's lifespan.

Furthermore, the standard announced by *Helsinn* implicitly permits other forms of commercial exploitation that unfairly extend monopolies only for large companies. Extensive and intense marketing campaigns are permissible under the on-sale bar so long as they do not rise to the level of a formal offer for sale.[85] Extensive pre-release marketing strategies drum up demand for a product before it is ever actually available for sale, providing clear commercial benefit that arises outside the duration of the patent period, even though that benefit is only collected once the patent period begins.[86] However, this strategy is only available to large companies that possess the internal resources to market their product. If the policy concern is that inventors will commercially benefit from their inventions outside the patent period, it is hypocritical to permit large companies to functionally (if not technically) have a longer, and more fruitful, monopoly period than an equally innovative individual or small company.

D. Policy in Favor of Giving Inventors a Reasonable Amount of Time After First Sale to Determine if a Patent Is Worth Pursuing

This underlying policy consideration is not directly implicated by the idea of narrowing the on-sale bar to exclude pre-commercialization transactions that do not disclose the invention because this policy concern only comes into play once a sale occurs and the one-year grace period has started. However, the spirit of this policy concern is mirrored in the policy concern forwarded by this Note, which argues inventors should have a chance after the date of invention to determine and put in place the best strategy for commercialization. The *Medicines* court rejected the idea that an inventor's stockpiling the product in preparation for going to market was commercial activity that triggered the on-sale bar, in part by referring to the Court of Claims's statement that "[i]t appears certain that the purpose of the on sale bar and the 1-year grace period is an attempt by Congress to balance the interests of the inventor with the interests of the public."[87]

This broader policy of balancing the interests of inventors against the interest of the public in quick disclosure of innovations can also be seen in the rationale of the experimental-use exception to the on-sale bar. The experimental-use exception to the on-sale bar serves the purpose of balancing

85. Taub, *supra* note 75, at 1500.

86. *Id.* at 1500–01.

87. Meds. Co. v. Hospira, Inc., 827 F.3d 1363, 1378 (Fed. Cir. 2016) (quoting Gould, Inc. v. United States, 579 F.2d 571, 580 (Ct. Cl. 1978)).

an inventor's need to refine the invention and assess its utility before commercializing it against the public's interest in having disclosure as soon as possible.[88] This provides yet another analogous scenario that suggests it would be wise to interpret the on-sale bar as not covering pre-commercialization transactions that do not disclose the invention. Just as the law permits inventors the opportunity to experiment with and assess the utility of their invention, so too should the law permit inventors to assess and explore their options for eventual commercialization. While this fourth policy consideration does not directly bear on the issue of whether semi-secret, pre-commercialization sales should trigger the on-sale bar, it certainly does not weigh against such a suggestion; and an extrapolation from the basic principles of balancing the considerations of inventors against those of the public tends to support the proposed narrowing of the on-sale bar.

E. Incentivizing Innovation Generally

All four of the preceding policy considerations are subservient to and inextricably connected to the broader purpose of the patent system—to incentivize innovation. As laid out in the Constitution of the United States, Congress has the power to "promote the Progress of Science and the useful Arts."[89] Because the on-sale bar disproportionately burdens small companies, it inhibits their ability to innovate in several ways. Small businesses and individual inventors, while certainly possessing fewer patents per capita, represent a significant source of innovation, and there is some argument that, in certain industries, small businesses are actually more innovative than large ones.[90] A formation of the law that systemically disincentivizes innovation amongst a whole class of innovators is operating sub-optimally and should be critically reevaluated.

The first reason that disproportionately burdening small inventors with the on-sale bar is contrary to the goal of incentivizing innovation is that having discriminatory policies (or ones with discriminatory impacts) serves to narrow the universe of potential paths to innovation by disproportionately rewarding certain organizational structures and business models over others, regardless of merit in the arena of innovation. The current interpretation of the on-sale bar directly contravenes the policy consideration of "antidiscrimination"[91] that seeks to keep open as many channels to innovation as possible. Patent antidiscrimination policies are not rooted in ideas of fairness but instead arise out of a practical concern for ensuring that

88. Levy, *supra* note 17, at 195–96.

89. U.S. CONST. art. I, § 8, cl. 8.

90. *See* Mark A. Lemley, *Reconceiving Patents in the Age of Venture Capital*, 4 J. SMALL & EMERGING BUS. L. 137, 140 (2000) ("Another objection to patents notes that big companies patent, but small companies innovate. This is something that's true in some industries but not others.").

91. John M. Golden, *Principles for Patent Remedies*, 88 TEXAS L. REV. 505, 555 (2010) ("The antidiscrimination principle for patent remedies cautions against embracing approaches to remedies that explicitly or otherwise directly favor certain categories of business models . . . .").

innovation and development are pursued via as many avenues as possible.[92] If patent law were to favor certain business models or organizational practices over others, it would potentially disincentivize inventors from pursuing new ideas via different methods than are currently normative.[93]

Innovation is defined as "the introduction of something new" or "a new idea, method, or device."[94] It is entirely antithetical to the definition of innovation as something "new" to always expect it to arise from the same people applying the same methods in the same way. Thus, adhering to a policy of antidiscrimination, which acknowledges that new ideas may arise in ways not currently normative, serves the affirmative policy function of ensuring that the amount of innovation in society is maximized. The current interpretation of the on-sale bar, by disproportionately harming small businesses or individual inventors, may cut off or discourage innovations that would only occur in the unique intellectual ecosystems offered by such organizations.

One possible rebuttal to the argument that the on-sale bar should be modified to adhere more closely to a policy of antidiscrimination is that antidiscrimination does not mean *no* discrimination, as disparate impacts are tolerated or encouraged in other areas of patent law.[95] While it is true that disparate impacts are permitted in certain areas of patent law, antidiscrimination calls for a showing of "reasoned justification" for such discriminatory practices.[96] As discussed in subparts IV(A)–(D), the disparate impact of the modern on-sale bar is unsupported by any "reasoned justification" as it is not based upon (and in many cases undermines) the policy foundations of the on-sale bar itself.

A second reason that the Federal Circuit's current interpretation of the on-sale bar fails to maximize potential innovation is that it discourages distribution of risk between small inventors and third parties. The case of Helsinn's development of palonosetron is an excellent case study to illustrate the importance of risk-sharing in the development of new technologies. Without investment from a third party, Helsinn would not have been able to afford the massive expenses of clinical testing.[97] After Helsinn was rejected by numerous large pharmaceutical companies, MGI agreed to partner with Helsinn and share the risk of development and testing in exchange for the

92. *Id.*

93. *Id.* ("By prejudicing a law-shaped marketplace against alternative approaches to invention or innovation, such a rule can discourage pursuit of new and different business models that might prove superior to the present norm.").

94. *Innovation*, MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY 645 (11th ed. 2003).

95. For a more detailed discussion of instances in which discriminatory effects are accepted in the patent system, see Golden, *supra* note 91, at 560–61.

96. *Id.* at 561.

97. The Biotechnology Innovation Organization (BIO) as Amicus Curiae Supporting Rehearing En Banc at 5, Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc., 855 F.3d 1356 (Fed. Cir. 2017) (Nos. 2016-1284, -1787).

ability to potentially commercialize the invention in the future.[98] The agreement between MGI and Helsinn is an excellent example of the types of agreements that are necessary to ensure new ideas can be brought to fruition and provide benefits to the public.

Small inventors may not possess the resources to reduce their invention to practice or, particularly in the case of pharmaceuticals, may not have the resources to perform adequate testing or comply with government-mandated approval procedures.[99] Sharing risk with third-party investors or partners enables small companies to develop ideas that larger firms, like the pharmaceutical companies that rejected Helsinn, may not view as worthwhile. While one could argue that such partnerships could be legally structured so as to attempt to avoid triggering the on-sale bar (such as by not transferring title of the invention), there are three distinct disadvantages to this: (1) it adds an additional transaction cost by requiring more complex legal work; (2) there is still a degree of uncertainty concerning what will constitute an invalidating sale;[100] and (3) third-party partners may desire a transfer of title as adequate compensation for the risk they take on. Making pre-commercialization agreements with third-party partners or investors more difficult to obtain without risking the validity of one's patent puts a hurdle in the way of innovation. Without its agreement with MGI, Helsinn may very well not have succeeded in developing its drug or, at the very least, the release of the drug to the public would have come later (once a large pharmaceutical company decided it was worthwhile). If the purpose of patent law is to drive innovation and get new inventions into the hands of the public, then making agreements, such as the one in *Helsinn*, difficult or risky to form is in direct opposition with that purpose.

Both of these issues strike at the very heart of the patent system's purpose: to create an environment in which innovation can flourish. The current, strict on-sale bar directly undermines patent law's central objective by disfavoring new or different organizational structures and development methods as well as by making it more difficult for small inventors to establish risk-sharing relationships with third-party investors or partners. Furthermore, the disparate impact of the Federal Circuit's interpretation of the on-sale bar lacks any foundation in the four underlying policy considerations that define the scope of the bar. From a policy perspective, there appears to be no support for an on-sale bar that favors large, vertically integrated companies over small inventors by limiting the ability of small firms to engage in critical pre-commercialization activities that large companies either have no need for or are able to do in-house. The looser on-sale bar proposed by this Note, one that would exclude pre-commercialization transactions, would better serve the policies underlying the on-sale bar as well as drive innovation more generally.

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98. *Id.*

99. *Id.* at 4–5.

100. *See supra* notes 26–28 and accompanying text.

V. Conclusion

The Federal Circuit's decision in *Helsinn* represents a missed opportunity. The change in the statutory language of the novelty provision by the passage of the AIA provided the Federal Circuit with the chance to reevaluate how the on-sale bar had been applied for decades and determine if it was justifiable. However one feels about the debate surrounding how the statutory language should have been interpreted, the mere existence of such a debate gave the court leeway to change the law if it so wished. Unfortunately, the Federal Circuit decided not to take the opportunity to narrow the on-sale bar and instead seemed to signal (though not explicitly state) that the old meaning of the on-sale bar persists and that semi-secret sales trigger the on-sale bar even if they do not disclose the nature of the invention to the public. This holding means that many types of pre-commercialization transactions critical to the ability of small firms to innovate are now potential landmines that could blow up and invalidate their patents. Large firms, on the other hand, are largely unaffected by the strictness of the on-sale bar because they possess the resources to perform pre-commercialization activities in-house, with no risk of running afoul of the bar. This disproportionate burdening of small firms is unsupported by the policy considerations that define the scope of the on-sale bar; furthermore, it actively undermines the patent system's core goal of driving innovation by disincentivizing certain types of innovation and by making it more difficult for small companies to share risk and gain partners.

However, there is still hope that a more narrow and policy-oriented on-sale bar could be developed. The Supreme Court's granting of Helsinn's petition for a writ of certiorari is a promising development. Additionally, further empirical study into exactly how severely the current on-sale bar harms small inventors could provide a powerful foundation for lobbying the Legislature to more clearly limit the scope of the on-sale bar to exclude pre-commercialization transactions. Additionally, the narrowness of the Federal Circuit's holding in *Helsinn* does provide a chance for the court to revisit the issue in the future.[101] The court's refusal to directly answer the question of how the new statutory language of § 102 should be interpreted gives them the freedom in a later case to adopt an interpretation of the on-sale bar more in line with that advocated for by this Note by choosing to distinguish *Helsinn* on a factual basis. These possibilities provide plenty of opportunity to adopt a more critical, and hopefully more policy-oriented, view of the on-sale bar in the future. In the meantime, small companies will have to continue grappling with the uncertainty of the existing bar.

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101. *See supra* subpart III(A).