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THE PATENT ON-SALE BAR POST-*HELSINN* AND ITS EFFECT ON THE PHARMACEUTICAL INDUSTRY

BY

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ABSTRACT

The purpose of the patent on-sale bar is to discourage inventors from misusing the patent system and unfairly extending their patent exclusivity period. In *Helsinn Healthcare v. Teva Pharmaceuticals*, the Federal Circuit has distorted this doctrine far beyond its purpose. By including non-public business transactions within the scope of the on-sale bar, the Federal Circuit's decision contradicts legislative history and express statutory language from the America Invents Act ("AIA"). This interpretation also makes the U.S. the only major patent system where a non-public sale can lead to the forfeiture of an inventor's patent rights.

The inclusion of non-public agreements within the scope of invalidating prior-art is a particularly harsh result for small pharmaceutical companies. These companies routinely enter into private license and supply agreements both to raise capital and to ally with experienced industry players who can help them navigate through the challenging FDA approval process. The Federal Circuit's *Helsinn* decision restricts the ability of small pharmaceutical companies to collaborate with others, and therefore impedes

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their ability to innovate. *Helsinn* also makes the on-sale bar inquiry extremely fact-specific and injects unnecessary uncertainty into routine business deals.

This paper suggests that the Federal Circuit's decision in *Helsinn* misinterprets the AIA's statutory text, ignores significant legislative history, and is logically at odds with the economic realities of the pharmaceutical industry. This paper also provides some practical suggestions for how pharmaceutical companies can structure commercial transactions without stepping on the on-sale bar minefield.

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I. INTRODUCTION

The Federal Circuit's recent application of the on-sale bar[1] is unmoored from the doctrine's original purpose[2]- to prevent inventors from misusing the patent system and unfairly removing inventions from the public domain. In holding that private business deals trigger the on-sale bar, even ones that did not place an invention in the public domain, the Federal Circuit has turned the on-sale bar into a trap for the unwary. As evidenced by a spate of recent cases,[3] the Federal Circuit's flawed approach to the on-sale bar has been especially disruptive for the pharmaceutical ("pharma") industry. Due to the high cost and complexity of drug development, pharma companies frequently enter into early-stage business partnerships to fund their research activities. These partnerships often take the form of license and supply agreements.[4] The Federal Circuit's expansive interpretation classifies many of these private agreements as a "sale" for purpose of the on-sale bar.[5] A "sale" initiates a one-year countdown from the time of the agreement and invalidates future patents if an application is not filed within one year. Many of the companies entering into such license or supply agreements do not recognize the ticking one-year clock, as they do not realize that their innocuous business agreements were a "sale" of their inventions. This puts pharma companies at risk of losing out on patent protection after spending a significant amount of money and time in developing their inventions.[6] This outcome is exceptionally disastrous as they rely heavily on market exclusivity provided by the patent system to recoup their high up-front development expenses. By making it harder for small pharma companies to continue innovating, the Federal Circuit's interpretation is detrimental to "the progress of science and useful arts."[7] This paper further argues that not only is the Federal Circuit's interpretation detrimental to the pharma

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

2. *In re* Mahurkar Double Lumen Hemodialysis Catheter Patent Litig., 71 F.3d 1573, 1577 (Fed. Cir. 1995).

3. *See Helsinn Healthcare S.A.*, 855 F.3d at 1371; Merck & Cie v. Watson Labs., Inc., 822 F.3d 1347, 1355 (Fed. Cir. 2016); Abbott Labs. v. Geneva Pharm., Inc., 182 F.3d 1315, 1319 (Fed. Cir. 1999); C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1375–76 (Fed. Cir. 1998).

4. *See* David Thomas & Chad Wessel, *Emerging Therapeutic Company Investment and Deal Trends*, BIO, 32 (May 2018), http://go.bio.org/rs/490-EHZ-999/images/BIO%20Emerging%20Therapeutics%20Company%20Investment%20and%20Deal%20Trends%20Report%202008-2017.pdf?_ga=2.45656556.936831433.1543089094-905210238.1524285270.

5. *See, e.g.*, *Helsinn Healthcare S.A.*, 855 F.3d at 1371.

6. *See, e.g.*, *id.*

7. U.S. CONST. art. I, § 8, cl. 8.

industry, it also misinterprets statutory text and ignores significant legislative history.

The original intent of the on-sale bar was straightforward.[8] The U.S. patent system is an elaborate quid-pro-quo system where the inventor offers to publicly disclose the invention in return for a period of exclusivity granted by the patent. An inventor who has already made an invention available to the public by selling it has nothing more to offer in return for the grant of a patent. Therefore, the on-sale bar prevents an inventor from obtaining a patent if the invention was publicly on-sale for more than a year before filing the patent application. The one-year grace-period provides the inventor with some leeway to assess the viability of the invention before filing the patent application. The on-sale bar also intends to prevent the prejudicial removal of "existing knowledge from public use."[9] Judicial interpretations have, over time, warped this simple doctrine to its current form where the doctrine is unnecessarily expansive and penalizes even those business deals that do not make an invention publicly available. Part II of this paper discusses the historical underpinnings of the modern on-sale bar, the attempt to fix the doctrine through the AIA, and the Federal Circuit's refusal to acknowledge Congress' statutory fix in *Helsinn Healthcare v. Teva Pharm.*[10]

While other scholars have commented on the on-sale bar in general, Part III of this paper identifies some unique issues that this doctrine presents to the pharma industry, especially smaller companies. The *Helsinn* decision hamstrings the ability of small pharma companies to raise money for early-stage research. Post-*Helsinn*, pharma companies need to be much more cautious about structuring agreements to avoid inadvertently triggering the on-sale bar.

Part IV of this paper analyzes the changes made by the AIA to 35 U.S.C. § 102(a) and its impact on the scope of on-sale bar. AIA added the phrase "or otherwise available to the public" to the definition of "prior art" in U.S.C. § 102(a)(1).[11] This addition signals Congress' intent to remove non-public business deals from the ambit of the on-sale bar. Floor statements from the sponsors of the AIA, as well as excerpts from the Congressional report, confirm that the updated on-sale-bar applies only to "public sales."[12] This section, therefore, argues that the Federal Circuit's interpretation of the on-

8. *See In re* Mahurkar Double Lumen Hemodialysis Catheter Patent Litig., 71 F.3d 1573, 1577 (Fed. Cir. 1995).

9. Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 64 (1998).

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

11. 35 U.S.C. § 102 (2012).

12. 157 CONG. REC. 3415 (2011).

sale bar is at odds with updated statutory text and defies compelling legislative history.

Part V recognizes that until further guidance is received from the Supreme Court, the Federal Circuit's interpretation is controlling for future on-sale bar cases. It summarizes observations from recent Federal Circuit case-law to provide suggestions for small pharma companies. It also suggests ways to structure business transactions that may avoid setting off the on-sale bar minefield.

II. HISTORICAL DEVELOPMENT OF THE ON-SALE BAR DOCTRINE

A. THE STATUTE IS SIMPLE AND LOGICAL

The statutory on-sale bar was first enacted by Congress in 1839.[13] It prevented inventors from obtaining a patent if they had placed their invention "on-sale" or in "public use," for more than two years before filing the patent application.[14] The grace period was changed to one year in 1939, as it remains to-date.[15] The purpose of the doctrine was simple: it prevented inventors from removing inventions from the public sale after the public reasonably believed the invention to be in public space.[16] The forfeiture of the inventor's patent rights was a direct result of their decision to place the invention on-sale or in public use for an extended period of time. The doctrine also encouraged the early filing of patents and discouraged inventors from keeping their invention secret to unfairly extend the exclusivity period.[17] The basics of the on-sale bar remained largely unchanged from 1939 until the 2012 enactment of the AIA. Judicial interpretation of the statute has, however, varied dramatically over time.

B. COURTS HAVE STRUGGLED TO APPLY THE ON-SALE BAR DOCTRINE

The primary struggle for courts has been to define when an invention is "on-sale" for the purpose of the statute. The earliest and most straightforward

13. Patent Act of 1839, ch. 88, § 7, 5 Stat. 353, 354 (1839).

14. *Id.*

15. Patent Act of 1939, ch. 450, § 1, 53 Stat. 1212 (1939).

16. Erol C. Basol, *Fabless Semiconductor Companies, the Patent On Sale Bar, and the New America Invents Act: Have Fabless Companies Been Shortchanged, or Is Change Coming?*, 16 UCLA J.L. & TECH. 1, 7 (2012).

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).

answer to this question was the "on-hand" rule.[18] To trigger the on-sale bar, the on-hand rule required an invention to be physically manufactured and available for sale a year before the patent application was filed.[19] Concern that inventors would delay physically manufacturing the inventive product to unfairly extend their exclusivity period led courts to de-link physical reduction to practice from the application of on-sale bar.[20] However, defining when a product that did not physically exist was "on-sale" proved to be a slippery task for appellate courts. The Federal Circuit cycled through the "totality of circumstances test,"[21] the "completed invention test,"[22] and the "substantially complete test"[23] in quick succession. Frequent reversals by the Federal Circuit, and ensuing confusion in lower courts, convinced the Supreme Court to grant certiorari in *Pfaff v. Wells Electronics, Inc.*[24] In *Pfaff*, the Supreme Court created a new two-prong test for the application of the on-sale bar.[25] The first prong requires an invention to be the subject of a "commercial offer for sale,"[26] and the second prong requires that the invention be "ready for patenting."[27]

The *Pfaff* test has, at best, had limited success in reducing confusion about when the on-sale bar is triggered. At times, the Federal Circuit found that the "ready for patenting" prong is satisfied without proof of conception,[28] and at other times, it has required both conception and reduction to practice.[29] Interpretation of the "commercial offer for sale" prong has not fared much better. In some cases, the Federal Circuit has looked at the Uniform Commercial Code ("UCC") to define when a sale occurs.[30] In other cases, it has relied on the usage of trade and course of dealing within a specific industry.[31] In *Special Devices, Inc. v. OEA, Inc.*, the Federal Circuit held that there is no "supplier" exception to the on-sale bar,

18. McCreery Eng'g Co. v. Mass. Fan Co., 195 F. 498, 501 (1st Cir. 1912) (noting the substantial difference between "an executory contract to construct and to pass title in the future and putting an article 'on sale'").

19. *Id.* at 501–02.

20. UMC Elecs. Co. v. United States, 816 F.2d 647, 655–56 (Fed. Cir. 1987).

21. *Id.* at 656.

22. Seal-Flex, Inc. v. Athletic Track & Court Constr., 98 F.3d 1318, 1324 (Fed. Cir. 1996).

23. Micro Chem., Inc. v. Great Plains Chem. Co., 103 F.3d 1538, 1545 (Fed. Cir. 1997).

24. Pfaff v. Wells Electronics, Inc., 525 U.S. 55, 60 (1998).

25. *Id.* at 67–68.

26. *Id.* at 67.

27. *Id.* at 68.

28. Abbott Labs. v. Geneva Pharm., Inc., 182 F.3d 1315, 1318 (Fed. Cir. 1999).

29. Robotic Vision Sys. v. View Eng'g, Inc., 249 F.3d 1307, 1313 (Fed. Cir. 2001).

30. Lacks Indus. v. McKechnie Vehicle Components USA, Inc., 322 F.3d 1335, 1347 (Fed. Cir. 2003).

31. Cargill, Inc. v. Canbra Foods, Ltd., 476 F.3d 1359, 1370 (Fed. Cir. 2007).

and an outsourced manufacturing agreement was an invalidating "sale."[32] In *Medicines Co. v. Hospira*, [33] the Federal Circuit reached the opposite conclusion *en banc* and found that a manufacturing agreement did not involve title transfer and therefore did not trigger the on-sale bar. Congress attempted to ameliorate this inconsistent application of the on-sale bar through the AIA.[34]

C. AIA ATTEMPTS TO SIMPLIFY THE ON-SALE BAR

The AIA, enacted in September 2012, is the most comprehensive reform of the U.S. patent system in decades. This legislation affected the on-sale bar through an update to the definition of "prior art." The AIA defines prior-art as inventions that are "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*."[35] While the definition uses terms similar to the pre-AIA definition, the addition of the phrase "or otherwise available to the public. . ." has been considered significant. Commentators, some of whom were involved in drafting the AIA, thought that this phrase removed secret-sales from the scope of the on-sale bar.[36] They also believed that the policy intent of the on-sale bar was better served by removal of secret-sales from its scope.[37] Requiring public knowledge also makes it easier to identify the critical date when the invention is placed on-sale, for purpose of the statute, thus providing more certainty to inventors.[38]

D. USPTO EMBRACES THE NEW ON-SALE BAR

The United States Patent and Trademark Office ("USPTO") embraced the modified scope of on-sale bar by updating the Manual of Patent Examining Procedure ("MPEP"). The updated MPEP states: "The phrase 'on sale' in AIA 35 U.S.C. § 102(a)(1) is treated as having the same meaning as

32. Special Devices, Inc. v. OEA, Inc., 270 F.3d 1353, 1355 (Fed. Cir. 2007).

33. Meds. Co. v. Hospira, 827 F.3d 1363, 1375 (Fed. Cir. 2016).

34. Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011).

35. 35 U.S.C. § 102(a) (2012) (emphasis added).

36. Joe Matal, *A Guide to the Legislative History of the America Invents Act: Part I of II*, 21 FED. CIR. B.J. 435, 467 (2012); Robert A. Armitage, *Understanding the America Invents Act and Its Implications for Patenting*, 40 AIPLA Q.J. 1, 53 (2012); Dmitry Karshtedt, *Did Learned Hand Get It Wrong?: The Questionable Patent Forfeiture Rule of Metallizing Engineering*, 57 VILL. L. REV. 261, 332 (2012).

37. *See also* Iftikhar Ahmed, *What They Don't Know Shouldn't Hurt You: Adding a Public Knowledge Prong to the On-Sale Bar Helps Provide Certainty to Inventors and Competitors Alike*, 45 HOUS. L. REV. 153, 182–83 (2008).

38. *Id.* at 185 ("Inventors could clearly identify the critical date because they will know if their sale has resulted in any public knowledge.").

'on sale' in pre-AIA 35 U.S.C. § 102(b), except that *the sale must make the invention available to the public*."[39] Examination guidelines stated that "the Office views the 'or otherwise available to the public' residual clause of the AIA's 35 U.S.C. § 102(a)(1) as indicating that secret sale or use activity does not qualify as prior art."[40] Since this update to the MPEP, countless patents have been granted by the USPTO, many of them relying on the updated interpretation of the on-sale bar.[41] A controversy related to drug patents, and the tussle between novel and generic drug manufacturers, soon invited judicial review of this interpretation.[42]

E. HELSINN V. TEVA TESTED THE UPDATED INTERPRETATION OF THE ON-SALE BAR

The post-AIA interpretation of the on-sale bar was challenged in a drug patent case where the Federal Circuit reversed both the USPTO and the District Court of New Jersey to hold that the AIA did not modify the prior understanding of the on-sale bar statute.[43] It held that private business agreements can still trigger the on-sale bar.[44]

Helsinn is a small family-run pharma company that focuses on the development of drugs for the treatment of cancer symptoms.[45] In 1998, Helsinn paid drug giant Roche $10 million to buy the patent for the compound palonosetron.[46] Helsinn, after extensive research and a phase III clinical study, created a stable formulation using this compound.[47] The FDA approved this formulation as the drug Aloxi® to relieve nausea symptoms for patients undergoing chemotherapy.[48] Helsinn almost ran out of funds during the expensive development process and entered into a license and supply agreement with another small company, MGI, to raise additional money.

39. DEP'T OF COMMERCE, PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 2152.02(d) (9th ed. Rev. 1, Nov. 2013) (emphasis added).

40. Examination Guidelines for Implementing the First Inventor To File Provisions of the Leahy-Smith America Invents Act, 78 Fed. Reg. 11059, 11062 (Feb. 14, 2013).

41. Brief for Pharmaceutical Research and Manufacturers of America as Amicus Curiae Supporting Petitioners at 7, Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc., 2018 WL 1583031 (Fed. Cir. 2017) (Nos. 16-1284, 16-1787), 2017 WL 3208579.

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

43. *Id.* at 1371.

44. *Id.*

45. *Our Mission and Values*, HELSINN, https://www.helsinn.com/about-us/our-mission-and-values/ (last visited Apr. 28, 2018).

46. Transcript of Trial, Helsinn Healthcare S.A. v. Dr. Reddy's Labs., Ltd., 2015 WL 13404191 (D.N.J. 2015) (No. 11-3962).

47. Brief of Plaintiffs-Appellees at *4–6, Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc., Nos. 16-1284, 16-1787 (Fed. Cir. Apr. 25, 2016), 2016 WL 1698099.

48. *Id.* at *2.

MGI agreed to pay an upfront license fee in return for exclusive rights to market the final drug upon approval by the FDA.[49] Helsinn also promised to manufacture and supply the approved drug to MGI.[50] The license and supply agreements had a strict confidentiality clause aimed specifically at keeping the drug formulation out of public space.[51] MGI, in order to fulfill its obligations as a public company, disclosed in an SEC filing the fact that it had entered into an agreement with Helsinn,[52] but redacted all confidential information from the disclosure. Teva Pharmaceuticals approached the FDA to gain approval for a generic version of Helsinn's palonosetron formulation.[53] Helsinn, in turn, sued Teva for patent infringement.[54] Teva challenged the validity of Helsinn's patents under the on-sale bar doctrine, as the agreement with MGI had been signed more than a year before Helsinn filed its patent applications.[55] The District Court of New Jersey held that, since the license and supply agreement did not make the details of the invention public, it could not form the basis for triggering the on-sale-bar.[56] The Federal Circuit reversed the District Court's holding.[57]

The Federal Circuit concluded that the AIA had not updated the on-sale bar to exclude non-public sales. The court reasoned that if Congress wanted to modify the on-sale bar instead of simply adding a new phrase to the definition, "it would do so by clear language."[58] The AIA's legislative history, indicating Congressional intent to update the on-sale bar doctrine, also failed to sway the court's reasoning.[59] Additionally, Helsinn's confidential agreement was found to constitute an "offer for sale" and triggered the on-sale bar.[60] The court stated that post-AIA "if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms of sale"[61] to trigger the on-sale bar. After the denial of a petition for *en banc* review by the Federal Circuit, Helsinn filed a writ of

49. *Id.* at *5–7.

50. *Id.*

51. *Id.* at *9.

52. MGI Pharma Inc., Current Report (Form 8-K) (Feb. 13, 2001), https://www.secinfo.com/dvTEu.465.htm.

53. Helsinn Healthcare S.A. v. Dr. Reddy's Labs., Ltd., No. CV 11-3962 (MLC), 2016 WL 832089, at *2 (D.N.J. Mar. 3, 2016), *rev'd sub nom.* Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc., 855 F.3d 1356(Fed. Cir. 2017).

54. *Id.* at *1.

55. *Id.* at *2.

56. *Id.* at *64.

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

58. *Id.*

59. *Id.* at 1368.

60. *Id.* at 1371.

61. *Id.*

certiorari to the U.S. Supreme Court, which has been accepted for hearing in the next term.

III. THE *HELSINN* DECISION DISPROPORTIONATELY AFFECTS THE PHARMA INDUSTRY, ESPECIALLY THE SMALLER COMPANIES

The *Helsinn* decision can have a significant long-term impact on the pharma industry. The high up-front cost of drug development, combined with a long regulatory approval process, leaves the pharma industry especially susceptible to issues that impact the ability to raise capital and protect intellectual property. The *Helsinn* decision hurts the pharma industry, especially small companies on both fronts.

A. SMALL PHARMA COMPANIES ARE INNOVATIVE AND SERVE AN IMPORTANT PURPOSE

The pharma industry is a vibrant source of innovation that provides hope and relief to millions of patients around the world. Expected to grow at an impressive rate of five percent over the next five years, the global pharma industry is expected to be worth $8.7 trillion by 2020.[62] Contrary to popular belief, not all pharma companies are multi-billion-dollar behemoths. About 66 percent of the drugs approved by the FDA in recent years came from small and mid-size companies.[63] The ability of smaller pharma companies to take on more risk allows them to work, not only on potential blockbuster drugs, but also those aimed at rare diseases.[64] A case in point is Aloxi®, the drug that was the subject of the *Helsinn* case. A large pharmaceutical company, Roche, deemed the formulation too risky after unfavorable Phase II clinical study results.[65] Helsinn, a small family owned drug company, stepped in and acquired the formula from Roche.[66] It completed Phase III trials, obtained FDA approval, and brought the drug to market to help patients undergoing chemotherapy.[67]

62. Greg Reh, *2018 Global Life Sciences Outlook*, DELOITTE, https://www2.deloitte.com/global/en/pages/life-sciences-and-healthcare/articles/global-life-sciences-sector-outlook.html (last visited Apr. 28, 2018).

63. Jennifer Alsever, *Big Pharma Innovation in Small Places*, FORTUNE (May 13, 2016), http://fortune.com/2016/05/13/big-pharma-biotech-startups/.

64. *See* Syed Husain & Catherine Hanley, *Supporting the Pharma Industry Small Business Growth Engine*, PHARMA'S ALMANAC, https://www.pharmasalmanac.com/articles/supporting-the-pharma-industry-small-business-growth-engine (last visited Apr. 28, 2018).

65. Brief of Plaintiffs-Appellees at *3–4, Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc., 2016 WL 1698099 (Fed. Cir. 2016).

66. *Id.* at *4.

67. *Id.* at *4–5.

Thus, small drug companies promote innovation. They also fulfill an important social purpose by working on drugs that larger companies consider too risky. They, however, often lack the financial strength and regulatory knowledge to take their innovations to the market without entering into partnerships with larger companies. Patent laws should help these companies by making it easier to protect and commercialize inventions. *Helsinn* does the opposite.

B. UNCERTAIN PROTECTION OF PATENTS WILL HURT THE PHARMA INDUSTRY AND PATIENTS

Pharma companies rely heavily on patent protection to recover their initial investment before the low-cost generics flood the market. A systematic survey conducted across various research-intensive industries, showed the pharma industry consistently placed the most importance on patent protection.[68] Protection of patents cannot, however, be at the cost of the ability to raise money for research. Inventing new drugs is an expensive business, and the development of a new drug can cost up to $1 billion[69] and 15 years of research.[70] The combination of an expensive development process and a long lead-time to market makes it critical for drug companies to be able to raise money in early stages of research. Pharma companies often raise money by entering into licensing and supply agreements with larger companies. Over the last decade, more than $157 billion was raised by therapeutic companies through early R&D stage licensing and acquisition deals.[71] Smaller pharmaceutical companies gain a substantial additional advantage by allying with larger companies which can help them navigate the clinical trial and FDA approval process. A study conducted to evaluate the determinants of success for clinical trials found that a company's experience with clinical trials has a strong positive correlation with its chance of succeeding in meeting the end-points for a clinical trial.[72]

68. Richard C. Levin et al., *Appropriating the Returns from Industrial Research and Development*, 3 BROOKINGS PAPERS ON ECON. ACTIVITY, 783, 796–97 (1987).

69. Daniel Wheadon et al., *Finance Transformation in the Pharmaceutical Indus*try, RSM (Mar. 2014), http://rsmus.com/content/dam/mcgladrey/pdf_download/wp_finance_transformation_pharmaceutical_industry.pdf.

70. *Id.*

71. *See* David Thomas & Chad Wessel, *Emerging Therapeutic Company Investment and Deal Trends*, BIO, 5 (May 2018), http://go.bio.org/rs/490-EHZ-999/images/BIO%20Emerging%20Therapeutics%20Company%20Investment%20and%20Deal%20Trends%20Report%202008-2017.pdf?_ga=2.45656556.936831433.1543089094-905210238.1524285270.

72. Patricia M. Danzon et al., *Productivity in Pharmaceutical–Biotechnology R&D: The Role of Experience and Alliances*, 24 J. HEALTH ECON. 317, 332, 337 (2005) (noting that large pharma companies

Helsinn's interpretation of the on-sale bar doctrine penalizes business deals that companies use routinely to secure early-stage investment.[73] It also injects unnecessary uncertainty [74] into otherwise routine business transactions and makes it harder for companies to structure investment deals without the risk of triggering the on-sale bar.

While filing a patent application earlier into the development process would presumably resolve the on-sale bar problem, the answer is not so simple. The long FDA approval process eats into the overall patent exclusivity period for pharma companies leaving them a shorter amount of time to recover the initial investment. Therefore, drug manufacturers prefer to delay filing for a patent until the major clinical trials are complete to reduce the time gap between the issuance of a patent and the commercialization of the invention.[75] Cost also factors into when a patent application is filed. A pharma company may assess 200,000 to 1 million different compounds before one or two viable candidates emerge for the final drug compound.[76] Because the average cost of preparing and filing a patent is about $60,000,[77] it is impossible for small pharma companies to file patents for all candidates during the development process.

The Federal Circuit's interpretation of the on-sale bar not only impacts pharma companies; it may also hurt patients by discouraging research into drugs for treating serious illnesses. The ability to protect the patent for a drug strongly correlates with areas of focus for the pharma industry. Sometimes this correlation has a perverse impact. An example of this perverse impact can be seen in recent research related to cancer drugs.[78] Between 2009-2014, eight new cancer treatment drugs arrived on the market.[79] All of these drugs were intended for terminally ill patients in the most advanced stages of

have a 30 percent higher chance of success in clinical trials. Small companies may increase their chance of success by up to 15 percent if they ally with a large company).

73. *See* Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc., 855 F.3d 1356, 1371 (Fed. Cir. 2017) (holding that a confidential license and supply agreement triggered the on-sale bar).

74. *See* Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc., Nos. 16-1284, 16-1787, 2018 WL 1583031, at *3 (Fed. Cir. Jan. 16, 2018) (O'Malley, J., concurring) (noting that the on-sale bar is a fact-specific, case-by-case determination).

75. *See generally* Eric Budish et al., *Do Firms Underinvest in Long-Term Research? Evidence from Cancer Clinical Trials.*, 105 AM. ECON. REV. 2044(2015).

76. JP Hughes et al., *Principles of Early Drug Discovery*, 162 BR. J. PHARMACOL. 1239, 1248 (2011).

77. Russ Krajec, *What Do Patents Actually Cost?*, BLUEIRON, https://blueironip.com/what-do-patents-actually-cost/ (last visited Apr. 25, 2018).

78. Derek Lowe, *Is the Current Patent System Distorting Cancer Research?*, IN THE PIPELINE (August 11, 2014), http://blogs.sciencemag.org/pipeline/archives/2014/08/11/is_the_current_patent_system_distorting_cancer_research.

79. Budish et al., *supra* note 77, at 2044.

metastasized cancer.[80] None of the new drugs that were approved in the same timeframe targeted treatment of early-stage patients with localized cancers.[81] At least one study hypothesized that one possible reason for this difference might be the length of the clinical study required to obtain approval for such drugs.[82] While drugs targeted at late-stage patients conclude in a few years as a result of shorter incremental life-expectancy of the subjects, studies involving earlier stage patients require a longer follow-up period.[83] Because a longer duration of a clinical study essentially means a shorter duration of the patent-protected exclusivity period, private funding sources are hesitant to back research that involves early-stage cancer patients.[84] As this example shows, factors that reduce the strength of patent protection for a drug may also reduce the investment of money into drug development. Since *Helsinn* negatively impacts patent protection for new drugs by making it easier to trigger the on-sale bar, its impact may go beyond just hurting the pharma industry. *Helsinn* may end up hurting American patients by reducing the pace of development for new drugs.

IV. FEDERAL CIRCUIT'S INTERPRETATION DEFIES STATUTORY TEXT AND LEGISLATIVE HISTORY

The Federal Circuit's interpretation of the post-AIA on-sale bar belies plain reading of AIA's text, undermines Congressional purpose, and is unsupported by its legislative history.

A. § 102(A) INDICATES THAT THE ON-SALE-BAR APPLIES ONLY TO INVENTIONS DISCLOSED TO THE PUBLIC

In direct opposition to the AIA's statutory text, the Federal Circuit in *Helsinn* decided that the "Purchase and Supply Agreement" was invalidating prior art even though it did not make the contents of the invention available to the public.[85] After summarily rejecting the notion that AIA modified the scope of on-sale bar,[86] the Federal Circuit incorrectly relied on pre-AIA case

80. *Id.*
81. *Id.*at 2045
82. *Id.*
83. *Id.* at 2045, 2056.
84. Ray Fisman, *Why Aren't There More Cancer Vaccines? Blame America's Lousy Patent System*, SLATE (Aug. 26, 2013, 5:45 AM), http://www.slate.com/articles/health_and_science/the_dismal_science/2013/08/cancer_treatment_is_american_patent_law_hindering_the_discovery_of_more.html.
85. Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc., 855 F.3d 1356, 1371 (Fed. Cir. 2017).
86. *Helsinn Healthcare S.A.*, 855 F.3d at 1371.

law.[87] The *Helsinn* decision spends surprisingly little time on the most important tool of statutory interpretation: the plain language of the statute.[88]

The AIA updated 35 U.S.C. § 102(a)(1) to prohibit the issuance of a patent if "the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public."[89] As compared to the pre-AIA statute, the phrase "or otherwise available to the public. . ." is a new addition.[90] The textual arguments, in this case, hinge on the relationship of the term "or otherwise available to the public. . ." in § 102(a)(1) to the preceding term "on sale."[91] The District Court and USPTO held that the phrase "or otherwise available to the public" is a series-modifier that modifies the term "on sale."[92] The Federal Circuit panel disagreed.[93]

This difference in opinion regarding the sentence structure in § 102(a)(1) does not need to be debated on a clean slate. The Supreme Court has already interpreted a similar sentence structure where it held that "[w]hen several words are followed by a clause which is applicable as much to the first and other words as to the last, the natural construction of the language demands that the clause be read as applicable to all."[94] Even the Federal Circuit's own past case law has held that "[w]hen a modifier is set off from a series of antecedents by a comma, the modifier should be read to apply to each of those antecedents."[95] Recognition of the fact that the phrase "or otherwise available to the public" modifies the meaning of "on sale" leads to the inevitable conclusion that a sale can only be invalidating when it makes the claimed invention available to the public. The Federal Circuit's holding in *Helsinn* is therefore inconsistent with the Supreme Court's previous holding and the Federal Circuit's own prior constructions.[96]

A further indication of Congress's intent can be gleaned from the change in title for the statutory section describing the on-sale bar. While pre-

87. *See* Pierce Cty. v. Guillen, 537 U.S. 129, 145 (2003) ("[w]hen Congress acts to amend a statute, we presume it intends its amendment to have real and substantial effect.").

88. Jimenez v. Quarterman, 555 U.S. 113, 118 (2009); *see Helsinn Healthcare S.A.*, 855 F.3d at 1367–71.

89. 35 U.S.C. § 102 (2012).

90. *Helsinn Healthcare S.A.*, 855 F.3d at 1368.

91. *See* 35 U.S.C. § 102 (2012).

92. *See* Helsinn Healthcare S.A. v. Dr. Reddy's Labs., Ltd., No. CV 11-3962 (MLC), 2016 WL 832089, at *45 (D.N.J. Mar. 3, 2016), *rev'd sub nom.* Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc., 855 F.3d 1356 (Fed. Cir. 2017); *see also* DEP'T OF COMMERCE, PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 2152.02(d) (9th ed. Rev. 1, Nov. 2013).

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

94. Paroline v. United States, 134 S. Ct. 1710, 1721 (2014) (internal citation ommitted).

95. Finisar Corp. v. DirecTV Grp., Inc., 523 F.3d 1323, 1336 (Fed. Cir. 2008) (internal citation omitted).

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

AIA section § 102 was titled "Conditions for Patentability; Novelty and *loss of right to patent*," [97] the post-AIA section is titled "Conditions for Patentability; Novelty."[98] Removal of the words "loss of right to patent" signals that the post-AIA statute focuses solely on novelty to define invalidating prior art. It no longer focuses on actions by inventors that do not affect novelty but may still result in a loss of the right to a patent. Since sale agreements that do not disclose the contents of an invention to the public do not affect the novelty of the invention, the updated title to § 102 suggests that such sales are no longer within the scope of § 102.

The Federal Circuit primarily based its *Helsinn* holding on a two-part argument. First, the panel held out the premise that private sales were historically a bar to patentability by referring to the Supreme Court's holding in *Pennock v. Dialogue*.[99] The panel then argued that Congress would have used clearer text if it had wanted to effect a foundational change from this historical interpretation.[100] This argument fails on both counts. Firstly, the reliance on *Pennock* is misplaced. *Pennock*, a case prior to the codification of the on-sale bar statute, addressed a sale which *did* disclose the invention to the public.[101] It involved the sale of a new method of connecting two hose-pipes intended to reduce leakage.[102] While the initial sale of the invention to a manufacturer was private in nature, the claimed invention was apparent as soon as *products embodying the invention* were sold.[103] The Supreme Court confirmed that a patent can be granted for inventions "not known or used *by the public*, before the application."[104] The case further states that the patent law's grant of a monopoly is not appropriate if the "*public* were already in possession and common use of an invention[.]"[105] *Pennock* strongly supports the proposition that, historically, the on-sale-bar doctrine and its statutory logic applied only to uses and sales that made the invention available to the public.[106] Secondly, the Federal Circuit argued that since Congress re-used

97. 35 U.S.C. § 102 (2008) (emphasis added).

98. 35 U.S.C. § 102 (2012).

99. *Helsinn Healthcare S.A.*, 855 F.3d at 1369 ("[f]ailing to find such a [private] sale invalidating. . .would materially retard the progress of science and the useful arts.") (quoting Pennock v. Dialogue, 27 U.S. 1, 10 (1829).

100. *Id.* at 1371 *(*stating that *"*[i]f Congress intended to work such a sweeping change to our on-sale bar jurisprudence and wished to repeal . . . [these prior] cases legislatively, it would do so by clear language" (internal quotations omitted).

101. *See* Pennock, 27 U.S. at 14.

102. *See Pennock*, 27 U.S. 1 at 3.

103. *See id.*

104. *Id.* at 19. (emphasis added).

105. *Id.* at 23 (emphasis added).

106. Dmitry Karshtedt, *The Riddle of Secret Public Use: A Response to Professor Lemley*, 93 TEX. L. REV. 159, 163 (2015).

the term "on-sale" when enacting the AIA, it also intended to re-use the historical scope for the on-sale bar. This argument is contrary to Supreme Court precedent that held that the presumption that Congress meant to give a term its previously held meaning is true only "when it re-enacts a statute without change."[107] Since the AIA was not a re-enactment, but a large-scale overhaul of the statute, the panel's argument is not convincing. Additionally, the text of the statute was supplemented with the phrase "or otherwise available to the public," which is a clear signal of Congress' intent to remove private sales from the ambit of the on-sale bar.

An additional glimpse into the Federal Circuit's reasoning comes from the concurrence written by Judge O'Malley to the court's denial of Helsinn's petition for *en banc* review. Judge O'Malley's primary assertion was that "on sale" was not modified by the phrase "or otherwise available to the public."[108] Instead, the phrase is an independent catch-all provision that encompasses all other ways an invention can be disclosed to the public.[109] While this argument initially seems plausible, it suffers from a fatal flaw. In articulating her argument, Judge O'Malley only accounted for a part of the phrase that was added by Congress. The complete phrase states, "or otherwise available to the public *before the effective filing date of the claimed invention*."[110] If Judge O'Malley's interpretation is correct, even the second part of the new phrase—"before the effective filing date of the claimed invention"—would not apply to the terms "on sale," "in public use," and "described in a patented publication." Thus, a public use or description in a patented publication will be invalidating even if the use or publication occurred *after* the effective filing date of the invention. This is an illogical result. Therefore, Judge O'Malley's interpretation cannot be correct.

The policy reason articulated by Judge O'Malley is similarly weak. The concurrence correctly identifies that the removal of inventions from public domain was not the only ill intended to be addressed by the on-sale bar.[111] The bar was also intended to prevent an unfair extension of the patent exclusivity period by the inventor.[112] While this would have been a fair argument in the pre-AIA patent statute, it does not hold water post-AIA. Pre-AIA, it is conceivable that an inventor could unfairly extend the patent exclusivity period by not filing a timely patent application. They would be

107. Lorilland v. Pons, 434 U.S. 575, 580 (1978).

108. Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc., Nos. 16-1284, 16-1787, 2018 WL 1583031, at *3 (Fed. Cir. Jan. 16, 2018) (O'Malley, J., concurring) (applying the last antecedent doctrine).

109. *Id.*

110. 35 U.S.C. § 102 (2012) (emphasis added).

111. *Helsinn Healthcare S.A.*, 2018 WL 1583031, at *5.

112. *Id.*

secure in knowing that their claim would still take priority over a subsequent inventor who independently invented and applied for a patent on the same subject matter. The on-sale bar would be a necessary tool to reach the fair result by denying patent protection to an inventor who had not filed an application for a year or more after they commercialized their invention. The AIA, however, replaced the first-to-invent patent system with a first-to-file system.[113] Post-AIA, an inventor who files an application first can obtain a patent even if their inventive activity occurred later in time.[114] Knowing that another inventor can trump their invention by filing for a patent first removes the incentive for inventors to delay filing a patent just to extend their exclusivity period. Thus, the on-sale bar is no longer a necessary tool post-AIA to prevent an unfair extension of the patent exclusivity period by inventors.

The Federal Circuit's interpretation of the on-sale bar does not find any support in the text of the statute and does not have any compelling policy underpinnings. It should, therefore, be reversed. It is also wholly unsupported by the AIA's legislative history.

B. THE LEGISLATIVE HISTORY INDICATES THAT THE FEDERAL CIRCUIT'S INTERPRETATION OF THE ON-SALE BAR UNDERMINES CONGRESSIONAL INTENT

While not a statement of the law, legislative history can be an extremely valuable aid in "our understanding of a law."[115] In deciding that the post-AIA on-sale-bar included secret sales, the Federal Circuit ignored compelling legislative history and ignored floor statements from the lead sponsors of the AIA, Senator Patrick Leahy and Congressman Lamar Smith. Senator Leahy said that the statute would "do away with precedent under current law that private offers for sale or private uses of secret processes . . . may be deemed patent-defeating prior art."[116] His colleague, Congressman Lamar Smith, concurred, stating: "[C]ontrary to current precedent, in order to trigger the bar in the new [Section] 102(a) in our legislation, an action must make the patented subject matter 'available to the public' before the effective filing date."[117]

113. Vance Woodward, *Patent Innovation: The Leahy-Smith America Invents Act Has Introduced Many Welcome Reforms to American Patent Law*, 38 L.A. LAW. 21, 21 (Mar. 2015).

114. *Id.*

115. Dig. Realty Tr., Inc. v. Somers, 138 S. Ct. 767, 782 (2018).

116. 157 CONG. REC. 3415 (2011).

117. 157 CONG. REC. 9782 (2011.

The Federal Circuit not only ignored floor statements, it also discounted committee reports that the Supreme Court has found to "represen[t] the considered and collective understanding of those Congressmen involved in drafting and studying proposed legislation."[118] The AIA, enacted as H.R. 1249, was legislated in response to the House Report H.R. 112-98.[119] This report, which neither of the Federal Circuit opinions considered, states 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*."[120] The House Report, H.R. 112-98, also states in its discussion related to § 102(a)(1) that "[p]rior art . . . will typically include all art that *publicly* exists prior to the filing date, other than disclosures by the inventor within 1 year of filing."[121] Similar sentiments are also expressed in the Senate Colloquies that documents opinions presented by senators who sponsored the AIA. Senator Kyl specifically warned against the type of interpretation that the Federal Circuit reached by saying "[a] contrary construction of section 102(a)(1), which allowed private and non-disclosing uses and sales to constitute invalidating prior art, would be fairly disastrous for the U.S. patent system."[122] Senator Leahy stated his understanding that "disclosure" under § 102(a)(1) is synonymous with "public disclosure."[123] Senator Leahy further clarified by saying that "and by a 'public disclosure' I mean one that results in the claimed invention being 'described in a printed publication, or in public use, on sale, or otherwise available to the public.'"[124]

These statements from sponsors of the Leahy-Smith bill, supported by the finding of the House Report, provide compelling evidence that Congress made a conscious decision while updating the definition of prior art in §102(a)(1) to remove non-disclosing, non-public sales from the category of invalidating prior art. This evidence is further strengthened by the complete absence of any floor statements, or recorded opinions of Senators or Congressmen, opposing this stance.

118. Garcia v. United States, 469 U.S. 70, 76 (1984) (alteration in original).
119. H.R. REP. No. 112-98, pt. 1, at 1 (2011).
120. *Id.* at 43 (emphasis added).
121. *Id.* at 42 (emphasis added).
122. 157 CONG. REC. 3424 (2011).
123. 157 CONG. REC. 3415 (2011).
124. *Id.*

C. THE ON-SALE BAR FOR NON-PUBLIC SALES IS OUT OF SYNC WITH INTERNATIONAL PATENT LAWS

The "sense of Congress" provisions in the AIA state that one of its goals is to "promote greater international uniformity and certainty in the procedures. . ."[125] The Federal Circuit's interpretation that a non-public sale can trigger a bar to patentability is in direct opposition to this stated goal. A review of the patent systems in other major jurisdictions, that along with the United States account for 90 percent of worldwide patent filings,[126] shows that forfeiture of patent rights due to commercial transactions that do not publicly disclose the invention is unique to the U.S. patent system. A quick summary is presented below for prior art definitions in the non-U.S. IP5[127] countries.

Europe: European patent law does not envision something as prior art unless it is "*available to the public* . . . by use, or in any other way . . . before the date of filing of the European patent application."[128] The European Patent Board of Appeals demonstrated this principle by holding that the sale of a microchip containing the inventive program did not constitute invalidating prior art when "the principle underlying [invention] is not discernible [to the public] by inspection."[129]

China: In Chinese patent law, prior art encompasses inventions that are "known to the public both domestically and abroad before the date of application." [130] The disclosure of an invention made by selling an embodiment can only serve as prior art if it makes the "technical content available to the public."[131]

125. Leahy-Smith America Invents Act, H.R. 1249, 112th Cong. § 3(p) (2011-2012).

126. *See IP5*, USPTO, https://www.uspto.gov/patents-getting-started/international-protection/office-policy-and-international-affairs-ip5 (last visited Apr. 28, 2018) (identifying Europe, China, Korea and Japan as the five largest intellectual property offices in the world which account for 90 percent of all patent filings).

127. *Id*.

128. Convention on the Grant of European Patents art. 54(2), Oct. 5, 1973, 1065 U.N.T.S. 199 (emphasis added).

129. EPO Case Number T 0461/88 (Apr. 17, 1991), available at http://www.epo.org/law-practice/case-law-appeals/recent/t880461ep1.html#q.

130. Patent Law of the People's Republic of China, art. 22 (1984) (amended Dec. 2008), available at http://english.sipo.gov.cn/laws/lawsregulations/201101/t20110119_566244.html.

131. Guidelines for Patent Examination, (promulgated by the State Intellectual Property Office of the People's Republic of China, 2010), ch. 3 § 2.1.2.2, available at http://www.sipo.gov.cn/zlsqzn/sczn2010eng.pdf (China).

South Korea: South Korea defines prior art as an invention that is "publicly known or executed in the Republic of Korea. . ."[132] where the definition of "executed" includes the act of selling the invention.[133]

Japan: Japan utilizes a definition like South Korea for prior-art "inventions that were publicly known in Japan [or] publicly worked in Japan or a foreign country, prior to the filing."[134] The definition of "working" includes "producing, using, assigning, etc."[135]

Helsinn's interpretation of the on-sale bar is unlike that in any of the other IP5 countries. It, therefore, cuts against Congress' stated intent to harmonize the U.S. Patent system with the rest of the world. The Federal Circuit's interpretation of the on-sale bar, as exemplified in *Helsinn*, is contrary to the AIA's text, legislative history, and Congressional intent. It is, however, the applicable law until the Supreme Court or Congress steps in to overrule *Helsinn*. Pharma companies should be cautious about structuring any license and supply agreements so that they do not trigger the on-sale bar as per Federal Circuit's current case law.

V. TIPS TO NAVIGATE THE CURRENT ON-SALE-BAR MINEFIELD

The *Helsinn* decision has not only made it harder for small pharma companies to raise capital, it has also injected uncertainty into otherwise routine commercial transactions. Post-*Helsinn*, the on-sale bar inquiry is extremely fact specific where "[e]ach case [is] decided based on its own facts."[136] *Helsinn* did, however, identify some common factors in Federal Circuit decisions where the on-sale bar was found not to be applicable. It noted that "the absence of the passage of title, the confidential nature of a transaction, and the absence of commercial marketing of the invention all counsel against applying the on-sale bar."[137] Similarly, the *Medicines* decision found that the "absence of title transfer [and] the confidential nature of the transactions" counsels against application of the on-sale bar even though it is not of "talismanic significance."[138] Utilizing the common factors

132. Patent Act, Act No. 950, Dec. 31, 1961, *amended by* Act. No. 14112, Mar. 29, 2016, art. 29(1) (S.Kor.).

133. *Id.* at art. 2(3).

134. Tokkyoh [Patent Act], Law No. 121 of 1959, *amended by* Law No. 36 of 2014, art. 29(1) (Japan).

135. *Id.* at art. 2(3).

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

137. *Id.* at 1364.

138. Meds. Co. v. Hospira, Inc., 827 F.3d 1363, 1376 (Fed. Cir. 2016).

noted in *Helsinn* and *Medicines*, this section will provide some suggestions on how to structure transactions to sidestep the on-sale bar minefield.

A. AVOIDING TITLE TRANSFER MAY AVOID TRIGGERING THE ON-SALE BAR

Federal Circuit case law has consistently looked to the UCC to determine what activities constitute "sale."[139] The UCC defines sale as "passing of title from the seller to the buyer for a price."[140] The Federal Circuit panel in *Helsinn* found that the supply agreement drafted by the parties triggered the on-sale bar as it "expressly contemplated" the passage of title.[141] In contrast, the Federal Circuit *en banc* found that a manufacturing services agreement did not trigger the on-sale bar because there was an "absence of title transfer."[142] Similarly, transactions that resemble "potential or eventual marketing," rather than "actual commercial marketing" of inventions, do not trigger the on-sale bar.[143]

Therefore, license agreements and distribution services agreements that allow investors to derive commercial benefit from a patent without transferring title can be used to avoid the on-sale bar. Federal Circuit case-law differentiates between transactions that transfer legal rights in the invention from ones that transfer title in products embodying the invention.[144] For example, a license agreement that transferred process know-how and contemplated the sale of "resultant products" manufactured by the licensee did not trigger the on-sale bar.[145] Similarly, the Federal Circuit has found that transfer of "production rights in the invention"[146] or "the exclusive right to market the invention" is not a sale of the invention itself, and therefore does not trigger the on-sale bar. While it avoids the on-sale bar minefield, the licensing agreement approach has other limitations. Getting a license to a technology is not the same as getting a commercial product, and the licensee must still invest in infrastructure to produce a

139. Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc., Nos. 16-1284, 16-1787, 2018 WL 1583031, at *2 (Fed. Cir. Jan. 16, 2018).

140. U.C.C. § 2-106 (AM. LAW INST. & UNIF. LAW COMM'N 2002).

141. *Helsinn Healthcare S.A.*, 855 F.3d at 1364.

142. *Meds. Co.*, 827 F.3d at 1375.

143. *Id.* at 1377.

144. Grp. One, Ltd. v. Hallmark Cards, Inc., 254 F.3d 1041, 1049 (Fed. Cir. 2001) (". . . a sale of rights in a patent, as distinct from a sale of the invention itself, is not within the scope of the statute, and thus does not implicate the on-sale bar."); *id.* at 1052 (Lourie, J., additional comments) ("A license is analogous to granting or waiving rights under the patent, which is distinct from selling the machine covered by the patent.").

145. *In re* Kollar, 286 F.3d 1326, 1330 (Fed. Cir. 2002).

146. *Id.* at 1331 (citing Mas-Hamilton Grp. v. LaGard, Inc., 156 F.3d 1206 (Fed. Cir. 1998)).

sellable product. While some licensees may be open to such an investment, others may still prefer to directly obtain sellable units from the inventor. Similarly, a distribution services agreement leaves the title, and therefore risk of the product, with the inventor and may be less preferable to a sale agreement where the risk of the product transfers to the buyer upon delivery of the product.

B. AN INDEFINITE AGREEMENT FOR FUTURE SALES MAY NOT TRIGGER ON-SALE

Some licensees/investors do not wish to manufacture the patented product themselves. As a result, it is common to pair a license agreement with a future supply agreement where the inventor manufactures and supplies products that the licensee can sell. If a future supply agreement contains definite terms, it may qualify as an "offer for sale" and therefore trigger the on-sale bar. A case in point is *Helsinn* where a letter of intent ("LOI") that contained "specific terms, such as price, method of payment, and method of delivery . . . constituted a commercial sale or offer for sale for purposes of [on-sale bar]."[147] Conversely, agreements that do not contain all terms required for a definitive agreement do not trigger the on-sale bar, as seen in *Elan Corp., PLC v. Andrx Pharm., Inc.*[148] The transaction in *Elan Corp.* was structured with an upfront license/royalty fee with payments tied to the inventor achieving certain milestones such as filing the New Drug Application, approval by the FDA and patient enrollment in the clinical study. As is common in such deals, the license agreement was paired with a future supply agreement. The inventor agreed to supply the patented drug product to the licensee at a bulk price that allowed an "initial gross margin based on current [drug] prices of not less than 70 percent after taking into account [the] processing charge."[149] The Federal Circuit noted that this agreement "lacked any mention of quantities, time of delivery, place of delivery"[150] and "[u]ntil the formulation had been finalized . . . there was no way it could [be] determined what . . . the offering price would be."[151] The on-sale bar was not triggered in this case due to the lack of specificity in the agreement.[152] The opposite outcome occurred in a different case where an inventor agreed to provide the investor with a fixed percentage of their

147. Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc., 855 F.3d 1356, 1365–67 (Fed. Cir. 2017).
148. 366 F.3d 1336, 1342 (Fed. Cir. 2004).
149. *Id.* at 1338.
150. *Id.* at 1341.
151. *Id.* at 1342.
152. *Id.*

worldwide requirements (quantity term) at reasonably competitive prices (price term).[153] Here, the agreement was found to be specific enough to qualify as an offer for sale, thus triggering the on-sale bar.[154] The Federal Circuit has summarized this distinction by stating that an agreement for future supply "rises to the level of a commercial offer for sale" when it contains all necessary contractual terms and a party "could make [it] into a binding contract by simple acceptance."[155]

These cases suggest that LOIs that stop short of defining all terms required to give rise to a binding contract may avoid triggering the on-sale bar. LOIs can be a valuable tool to document the present agreement between the parties and create a jumping-off point for future negotiations. LOIs can document the terms that the parties have already agreed to and leave some terms for the parties to negotiate after the patent application has been filed.[156] Any concerns regarding the enforceability of an LOI during future negotiations can be alleviated through the inclusion of a "good-faith negotiation" clause.[157] Good-faith negotiation clauses are enforced by courts and obligate both parties to conduct future negotiations in good faith and in accordance with agreed-upon terms that are documented in the LOI.[158] Therefore, use of LOIs can enable parties to proceed with a transaction by agreeing on critical terms while leaving the overall agreement indefinite until a patent application is filed, thus side-stepping the on-sale bar minefield.

VI. CONCLUSION

The Federal Circuit's interpretation of the on-sale bar is not only built on a faulty legal rationale, it also defies any discernible public policy. In reaching this faulty interpretation, the Federal Circuit misread the statutory text of 35 U.S.C. § 102 and refused to take advantage of the AIA's legislative history. The Federal Circuit's reasoning also discounts Congress' conscious decision to add a new phrase "or otherwise available to the public" to the definition of prior-art. In negating the changes introduced by the AIA, *Helsinn* particularly injures small pharma companies by hurting their ability to obtain early-stage funding. By making it harder for small pharma companies to keep producing innovative new drugs, this decision not only hurts the industry but also puts patients at a disadvantage. Until the Supreme

153. Enzo Biochem, Inc. v. Gen-Probe, Inc., 424 F.3d 1276, 1279 (Fed. Cir. 2005).
154. *Id.*
155. Grp. One, Ltd. v. Hallmark Cards, Inc., 254 F.3d 1041, 1048 (Fed. Cir. 2001).
156. EQT Infrastructure Ltd. v. Smith, 861 F. Supp. 2d 220, 230 (S.D.N.Y. 2012).
157. SIGA Techs., Inc. v. PharmAthene, Inc., 67 A.3d 330, 345 (Del. 2013).
158. *Id.*

Court reverses *Helsinn*, and provides a more practical application of the on-sale bar, companies should carefully structure their supply agreements, manufacturing agreements, and license deals to avoid triggering the on-sale bar. Entering into license and distribution services agreements that avoid transfer of title may avoid application of the on-sale bar. Similarly, using LOIs that leave some terms open for future negotiation instead of entering into definitive contracts may avoid triggering the on-sale bar.