

No. 16-1284

IN THE
**United States Court of Appeals
for the Federal Circuit**

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United States Court of Appeals
For The Federal Circuit

HELSINN HEALTHCARE S.A., ROCHE PALO ALTO LLC,
Plaintiffs-Appellees

v.

TEVA PHARMACEUTICALS USA INC., TEVA PHARMACEUTICAL INDUSTRIES, LTD.,
Defendant-Appellants

*APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE
DISTRICT OF NEW JERSEY, HON. MARY COOPER, PRESIDING*

**BRIEF OF *AMICUS CURIAE* RON D. KATZNELSON
IN SUPPORT OF NEITHER PARTY**

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March 14, 2016

CERTIFICATE OF INTEREST

Pursuant to Rules 29(a) and 47.4 of the Federal Circuit Rules of Practice, counsel of record certifies as follows:

- (1) The full name of every party or amicus to this brief is **Ron D. Katznelson**, an individual residing in Encinitas, California.
- (2) The above-identified parties are the real parties in interest.
- (3) The corporate disclosure statement prescribed in Federal Rule of Appellate Procedure 26.1 is as follows: There is no parent corporation to or any corporation that owns 10% or more of stock in the above-identified parties or *amici curiae*.
- (4) The names of all law firms and the partners and associates that have appeared for the party in the lower tribunal or are expected to appear for the party in this court are: **Dr. Ron D. Katznelson**, appearing *pro se*, Encinitas, CA.

Dated: March 14, 2016



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INTEREST OF *AMICUS CURIAE*¹

Ron D. Katznelson, Ph.D., is a technology entrepreneur, inventor and an independent scholar of the patent system. He holds 23 U.S. patents and numerous applications in the areas of digital communication systems, digital signal processing and advanced television systems.

Having founded two startup companies, Dr. Katznelson experiences first-hand the tensions that pervade the decisions to pursue patent protection. In deciding whether to patent an invention, keep it as a trade secret, or abandon it, Dr. Katznelson was particularly mindful of the balance of risks in patenting as opposed to choosing one of the latter two alternatives. While patenting under current law provides substantial potential benefits, the patent system transfers to the patentee substantial risk of loss which would not exist under the two latter alternatives. Therefore, the meaning of the terms “on sale” and “public use” has profound significance for patent protection. The decision of this Court in this case may have significant effect on Dr. Katznelson’s ability to protect or exploit his inventions, and the ability of the public to benefit from ideas and innovations.

¹ Pursuant to Rule 29(c)(5) of the Federal Rules of Appellate Procedure, the undersigned states that this brief was authored by *amicus curiae* Ron D. Katznelson, and that no counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of the brief. No person or entity, other than *amici* made a monetary contribution to the preparation or submission of this brief. In addition, all parties have consented to the filing of this *amicus* brief, and their consent emails are on file with the undersigned as of March 11, 2016.

ARGUMENT

This case presents an important question: Does the meaning of the statutory terms of art “on sale” and “public use” in the patent law changed under the America Invents Act (“AIA”) of 2011? The answer is decidedly “No.” *Amicus curiae* therefore urges that on the sole issue of the interpretation of post-AIA § 102, judgment of the district court be reversed.

1 The terms “on sale” and “public use” are ingrained in the fabric of the American innovation practice

Over nearly two centuries of American jurisprudence, the terms “public use” and “on sale” in patent law have received specific and well-established meanings laid out in precedential case law spanning more than 640 federal cases identified in the American Law Reports. William G. Phelps, “When does on-sale bar of § 102(b) [] prevent issuance of valid patent,” 155 *A.L.R. Fed.* 1 (2010); Kurtis A. Kemper, “When is Public Use [] for Experimental Purposes, so that § 102(b) Does Not Prevent Issuance of Valid Patent,” 171 *A.L.R. Fed.* 39 (2010).

It is unnecessary for an invention to be disclosed while in “use” to be considered “public” so as to bar a patent under pre-AIA 35 U.S.C. § 102(b)—the invention need only be accessible to the public, even if access to the information is practically infeasible. *Hall v. Macneale*, 107 U.S. 90, 96 (1883) (inventor’s three “burglar-proof” safes were in public use, despite the invention being completely

concealed within safe); *New Railhead Mfg. v. Vermeer Mfg. Co.*, 298 F.3d 1290, 1299 (Fed. Cir. 2002) (patent held invalid for public use even though drill bit invention operating underground could not be viewed in operation). “It is not public knowledge of his invention that precludes the inventor from obtaining a patent for it, but a public use or [non-public] sale of it.” *TP Labs., Inc. v. Professional Positioners, Inc.*, 724 F.2d 965, 970 (Fed.Cir.1984). The term ‘public’ means merely ‘not secret.’ *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1549 (Fed.Cir.1983) (“The nonsecret use of a claimed process in the usual course of producing articles for commercial purposes is a public use”). Use of an invention is deemed not secret when “used by a person other than the inventor who is under no limitation, restriction, or obligation of secrecy to the inventor.” *In re Smith*, 714 F.2d 1127, 1134 (Fed.Cir.1983) (citing *Egbert v. Lippmann*, 104 U.S. 333, 336 (1881)).

Similarly, a definite offer for sale of the invention prior to the critical date need not itself disclose the claimed invention to make the patent invalid under the “on-sale” bar. *RCA Corp. v. Data General Corp.*, 887 F.2d 1056, 1060 (Fed.Cir.1989), *different part overruled by Group One v. Hallmark*, 254 F.3d 1041 (Fed.Cir.2001). Where a method is kept secret, and remains secret after a sale of the product of the method, that sale will not bar another inventor from patenting

that method. It will, however, bar a patent if the sale of the product was made by the applicant for that patent or his assignee. *D.L. Auld Co. v. Chroma Graphics Corp.*, 714 F.2d 1144 (Fed.Cir.1983). Indeed, a long line of precedent holds that secret commercialization by the inventor bars patentability. “If an inventor should be permitted to hold back from the knowledge of the public the secrets of his invention,” commercially exploit it exclusively and later “take out a patent,” that “would materially retard ‘the progress of ... the useful arts’” and “give a premium to those ... least prompt to communicate their discoveries.” *Pennock v. Dialogue*, 27 U.S. 1, 19 (1829) (quoting U.S. Const. Art. I, §8, cl. 8). “It is a condition upon the inventor’s right to a patent that he shall not exploit his discovery competitively after it is ready for patenting; he must content himself with either secrecy or legal monopoly.” *Metallizing Engineering Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516, 520 (2nd Cir. 1946), *cert. denied*, 328 U.S. 840 (1946); *Bonito Boats v. Thunder Craft Boats*, 489 U.S. 141, 149 (1989) (quoting *Metallizing* with approval); *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68 (1998) (quoting *Metallizing* with approval).

The time-limit for filing a patent application after its first public use or commercial exploitation is grounded in the U.S. Constitution, as suggested in *Pennock*. From the Patent Act of 1790 to the present day, any sale or public use of

an article ready for patenting, if not closely followed by filing a patent application, has acted as a *forfeiture* of patent protection for any idea embodied in the article or its manufacture. “[T]he inventor who designedly, and with the view of applying it indefinitely and exclusively for his own profit, withholds his invention from the public comes not within the policy or objects of the Constitution or acts of Congress. He does not promote, and, if aided in his design, would impede, the progress of science and the useful arts.” *Kendall v. Winsor*, 62 U.S. 322, 328 (1858) (citing U.S. Const. art. I, § 8, cl. 8).

Thus, the “on sale” and “public use” bars to patentability are distinct from prior art bars. Quite apart from any disclosure considerations, “on sale” and “public use” define *conduct* under which inventors *forfeit* their rights to patents *as a matter of policy* grounded in our Constitution. These Constitutionally-grounded policies could not have been repealed by Congress’ enactment of the AIA in 2011.

2 In enacting the AIA, Congress did not change the meaning of “on-sale” and “public use”

Post-AIA 35 U.S.C. § 102(a)(1) bars 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* before the effective filing date of the claimed invention.” (Emphasis added).

The plain language here shows that Congress did not overturn the settled meaning of “on sale” and “public use” by adding the new category “or otherwise available to the public.” The new term “otherwise available to the public” is a disjunctive that captures disclosures through media not disclosed “in a printed publication.” The construction adopted by the district court, however, is that the phrase “or otherwise available to the public” indirectly changed the meaning of “on sale” and “public use” so that the statute no longer covered confidential sales or non-disclosing public use. Supp. Op. at ___.

In other words, the district court held that Congress impliedly *repealed* the well-settled forfeiture bars for secret commercialization and non-informing public use. Under this construction, the plain language use of the word “or” as a disjunctive must be read as a conjunctive “and”—the last term “available to the public” being a modifier of the terms “on sale” and “public use,” purportedly giving them the narrower meaning sought by Helsinn. The district court adopted this construction by invoking the “series-qualifier” doctrine used in *Paroline v. United States*, 134 S. Ct. 1710, 1721 (2014) (quoting *Porto Rico Railway, Light & Power Co. v. Mor*, 253 U.S. 345, 348 (1920)), positing that “when 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,” citing *Finisar Corp. v. DirecTV Grp., Inc.*, 523 F.3d

1323, 1336-37 (Fed.Cir.2008). Supp. Op. at 92.

For the series-qualifier doctrine to be applicable, however, two textual signals should be present: (i) “several words are followed by a clause which is applicable *as much to the first and other words as to the last*,” (*Porto Rico* 253 U.S. at 348 (emphasis added)); and (ii) “special reasons exist for so construing the clause in question” *id.* Courts must also consider the “*manifest*” purpose of the statutory provision: “If the application of the clause were doubtful, [courts] should so construe the provision as to effectuate the general purpose of Congress.” *Id.*

An alternative construction is based on the syntactic canon known as “the last antecedent,” according to which “[a] pronoun, relative pronoun, or demonstrative adjective generally refers to the nearest reasonable antecedent.” Antonin Scalia and B. A. Garner, “*Reading Law: The Interpretation of Legal Texts*,” Thomson/West (2012) at 144. In the seminal decision on this subject, the Supreme Court explained: “a limiting clause or phrase ... should ordinarily be read as modifying only the noun or phrase that it immediately follows. Referential and qualifying words and phrases, where no contrary intention appears, refer solely to the last antecedent.” *Barnhart v. Thomas*, 540 U.S. 20, 26 (2003) (quoting 2A N. Singer, *Sutherland on Statutory Construction* § 47.33, p. 369 (6th rev. ed. 2000)). The Court clarified that “[w]hile this rule is not an absolute and can assuredly be

overcome by other indicia of meaning, we have said that construing a statute in accord with the rule is quite sensible as a matter of grammar.” *Barnhart*, 540 U.S. at 26 (quotation and citation omitted). Applying the “last antecedent” doctrine to post-AIA § 102(a)(1), the phrase “to the public” modifies only the last antecedent—“otherwise available”—leaving the settled meaning of “on-sale” and “public use” intact.

For the reasons detailed below, the “last antecedent” doctrine applies here and the district court erred in applying the “series-qualifier” doctrine. First, the “series-qualifier” theory does not apply by its own terms—as it holds that “the modifier should be read to apply to *each* of those [series of] antecedents [set off by a comma].” (Emphasis added.) Here, at least two of the antecedents set off by a comma—“patented” and “described in a printed publication”—cannot reasonably be *modified* by the phrase “to the public” because they already are available to the public, rendering the modifier illogical and superfluous. This “series-qualifier” syllogism thus fails the first criterion for application of the rule—that the modifier clause “is applicable as much to the first and other words as to the last.” *Porto Rico Railway*, 253 U.S. at 348.

Second, the “last antecedent” doctrine should apply “where no contrary intention appears.” *Id.* ; *Anhydrides & Chemicals, Inc. v. United States*, 130 F.3d

1481, 1483 (Fed.Cir.1997). But here, in drafting the AIA, Congress consistently maintained, if not strengthened, the “on-sale” and “public use” forfeiture bars; and no “special reasons exist for ... construing the clause in question” to do otherwise. *Id.* Therefore, while there may be statutes for which the “series-qualifier” enunciated in *Porto Rico Railway* and *Finisar* properly apply, Post-AIA § 102(a)(1) is not one of them.

Third, basic tenets of statutory construction show that the additional phrase “or otherwise available to the public” did not change the settled meaning of the terms “on sale” and “public use.” Leading patent law scholars analyzed this in detail and explained that as a matter of statutory interpretation, it is unlikely that Congress intended to change the meaning of these terms, not only because it readopted existing statutory language but because other parts of the statute make no sense under the alternative interpretation now adopted by the district court. Moreover, the district court’s holding would undermine confidence that other terms reenacted in the AIA have the same meaning they have accrued in decades of common law. R.P. Merges, “Priority and Novelty Under the AIA,” 27 *Berkeley Tech. L.J.* 1023 (2012); accord M.A. Lemley, “Does ‘Public Use’ Mean the Same Thing It Did Last Year?,” 93 *Tex. L. Rev.* 1119 (2014-2015).

The leading scholars were right on this issue. After all, “it is a cardinal rule

of statutory construction that, when Congress employs a term of art, it presumably knows and adopts the cluster of ideas that were attached to each borrowed word in the body of learning from which it is taken.” *FAA v. Cooper*, 132 S.Ct. 1441, 1449 (2012) (internal quotation marks omitted). *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 243 (2011) (“When all (or nearly all) of the relevant judicial decisions have given a term or concept a consistent judicial gloss, we presume Congress intended the term or concept to have that meaning when it incorporated it into a later-enacted statute.” (Internal quotations omitted); accord *Merrill Lynch, Pierce, Fenner & Smith Inc. v. Dabit*, 547 U.S. 71, 85–86 (2006) (“[W]hen judicial interpretations have settled the meaning of an existing statutory provision, repetition of the same language in a new statute indicates, as a general matter, the intent to incorporate its ... judicial interpretations as well.”) (Internal quotation marks omitted). Both “on-sale” and “public use” are such established terms of art.

Moreover, the district court’s construction of Post-AIA § 102(a)(1) appears to render it unconstitutional because its repeal of the forfeiture bars to patenting may exceed the Constitutional “limited times” and “progress” limits on Congress’ authority. See R.D. Katznelson, “The America Invents Act May Be Constitutionally Infirm if It Repeals the Bar Against Patenting After Secret Commercial Use,” 13 *Engage: J. Fed. Soc’ys Prac. Groups*, 73, 74-76 (October

2012); D.H. Crawley, “America Invents Act: Promoting Progress or Spurring Secrecy?,” 36 *U. Haw. L. Rev.* 1, 24-25 (2014) (allowing “patenting even after years of secret commercialization” would violate “the constitutional mandate”; “Without the public disclosure of patenting, other inventors cannot build on the invention to advance technology, and the progress of science and the useful arts is retarded, not promoted.”) The U.S. Constitution cabins Congress’ authority to “securing for *limited times* to authors and inventors the *exclusive right*.” Under the district court’s construction of post-AIA § 102(a)(1), however, Congress authorized inventors to receive a patent after an *indefinite* period of secret *exclusive* exploitation of their invention, and therefore necessarily *secured* the *exclusive* period for an *indefinite* duration at the *inventors’* discretion. Katznelson, *Supra.* at 76. This de facto indefinite extension of exclusive use of the invention is distinguishable from extending it by a set duration. *Cf. McClurg v. Kingsland*, 42 U.S. 202, 206 (1843) (sustaining a limited extension of existing patent terms); *Eldred v. Ashcroft*, 537 U.S. 186, 209-10 (2003) (existing copyright terms extended 20 years by Congress remained “limited,” not “perpetual”).

Moreover, by allowing the inventor to delay indefinitely the disclosure of the invention, Congress would “not promote,” but “would impede, the progress of science and the useful arts.” *Kendall* 62 U.S. at 328. While the courts must grant

the AIA the full measure of deference owed to federal statutes, if as explained above, the district court's construction of post-AIA § 102(a)(1) appears unconstitutional, the Supreme Court has explained that "every reasonable construction must be resorted to, in order to save a statute from unconstitutionality." *Hooper v. California*, 155 U. S. 648, 657 (1895); *Rust v. Sullivan*, 500 U.S. 173, 190 (1991) ("[A]n Act of Congress ought not be construed to violate the Constitution if any other possible construction remains available."); *Crowell v. Benson*, 285 U.S. 22, 62 (1932) ("When the validity of an act of the Congress is drawn in question, and even if a serious doubt of constitutionality is raised, it is a cardinal principle that this Court will first ascertain whether a construction of the statute is fairly possible by which the question may be avoided."). Here, this Court need not determine that the statute as read by the district court would be unconstitutional; it is merely "obligated to adopt a saving construction even when the interpretation finds little support in the literal language of the statute." *SKF USA, Inc. v. U.S. Customs & Border Prot.*, 556 F.3d 1337, 1349-50 (Fed. Cir. 2009) ("While we need not go so far to sustain the statute here, ... the doctrine of constitutional avoidance is not 'irrelevant'.")

2.1 Without defining the meaning of public availability, the determination that an invention was "otherwise available to the public" is defective

The district court held that Congress modified the terms "on sale" and "public

use” by the phrase “otherwise available to the public.” However, it failed to define what the new term “available to the public” means. Does this term have the meaning given to it in 17 U.S.C. § 101, as available “in place open to the public or at any place where a substantial number of persons [are] gathered”? Or does it mean available “without limitation or restriction,” even if “confined to one person”? *Egbert* 104 U.S. at 336. Or does it have the meaning given to the term “publicly available” in the Freedom of Information Act 5 U.S.C. § 552(g)? Without defining the meaning of this term, the district court cannot properly arrive at its determination that the invention was “available to the public.” Nor can it ascertain, as it must for making its decision, the new meaning that Congress purportedly gave to the *modified* terms “on sale” and “public use.”

3 Congress did not intend to repeal the patent forfeiture bars

Throughout Congress’ patent policy trajectory over the years one sees consistent efforts to maintain, if not strengthen, the forfeiture bars against pre-grant delays after invention; taken as a whole, Congress did not disturb the established meaning of the terms “on sale” and “public use.”

3.1 The purported repeal means an *indefinite* grace period for secret exploitation of inventions which Congress could not have intended

Repealing the patent forfeiture bars for secret commercialization and non-informing public use would allow inventors to indefinitely extend their period for

secretly practicing their inventions prior to filing an application, effectively making the pre-AIA's one-year grace period for such activities *indefinite* under post AIA law. If that was truly a goal of the AIA, which it is not, it would be a radical departure from Congress' clear historical policy record since the mid-19th century. Congress' policy record is that of *shortening*—not extending—the exclusive period from invention to patent expiration. This was done by statutes shortening the permitted period between invention and filing, by shortening the period between filing and patent grant, or by shortening the period over which the patent is in force. The following list is illustrative:

- (a) In the Act of Mar. 2, 1861, Ch. 88, § 16, 12 Stat. 249 (1861), Congress repealed patentees' ability to extend their patent term up to 21 years after grant and set the patent term at 17 years from grant.
- (b) In the Act of March 3, 1863, Ch. 102, §3, 12 Stat, 796 (1863), Congress shortened the period to pay the patent issue fee to 6 months after allowance, or the application considered abandoned, eliminating applicant practice of delaying the patent grants.
- (c) In the Act of March 3, 1897, Ch. 391, § 4, 29 Stat, 693 (1897), Congress shortened the time to complete an application for examination from 2 years to 1 year after initial filing, and shortened the time to respond to all Office actions from 2 years to 1 year. Failing to meet these deadlines results in forfeiture (abandonment) of the application.
- (d) In the Act of May 23, 1908, PL 60-133, Ch. 189, 35 Stat, 246 (1908), Congress provided that patents shall issue 3 months from payment of issue fees, eliminating patent grant delays by the Patent Office.
- (e) In the Act of June 25, 1910, PL 61-296, Ch. 414, 36 Stat, 843 (1910), Congress repealed R.S. § 4902, the statute that allowed inventors to file

caveat patent disclosure in the patent office, as means of deferring for up to one year their filing an application, during which time the Patent Office would notify the caveat holder of any similar applications on the same subject matter if and when filed.

- (f) In the Act of March 2, 1927, PL 69-690, Ch. 273, 44 Stat, 1335 (1927), Congress shortened the time to complete an application for examination from 1 year to 6 months after filing, and shortened the time to respond to all Office actions from 1 year to 6 months. Failing to meet these deadlines results in abandonment of the application.
- (g) In the Patent Act of 1939, PL 76-286, Ch. 450, 53 Stat, 1212 (August 5, 1939), Congress *reduced the grace period* for inventors' disclosures, publications, "on-sale," and "public use" activities from two years to one year before filing an application. "Under present conditions 2 years appears unduly long and operates as a handicap to industry. Reduction of the period would serve to *bring the date of patenting closer to the time when the invention is made*, and would expedite applications, not only in their filing but also in their progress through the Patent Office." S. Rep. 876, 76 Congress, 1st Sess. (July 18, 1939) at 1. (Emphasis added).
- (h) In the Act of August 7, 1939, PL 76-341, Ch. 568, 53 Stat, 1254 (1939), Congress provided the Commissioner with authority to set shorter times for reply to an office action not to be less than 30 days and not to exceed 6 months. This flexibility reduces pendency—the total time from filing to patent grant.
- (i) In the Act of August 9, 1939, PL 76-358, Ch. 619, 53 Stat, 1293 (1939), Congress repealed R.S. § 4897, which, as a matter of right, provided for revival of an application for which the issue fee was not timely paid, referring instead the decision to revive to the discretion of the Patent Commissioner. The previous statute "readily permits the deliberate postponement of the issuance of a patent and is resorted to mainly for this purpose. [] The proposed change eliminates renewals, consequently simplifying the practice and abolishing causes and opportunities for delays." S. Rep. 878, 76 Congress, 1st Sess. (July 19, 1939) at 1-2.
- (j) In the Patent Fee Act of 1965, PL 89-83, 79 Stat. 259 (July 24, 1965), Congress provided that patent issue fee be paid earlier after allowance, with

ability for later corrective payment to cover the (initially unknown) printed page count fee component. “This particular arrangement will permit the Patent Office to issue patents substantially sooner and make new technology available to the public at an earlier date.” S. Rep. 301, 89th Cong., 1st Sess. (June 8, 1965) at 5.

- (k) In the Patent Office Appropriations Act of August 27, 1982, PL 97-247, 96 Stat, 317 (1982), Congress amended 35 U.S.C. § 41 to provide graduated discounted extension-of-time fees to incentivize applicants to reply sooner than 6-months to an Office Action; it also established escalating maintenance fees to incentivize early expiration of unexploited patents. Both factors have the effect of shortening the exclusive period ending on patent expiration.
- (l) In the Uruguay Round Agreements Act of 1994, PL 103-465, 108 Stat 4809, (December 8, 1994), Congress changed the term of a patent from 17 years after grant to 20 years counted from the original application date. For substantial number of applications, this had the effect of shortening the exclusive period from invention to patent expiration.

To be sure, Congress also enacted statutes that extend the patent term, but only to compensate patentees on a day-per-day basis for erosion of their patent term due to unusual government agency delay. *Cf. Drug Price Competition and Patent Term Restoration Act of 1984*, PL 98-417, 98 Stat. 1585 (Sept. 24, 1984); *Patent Term Guarantee Act of 1999*, PL 106-113, 113 Stat. 1501A-557.

Congress’ persistence in forbidding patenting and disclosure delays is unmistakable even leading up to the AIA through previous iterations of patent reform bills that included first-to-file provisions. In adopting and reporting H.R. 1908, a precursor bill to the AIA passed by the House, the Judiciary Committee Report explained:

“The Committee uses the current § 102(b) as the template from which to define the scope of prior art in the Act, primarily because of how the terms “in public use” and “on sale” have been interpreted by the courts. The provisions of § 102(b) are meant to serve a set of very specific policy goals which include 1) encouraging inventors *to file early* for patent protection, 2) *preventing inventors from extending their monopoly* in the invention and 3) not taking away from the public what it justifiably believes is in the public domain. Additionally, there is nothing inherent in a first-to-file system that will deter inventors from making use of their inventions as trade secrets and then some time later filing a patent application for the invention. *Thus, the maintenance* of the “public use” and “on sale” definitions of prior art *are needed to prevent such activity.*”

H. Rep. 110–314, 110th Cong., 1st Sess. (Sep. 4, 2007) at 57 (emphasis added).

More generally, Teva lists multiple iterations of the statute from 2005 to 2008 that did not include the terms “on sale” and “public use,” and demonstrates that those bill versions were not adopted, but were ultimately displaced by versions that reinserted the terms “on sale” and “public use.” Teva Br. at 60. Although *some* lawmakers, even the AIA bill managers, sought to “clear” ambiguities in the statute and explain their intent to repeal the bar of secret “on sale” and “public use,” their explanations appear in an *ex post* colloquy:

“One of the implications of the point we are making is that subsection 102(a) was drafted in part to do away with precedent under current law that private offers for sale or private uses or secret processes practiced in the United States that result in a product or service that is then made public may be deemed patent-defeating prior art. That will no longer be the case.”

157 Cong. Rec. S1496 (daily ed. Mar. 9, 2011) (Sen. Leahy).

But this Senate colloquy did not take place on the Senate floor prior to passage of the AIA bill (S.23) on March 8, 2011. Rather, as the daily record shows, it was inserted one day *after passage*. As such, it is “not a legitimate tool of statutory interpretation” of the bill as passed by the Senate. *Cf. Bruesewitz v. Wyeth LLC*, 131 S.Ct. 1068, 1081-82 (2011) (“Post-enactment legislative history (a contradiction in terms) is not a legitimate tool of statutory interpretation. ... [P]ost-enactment legislative history by definition could have had no effect on the congressional vote.”) (Citation omitted).

Helsinn refers to, and the district court accepted, the House Judiciary Committee Report as “authoritative source on discerning legislative intent.” Supp. Op. at 90. Presumably, by citing the Senate colloquy, the Committee Report made the Senator’s “clarification” available for House members’ consideration prior to *their* vote. H. Rep. 112-98 Pt. 1, 122th Cong., 1st Sess. (June 1, 2011) at 43, n20.

However, as shown below, select legislative history cannot rescue the district court’s misinterpretation of §102(a)(1) because, try as they might, the AIA bill managers, both in the Senate and in the House, were unable through “strategic manipulations of legislative history to secure results they were unable to achieve through the statutory text.” *Exxon Mobil Corp. v. Allapattah Servs., Inc.*, 545 U.S. 546, 568 (2005). As late as after the AIA bill (H.R. 1249) was introduced in the

House, perhaps even in cognizance of the prior Senate colloquy of March 9, 2011, a Manager's Amendment to H.R. 1249's § 102(a)(1) proposed the indicated **strikeout and underlined insertion as follows:**

“(1) the claimed invention was patented, described in a printed publication, ~~or in public use, on sale,~~ or otherwise available disclosed to the public before the effective filing date of the claimed invention;”

Amendment to H.R. 1249 (Rep. Smith, April 14 2011). However, the Committee ultimately rejected that part of the Managers Amendment, leaving the terms “on sale” and “public use” in the statute. Transcript HJU104000, “Markup of H.R. 1249, the America Invents Act,” April 14, 2011, House Committee on the Judiciary. Even the bill managers clearly did not get their way.

Therefore, these “debates in Congress expressive of the views and motives of individual members are not a safe guide, and hence may not be resorted to, in ascertaining the meaning and purpose of [Congress].” *Duplex Printing Press Co. v. Deering*, 254 U.S. 443, 474 (1921). The legislative record of the AIA shows that “[e]ven the sponsor[’s] [remarks] are not controlling.” *Chrysler Corp. v. Brown*, 441 U.S. 281, 311 (1979). As the Supreme Court “repeatedly held, the authoritative statement is the statutory text, not the legislative history.” *Exxon*, 545 U.S. at 568.

Even if the legislative history were relevant, however, the record here shows

that “Congress reject[ed] ... the very language that would have achieved the result [that Helsinn] urges here,” which “weighs heavily against [the district court’s] interpretation.” *Hamdan v. Rumsfeld*, 548 U.S. 557, 579-80 (2006).

3.2 Congress has not considered the real effects of repealing the secret commercialization patent forfeiture bars

There is no evidence that Congress had considered the specific policy of repealing the forfeiture bars for secret commercialization and non-informing public use. For an industry sector to have pursued such repeal of secret commercialization bars, it would have been important to explain to members of Congress why the public interest would be best served by permitting an inventor to delay filing of a patent application of an invention ready for patenting after commercially exploiting it in secret.

For example, it would have been necessary for chemical companies or pharmaceutical companies to explain that the public interest would be best served if after taking out a patent on a *composition* of a compound or a drug, keeping the *process of making* the compound or the drug secret, they were allowed many years later to file and obtain a patent on the *process of making* the compound or the drug. In some circumstances, this policy would have effectively extended their de facto exclusive period by another patent term. There is no evidence that such policy case was ever made to Congress prior to the enactment of the AIA. There can be

very little doubt that if it had been directly presented, it would have been widely criticized and dismissed as dead on arrival. The holding that Congress actually changed the meaning of the terms “on sale” and “public use” is tantamount to the holding that Congress actually intended the change as described above for the benefit of a few companies at the expense of the public. Rather, evidence cited above is to the contrary.

The dominant policy matters discussed with respect to amending § 102 were matters regarding the First-to-File vs. the First-to-Invent systems, interferences, the virtual elimination of the grace period, and *other* effects of the redefinition of prior art. The prospect that inventors would be allowed—even incentivized—to delay for years in filing patent applications is inconsistent with the AIA’s first-to-file stated goal of prompt filing of patent applications. S. Rep. 110-259, 110th Cong., 2nd Sess. (Jan. 24, 2008) at 7 (“In addition, a first to file system encourages the prompt filing of patent applications.”); H. Rep. 110–314, 110th Cong., 1st Sess. (Sep. 4, 2007) at 57 (“The [first-to-file] provisions ... are meant to serve a set of very specific policy goals [including] encouraging inventors to file early for patent protection”).

3.3 There is no record evidence that Congress either considered or intended the collateral implications of abandoning the settled meaning of “on sale” and “public use.”

In the legislative history of the AIA, there is no evidence that Congress discussed the implications of abandoning the settled meaning of “on sale” and “public use.” For example, Congress never discussed the construction of § 102(a)(1) of “otherwise available to the public” adopted by the district court would eviscerate the carve-out in the settled safe harbor of the disclosing “experimental use” doctrine. According to the experimental use exceptions, disclosing public use intended to test or perfect the invention is deemed “experimental” and would not bar a patent. *City of Elizabeth v. American Nicholson Pavement Co.*, 97 U.S. 126 (1877) (A patent for an improved pavement held valid even though the segment of the pavement about 75 feet in length on a road by way of experiment was publicly used). Similarly, where a sale is primarily for a bona fide experimental purpose to test or perfect the invention rather than for commercial exploitation, the prior sale does not bar patent validity. *A.B. Chance Co. v. RTE Corp.*, 854 F.2d 1307, 1311 (Fed.Cir.1988). *Envirotech Corp. v. Westech Eng'g Inc.*, 904 F.2d 1571, 1574 (Fed. Cir. 1990).

In *Baker Oil Tools, Inc. v. Geo Vann, Inc.*, 828 F.2d 1558 (Fed. Cir. 1987), the Federal Circuit enunciated certain factors that may show the existence of an

experimental use. These factors include the necessity for the public testing, the amount of control retained over the operation, the extent of public testing in relation to the nature of the invention, the length of the test period, whether any payment was made, whether there was a secrecy obligation, whether progress records were kept, who conducted the experiments and the degree of commercial exploitation during the tests in relation to the purpose of the experimentation. *Id.* at 1564. However, under the district court's construction of the terms "on sale" and "public use," these terms' substantive modification by "otherwise available to the public" means that the inquiry under the Federal Circuit's factors above, particularly "the extent of public testing," would be abrogated as irrelevant because of the catchall *literal* statutory bar to patentability for *any* "public availability" of the invention.

This holding can fundamentally disrupt research and development, and established procedures in industries, including for example, in the biomedical technologies requiring FDA approval. Here, the sheer number of people involved and the public nature of the testing in large-scale trials to generate the necessary clinical data required by the FDA is likely to make the invention "available to the public." In addition, to defray costs, medical device manufacturers may charge the investigators performing the clinical testing or the patients for the new medical

device. While under some criteria the invention would be later (in hindsight) considered to have been ready for patenting before trials began, until clinical testing on humans, it may not be known whether the inventive device produces unwanted side effects even if it might work for its intended purpose.

Apparently, none of these consequences to entire industries that rely on “experimental use” for perfecting and vetting their inventions prior to filing complex patent applications have been discussed in Congress prior to the AIA passage. These issues are but the tip of the iceberg. Congress could not have intended to undermine entire industries by foreclosing on the “experimental use” through stealth grammatical punctuation exercises. *Whitman v. Am. Trucking Ass’ns*, 531 U.S. 457, 468 (2001) (“Congress ... does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes.”); *Kellogg Brown & Root Servs., Inc. v. U.S., ex rel. Carter*, 135 S. Ct. 1970, 1977 (2015) (“Fundamental changes in the scope of a statute are not typically accomplished with so subtle a move.”).

3.4 Congress could not have intended to effectuate the policies underlying the repeal of the forfeiture bars

If it prevails, the district court’s construction of the statute would enable companies to extend their commercial exclusivity indefinitely by hoarding, exploiting, and profiting secretly from certain technologies for years and then

taking out patents on these technologies. It would also permit market incumbent companies to “evergreen” old secret technologies into a windfall of patents on subject matter for which patent protection had long been previously forfeited under pre-AIA law. This windfall will disproportionately enrich older and established market incumbents to the detriment of early-stage young startups that are too young to have accumulated older secret technology.

Judge Markey remarked: “[O]ur Forefathers had some experience with that from the Guilds in Europe and did not want a secret technology. They created the patent system to encourage disclosures.” Howard T. Markey, “Some Patent Problems,” 80 *F.R.D.* 203, 206 (1978) (discussing the patent bargain). If inventors are afforded unlimited or unspecified exclusive period to exploit their inventions, they would have less incentive to disclose their invention early. Katznelson, *supra*, at 89; Crawley, *supra*, at 24. Consequently, substantial duplication of R&D may take place; and those participating in the patent system—those patent seekers who disclose early—will be subject to greater risks.

This is so for two reasons. First, there will be an asymmetric flow of information to the hoarder of secrets—the only beneficiary from this exchange. Second, because those seeking patents must disclose their technology and its progression, the hoarder of secrets can ambush the patent-seeker by tracking his or

her progress and preemptively filing a patent application on features not yet disclosed whenever it appears that the patent seeker is close to discovering the subject matter possessed by the hoarder of secrets. That would tip the balance against those who participate in the patent system. This is akin to card players in a rigged game wherein one player is subject to a rule requiring him to reveal his hand to his opponent who is not subject to the that rule and thus keeps his hand secret. This shift of risks from those who hoard secrets to those who participate in the patent system is nothing short of a recipe for undermining the American patent system.

CONCLUSION

For the foregoing reasons, the judgment of the district court regarding the interpretation of post-AIA Section 102 should be reversed.

Respectfully submitted,

A handwritten signature in black ink that reads "Ron Katznelson". The signature is written in a cursive, slightly slanted style.

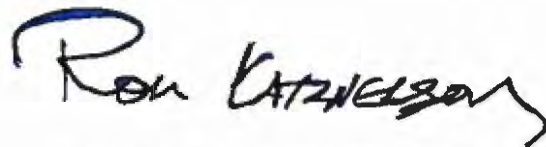
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MARCH 14, 2016

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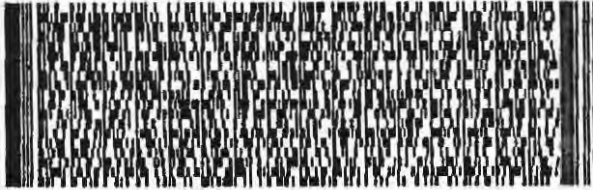
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