

2016-1284

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

HELSINN HEALTHCARE S.A.

Plaintiff-Appellee,

v.

**TEVA PHARMACEUTICALS USA, INC.,
TEVA PHARMACEUTICAL INDUSTRIES, LTD.,**

Defendants-Appellant.

*Appeal from the United States District Court for the District of New Jersey
in Nos. 3:11-cv-03962-MLC-DEA, 3:11-cv-05579-MLC-DEA,
3:13-cv-05815-MLC-DEA, Judge Mary L. Cooper.*

**BRIEF OF AMICUS CURIAE CONGRESSMAN LAMAR SMITH IN
SUPPORT OF PETITION FOR REHEARING EN BANC**

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United States Court of Appeals for the Federal Circuit

Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, 16-1284

CERTIFICATE OF INTEREST

Counsel for the amicus curiae Congressman Lamar Smith certifies the following:

1. The name of every party or amicus represented by me is:

Congressman Lamar Smith

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

Congressman Lamar Smith

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

Not Applicable

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me or are expected to appear in this Court are:

Not Applicable

Date: June 30, 2017

/s/ Robert A. Armitage

Signature of counsel

Robert A. Armitage

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INTEREST OF AMICUS

Congressman Lamar Smith is the “Smith” of the Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011), H.R. 1249, 112th Congress. He was the lead sponsor of the bill that became the AIA as enacted into law. Following his introduction of the bill in 2011, Congressman Smith managed the bill’s consideration through the U.S. House of Representatives.

His sole interest in this appeal is that 35 U.S.C. § 102(a)(1), as enacted under H.R. 1249, be interpreted in a manner faithful to the legislative text. He has no personal interest in the result of this appeal. No party to this appeal drafted any portion of this brief or contributed any money towards its preparation or filing.

SUGGESTED QUESTION FOR REHEARING EN BANC

Under the Leahy-Smith America Invents Act, does the absence of *availability to the public of the subject matter defined by a claim* preclude any finding that the claim is unpatentable under 35 U.S.C. § 102(a)(1) based upon alleged “on sale” activities attributable to the inventor?

ARGUMENT

The panel in this appeal has rendered the first decision by this court interpreting the AIA's new § 102(a)(1) in the context of "on sale" activities, attributable to the inventor, alleged to render the inventor's claims unpatentable. The panel decision invalidated a claim under § 102(a)(1) limited to a pharmaceutical formulation that (1) constitutes a single, unit dose (2) delivers 0.25 mg of its active ingredient, (3) contains two other ingredients (EDTA and mannitol), and (4) limits the presence of the EDTA and mannitol claim elements in the formulation to specified amounts.

The "on sale" activities at issue consisted of a "Supply and Purchase Agreement" that had become public in a Form 8K filing under the Securities and Exchange Act of 1934. The subject matter that became available to the public in the Form 8K apparently excluded any description of (1) the 0.25 mg amount of the active ingredient present in the unit dose of the claimed formulation, (2) the existence and amount of the EDTA in the claimed formulation, and (3) the existence and amount of the mannitol in the claimed formulation. Based on the above facts, the panel held that "after the AIA, if the *existence* of the sale is public, the *details of the invention* need not be publicly disclosed in the terms of the sale" for § 102(a)(1) to invalidate. [Emphasis supplied.] Slip op. 27.

Amicus believes that the panel's holding is wrong under the statute. Specifically, amicus contends that the specific question that the AIA requires the panel to have addressed is whether these "on sale" activities *rendered available to the public the subject matter defined by the invalidated claims*. This is the standard explicitly set out in the AIA's § 102(a)(1) when the *statutory definition of claimed invention* enacted in the AIA's new 35 U.S.C. § 100(j) of the patent statute is read together with new § 102(a)(1). Since the term "claimed invention" is now defined as the "subject matter defined by a claim in a patent" and the § 102(a)(1) "on sale" bar provision now requires that the "the *claimed invention* was ... on sale, or otherwise available to the public before the effective filing date of the claimed invention" (emphasis supplied), it follows that no § 102(a)(1) "on sale" bar to patenting can exist under the AIA unless *the subject matter defined by a claim was available to the public*. 35 U.S.C. § 102(a)(1) incorporating the AIA's new 35 U.S.C. § 100(j) definition.

Had the panel addressed the above question, it would have been obliged to undertake an element-by-element and limitation-by-limitation comparison of the claims at issue to the subject matter that the panel found had become available to the public, *i.e.*, to determine if each claim limitation had expressly or inherently become publicly accessible. Under such an

analysis, the panel should have concluded that execution of the Purchase and Supply Agreement coupled with the later Form 8K public disclosure of its existence and contents could not pose a § 102(a)(1) bar to patenting.

If amicus is correct in its view of the proper application of § 102(a)(1) to the facts of this appeal, then the failure of the panel to reconsider its decision may have profoundly adverse consequences for other inventors for whom the AIA offered the promise of more transparent, objective, predictable, and simple standards for securing valid and enforceable patents. Because this panel decision will be binding on future panels of this court, it will stand as controlling precedent under which the lower courts and the USPTO will be obliged to decide patentability issues, particularly where the basis for unpatentability is focused on “on sale” activities. If not reconsidered now, amicus believes that the panel’s holding will hereafter preclude lower courts and the USPTO from making a proper patentability analysis under § 102(a)(1)—unless and until the panel’s holding is finally reversed, either by this court sitting en banc or by the Supreme Court.

In the panel’s focus on the meaning to be given to the two words “on sale,” amicus believes that the panel failed to take account of the remarkably different overall statutory framework in which those words appear in the AIA’s new § 102 compared to its pre-AIA counterpart.

In contrast to the AIA, the pre-AIA § 102 contained only a more general and non-specific “on sale” provision; a patent could be denied to a person if “the invention was ... on sale in this country, more than one year prior to the date of the application for patent in the United States.” As outlined above, the old, pre-AIA patent statute did not specify that *what must be available to the public is the subject matter defined by the claim at issue*. In addition, the pre-AIA § 102(b) had been uniformly interpreted to impose a dual standard for “in public use or on sale” patentability analyses, based on the *attribution* of the use/sale activities. For “public use” and “on sale” activities not attributable to the inventor, only publicly accessible subject matter could render an invention unpatentable under pre-AIA § 102(b). *W.L. Gore & Assocs. v. Garlock*, 721 F.2d 1540, 1550 (Fed.Cir.1983). Had the Purchase and Supply Agreement at issue in this appeal been between two Shanghai-based pharmaceutical companies with no relationship to the appellee, *Gore v. Garlock* would require each claim limitation to be publicly accessible for an “on sale” bar to patenting to apply.

On the other hand, under the pre-AIA law, where the “in public use or on sale” activities—as in this appeal—were the result of actions attributable to the inventor, the inventor could suffer a *forfeiture* or *loss of the right to patent* even in the absence of the subject matter defined by the claim

becoming publicly accessible. This dual standard used to interpret pre-AIA § 102(b) could be justified under the pre-AIA statute on only two grounds.

First, the heading for pre-AIA § 102—“Conditions for patentability, novelty and loss of right to patent”—indicated that conditions other than just the traditional analysis for *novelty over prior art* were encompassed by § 102. The caption for pre-AIA § 102 indicated that it contained bars to patenting in which actions attributable to the inventor could cause the inventor to forfeit the right to patent. Second, the non-specific language of pre-AIA § 102(b) opened this subsection to the possibility that it might be construed to encompass such a forfeiture or other loss-of-right-to-patent provision. The general language in pre-AIA § 102(b) indicated that the patenting right could be lost for an “invention” that was merely “in public use or on sale,” with the term “invention” being merely circularly defined in 35 U.S.C. § 100(a) as an “invention or discovery.”

Under § 102’s new framework, Congress removed both these pre-AIA statutory hooks that might otherwise have allowed new § 102 to be construed as containing any such inventor’s forfeiture or loss of right to patent. First off, new § 102 is now captioned: “Conditions for patentability, novelty” and new § 102(a) is now captioned, “Novelty; prior art.” The pre-AIA reference to the “loss of right to patent” aspect of § 102 is now gone.

In the view of amicus, Congress was being unambiguously clear that the analysis required under § 102(a)(1) and its companion provision § 102(a)(2) was to be all about *novelty over the prior art*—and the dual standard formerly applied to uses and sales was to be no more.

Second, new § 102 replaced the circularly-defined term “invention” with the new—and newly defined—statutory term “claimed invention.” This new term now appears more than a dozen times in new § 102. In effect, the panel decided this appeal as though profound revisions to § 102 had not been enacted and, more specifically, new § 102(a)(1) had instead read: “the ~~claimed~~ invention was ... on sale, ~~or otherwise available to the public~~ before the effective filing date of the ~~claimed~~ invention.” The lined-out text cannot be dismissed as some mere a drafting accident by Congress.

To the contrary, there is the strongest possible evidence in the drafting history of § 102(a)(1) that the insertion of the *available to the public* limitation was entirely intentional. The bill enacted into law as the AIA, H.R. 1249 (112th Congress), was the subject of a detailed report by the Committee on the Judiciary of the House of Representatives, H.R. REP. NO. 112-98 (2011), that, in discussing § 102(a)(1), notes 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.*”

While the panel decision discusses floor statements made in the Senate, suggesting their questionable value in an effort by the courts to construe a statutory provision, the panel makes no mention of the H.R. 1249 committee report and the *public accessibility* touchstone the report notes now applies to all § 102(a)(1) questions, including to “on sale” activities.

Further, academic commentators have posed a legitimate question—when Congress uses “old” words in a “new” statute, does this force the courts to apply *every* old meaning given the old words, *e.g.*, does “on sale,” under the AIA necessarily mean *everything that it meant* under pre-AIA patent law, *irrespective of any new context or framework in the new statute*? The simple answer to this question is, of course, “no.” By comparison, the term “prior art” is used in the AIA in § 102 and § 103 to mean something far more expansive in certain respects compared to the pre-AIA § 103 use of the identical term, *e.g.* by now barring reliance on invention dates to avoid prior art, expanding prior art to include use/sale activities outside the United States, including as prior art an inventor’s publicly accessible experimental uses, and recognizing foreign priority dates as the effective prior art date for published U.S. patent filings.

More to the point, and as noted above, in the case of the phrase “in public use or on sale,” the pre-AIA patent law embraced a double standard

that gave “on sale” not one, but two, distinct and irreconcilable meanings. The AIA eliminated this double meaning by giving the term “on sale” the *same meaning* that it had in its pre-AIA, non-forfeiture context. This pre-AIA, non-forfeiture meaning for the words “on sale” was not only *preserved unchanged* from under the AIA, but this “old” meaning now applies under the AIA in all contexts—just as the AIA accomplished by keeping some aspects of the old, pre-AIA meaning for the words “prior art” as used in the AIA, but not others.

Finally, amicus urges the court to recognize that Congress was by no means inattentive to important patent policy concerns in stripping out of the law on patentability the pre-AIA inventor’s forfeiture and other loss of right to patent provisions—and thereby exclusively centering the remaining conditions for patentability on novelty and non-obviousness based upon prior art. In moving our patent laws to a first-inventor-to-file system, Congress recognized that the old policies underpinning the old first-to-invent system—ones that might have justified an inventor-specific forfeiture or loss of right to patent doctrine—should be superseded by new policies that not only dictated the affirmative abolition of such forfeiture doctrines in the first-inventor-to-file world, but further dictated the recognition of new patenting policies appropriate to a first-inventor-to-file system. Prominent

among these first-inventor-to-file policies is the notion of affording inventors a continuing incentive to make their discoveries available to the public—and thereby precluding the imposition of any bar to their right to patent—prior to the time a discovery becomes expressly or inherently publicly accessible.

Congress was not, at least in the view of amicus, blazing any new ground or undertaking some intemperate experiment in changing the U.S. law on patentability in some globally unprecedented way. Quite to the contrary, under the AIA, the United States joins 158 other countries of the World Trade Organization that operate their first-inventor-to-file-based patent systems by effectuating policies that afford inventors a continuing, forfeiture-free incentive to disclose that now operates in § 102(a)(1).

CONCLUSION

The grave problem posed by the panel decision is that it retards rather than advances—and complicates rather than facilitates—the promise of a sweeping set of seminal patent reforms under the AIA. Reconsideration should take full account of the entirety of the new statutory framework in deciding whether § 102(a)(1) means what it plainly says, *the subject matter defined by a claim must be available to the public before § 102(a)(1) can operate to invalidate a patent based on an inventor’s “on sale” activities.*

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on the date indicated below, I caused the foregoing **BRIEF OF AMICUS CURIAE CONGRESSMAN LAMAR SMITH IN SUPPORT OF PETITION FOR REHEARING EN BANC** to be filed via CM/ECF with the Clerk of the Court, thereby electronically serving it on all counsel of record in this matter.

Date: June 30, 2017

/s/ Robert A. Armitage

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CERTIFICATE OF COMPLIANCE

Counsel for amicus curiae certifies that:

1. The brief complies with the page limitation of Fed. Cir. R. 35(g) because, excluding the exempted portions as provided in Fed. R. App. P. 32(a)(7)(B)(iii) and Fed. Cir. R. 32(b), it does not exceed 10 double-spaced pages.

2. The brief complies with the typeface requirements of Federal Rules of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rules of Appellate Procedure 32(a)(5), because it has been prepared using Microsoft Word 2013 in a proportionally spaced typeface: Times New Roman, font size 14 point.

Date: June 30, 2017

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