

2016-1284, -1787

**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-Appellants.

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

**BRIEF OF THE BOSTON PATENT LAW ASSOCIATION
IN SUPPORT OF NEITHER PARTY**

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July 14, 2017

CERTIFICATE OF INTEREST

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

Boston Patent Law Association.

2. The name of the real party in interest (please only include any real party in interest NOT identified in Question 3. below) represented by me is:

Boston Patent Law Association.

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

None.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court (**and who have not or will not enter an appearance in this case**) are:

None

Attorneys for Amicus Curiae, Boston Patent Law Association.

Dated July 14, 2017

/s/ Ronald E. Cahill

Ronald E. Cahill

TABLE OF CONTENTS

	<i>Page</i>
Certificate of Interest	i
Interest of Amicus Curiae	1
Summary of Argument.....	1
Argument.....	2
I. The Court Should Decide En Banc Whether the AIA Changed the Meaning of “On Sale”	2
II. This is the Proper Case for En Banc Rehearing on This Issue.....	5
Conclusion	9
Certificate of Service	10
Certificate of Compliance	11

TABLE OF AUTHORITIES

Cases	<i>Page(s)</i>
<i>Amgen Inc. v. Hoeschst Marion Roussel Inc.</i> , 469 F.3d 1039 (Fed. Cir. 2006)	7
<i>Apple Inc. v. Samsung Elecs. Co., Ltd.</i> , 839 F.3d 1034 (Fed. Cir. 2016)	5, 7
<i>Bristol-Myers Squibb Co. v. Teva Pharms. USA, Inc.</i> , 769 F.3d 1339 (Fed. Cir. 2014)	6
<i>ClearCorrect Operating, LLC v. Int’l Trade Comm’n</i> , 819 F.3d 1334 (Fed. Cir. 2016)	5
<i>Helsinn Healthcare S.A. et al. v. Teva Pharmaceuticals USA, Inc.</i> , 855 F.3d 1356 (Fed. Cir. 2017)	3, 4, 7
<i>Pfaff v. Wells Elecs, Inc.</i> , 525 U.S. 55 (1998).....	5
<i>Secure Access, LLC v. PNC Bank Nat’l Ass’n.</i> , 2017 WL 2432299 (Fed. Cir. June 6, 2017).....	6

Statutes and Regulations

35 U.S.C. 102(a) (AIA).....	3
35 U.S.C. 102(b) (Pre-AIA).....	1
78 Fed. Reg. 11,059 (Feb. 14, 2013)	8

Other

Fed. R. App. P. 29(c)(5)	1
Fed. R. App. P. 35	2
Federal Circuit Rule 35(g)	1
Federal Circuit Rule 40(g)	1

INTEREST OF AMICUS CURIAE

The Boston Patent Law Association (“BPLA”) is a nonprofit professional association of approximately 1,000 attorneys and other professionals whose interests and practices are in the area of intellectual property law. Its members serve a broad range of clients, such as inventors, corporations, universities, and research hospitals, and provide a variety of patent-related services, including patent prosecution, litigation, and licensing. The BPLA therefore has an institutional interest in seeing that patent law develop in a clear, predictable, and coherent way in order to promote innovation and protect innovators.

The BPLA submits this brief with a motion for leave pursuant to Federal Circuit Rules 35(g) and 40(g). It has no direct stake in the result of this appeal. Pursuant to Fed. R. App. P. 29(c)(5), no party’s counsel authored the brief in whole or in part, no party contributed money intended to fund preparing or submitting the brief, and no person other than the BPLA or its counsel contributed money toward preparing or submitting this brief.

SUMMARY OF ARGUMENT

The BPLA believes that the patent system and its participants are best-served by clear and predictable patent laws. To that end, the BPLA believes the Court should grant *en banc* rehearing of this case to make clear whether the meaning of “on sale” as used in 35 U.S.C. § 102(a) retains the same meaning that “on sale” had

prior to the America Invents Act (“AIA”). Further, should the Court decide “on sale” has a different meaning under the AIA, the BPLA encourages the Court to provide a framework under which to analyze whether an invention is “on sale.” While the BPLA takes no position on the ultimate resolution of these issues, it nonetheless believes resolving them now is critical for the predictability of law that is essential to a well-functioning patent system.

The BPLA believes this is the appropriate case for this Court to provide clear guidance on the scope of “on sale” prior art for two reasons. First, the panel decision left undecided critical questions squarely raised in this case about the scope of “on sale” prior art under the AIA. Second, this is precisely the kind of case for *en banc* review: it raises an issue of exceptional importance bearing the hallmarks necessary for *en banc* consideration. See Fed. R. App. P. 35.

ARGUMENT

I. THE COURT SHOULD DECIDE EN BANC WHETHER THE AIA CHANGED THE MEANING OF “ON SALE”

Prior to the AIA, 35 U.S.C. § 102 provided that “[a] person shall be entitled to a patent unless . . . (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or *on sale* in this country, more than one year prior to the date of the application for patent in the United States.” 35 U.S.C. § 102, *amended by Leahy-Smith America Invents Act*, Pub. L. No. 112-29, 125 Stat. 284 (2011) (emphasis added). Numerous cases interpreting

the meaning of “on sale,” as used in pre-AIA section 102, held that the existence of a sale of the invention need not be public for the sale to preclude patentability. *Helsinn Healthcare S.A. et al. v. Teva Pharmaceuticals USA, Inc.*, 855 F.3d 1356, 1367 fn. 7 (Fed. Cir. 2017). The AIA amended the prior art provisions of section 102 to provide “[a] person shall be entitled to a patent unless—(1) the claimed invention was patented, described in a printed publication, or in public use, *on sale*, or otherwise available to the public before the effective filing date of the claimed invention.” 35 U.S.C. § 102(a) (emphasis added).

As made clear by the fact that the parties, the U.S. Patent and Trademark Office (“PTO”), and amici have taken varying positions in their briefs on whether, and how, the AIA changed the meaning of “on sale,” there is substantial confusion on the effect of these AIA amendments. The district court below, in an issue of first impression, concluded that the AIA did work a substantial change in the pre-AIA definition of “on-sale.” The parties vigorously contested that result in briefing before this Court. Under some of the competing interpretations, a wholly confidential sale could be prior art, as was the case before the AIA. Other interpretations, including the district court’s, would require that a sale make the details of the invention “available to the public” in order to be prior art.

Despite this confusion, the panel expressly declined to decide whether the AIA changed the meaning of “on sale.” *See Helsinn*, 855 F.3d at 1368. Instead, the

panel concluded “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 sale.” *Id.* at 1371. In tailoring its holding so narrowly, the panel decision provides little guidance on the scope of “on sale” prior art under the AIA.

Yet squarely at issue in this case is the broader question of whether the meaning of “on sale” changed under the AIA. In particular, the BPLA views the issue as whether the inclusion of the phrase “or otherwise available to the public” in section 102 changed the meaning of “on sale” in any way. The panel decision side-stepped this issue, cabining the decision to the facts of the case by only holding that “the AIA did not change the statutory meaning of ‘on sale’ *in the circumstances involved here.*” *Id.* at 1360 (emphasis added). Further, the panel decision altogether avoids the issue of whether non-public sales constitute “on sale” prior art.

These are foundational issues in patent law. All participants in the patent system must be able to determine what constitutes prior art under the AIA. It is essential for an inventor deciding whether to file a patent application to understand what is prior art and what is not. A company determining a strategy for enforcing its patents must also understand exactly what is prior art. Without this fundamental understanding, innovators cannot make reliable decisions.

Accordingly, the BPLA encourages the Court to rehear this case *en banc* and provide clear guidance on the meaning of “on sale,” including, to the extent

necessary, a framework for determining when an invention is “on sale” akin to the framework announced in *Pfaff*. See *Pfaff v. Wells Elecs, Inc.*, 525 U.S. 55 (1998) (holding the pre-AIA on-sale bar applies when two conditions are satisfied before the critical date: 1) the invention is subject of a commercial offer for sale and 2) the invention is ready for patenting). The Court should seize this opportunity to improve the predictability of patent law at the outset, before many district courts potentially reach conflicting conclusions on the effect of the AIA.

II. THIS IS THE PROPER CASE FOR EN BANC REHEARING ON THIS ISSUE

A. THIS CASE PRESENTS A STATUTORY INTERPRETATION QUESTION OF FIRST IMPRESSION

Historically, this Court rehears *en banc* questions of statutory interpretation, especially those of first impression. See *Apple Inc. v. Samsung Elecs. Co., Ltd.*, 839 F.3d 1034, 1086 (Fed. Cir. 2016), *petition for cert. filed*, No. 16-1102 (U.S. Mar. 10, 2017) (Reyna, J., dissenting) (“We also take cases *en banc* to review whether a panel properly interpreted a statute, such as in a case of first impression.”). Rehearing *en banc* allows the court to “rethink its decision” with respect to interpretation of the law. See *ClearCorrect Operating, LLC v. Int’l Trade Comm’n*, 819 F.3d 1334, 1346-7 (Fed. Cir. 2016) (Newman, J., dissenting from denial of rehearing *en banc*) (arguing the panel misinterpreted a statute by improperly confining its application and that rehearing *en banc* was appropriate).

The BPLA believes this rethinking is called for here. Rehearing *en banc* will provide the appropriate setting for this Court to perform a full analysis of “on sale” under the AIA and provide a clear statement on its correct interpretation. *See, e.g., Bristol-Myers Squibb Co. v. Teva Pharms. USA, Inc.*, 769 F.3d 1339, 1353-4 (Fed. Cir. 2014) (Taranto, J., dissenting from denial of *en banc* review) (“*En banc* review would allow a focus on and full analysis of the doctrinal issues, considering the language of section 103 (what it resolves and what it leaves open); the role of section 103 in the statute as a whole (which places a premium on early filing); Supreme Court precedents elaborating on the policy of section 103; our own precedents; congressional actions in light of those precedents; and pertinent, reliable information that may bear on assessing the real-world consequences of one answer or another in an industry where research is especially expensive and uncertain. The widened inquiry seems to me worthwhile.”). The widened inquiry is especially worthwhile here, where the panel avoided undertaking the full analysis of what “on sale” means by narrowly tailoring its holding to a very specific set of facts.

B. THE STATUTE AT ISSUE HAS MULTIPLE PLAUSIBLE INTERPRETATIONS

Rehearing *en banc* is appropriate, and is indeed necessary, as there are multiple, conflicting plausible interpretations of the statutory language, and the panel decision leaves open which is the correct interpretation. *Cf. Secure Access, LLC v. PNC Bank Nat’l Ass’n.*, 2017 WL 2432299, at *3 (Fed. Cir. June 6, 2017) (Taranto,

J., concurring) (noting that the absence of multiple plausible interpretations of statute weighed against *en banc* reconsideration); *see also* Brief of 42 Intellectual Property Professors as Amici Curiae in Support of Appellant at 21, *Helsinn*, 855 F.3d 1356 (characterizing the district court’s statutory reading of “or otherwise available to the public” as “not the only plausible [reading]”). Thus, rehearing *en banc* in this case is more than a “do over” of the Panel’s decision. Rather, it enables the Court to resolve questions unanswered by the panel essential to the understanding of the scope of “on sale” prior art. *See, e.g., Apple*, 839 F.3d at 1086-7 (Reyna, J., dissenting from grant of rehearing *en banc*) (observing “applicability of existing law,” “first interpretation of a statute,” and “greater understanding of the law” as “important issues” meriting *en banc* rehearing).

C. RESOLUTION OF THE UNDERLYING QUESTIONS IN THIS CASE HAS BROAD IMPLICATIONS ON THE PATENT SYSTEM AND ITS PARTICIPANTS

The scope of the prior art is a foundational issue in our patent system. As such, the need for resolving the scope of “on sale” under the AIA extends far beyond this particular case and these particular parties. *Cf. Amgen Inc. v. Hoeschst Marion Roussel Inc.*, 469 F.3d 1039, 1043 (Fed. Cir. 2006) (Lourie, J., concurring in denial of rehearing *en banc*) (finding rehearing *en banc* inappropriate where the question presented is “case-specific” and does not seem to be of “exceptional importance” to the law).

Leaving these issues unresolved now will materially impact all participants in the patent system. Predictability of the law is essential to a well-functioning patent system because participants adjust their behavior and investment of resources based on their understanding of the patent laws. Uncertainty regarding the most basic laws of patentability can reduce participation in the patent system.

The importance of resolving these issues, and doing so now, is most apparent as it concerns the PTO's examination of new patent applications. The PTO determined that the AIA did change the meaning of "on sale," concluding "[t]he phrase 'on sale' in AIA 35 U.S.C. 102(a)(1) is treated as having the same meaning as 'on sale' in pre-AIA 35 U.S.C. 102(b), except that the sale must make the invention available to the public." See Examination Guidelines for Implementing the First Inventor to File Provisions of the Leahy-Smith America Invents Act, 78 Fed. Reg. 11,059, 11,075 (Feb. 14, 2013) (emphasis added). The PTO, and the entire patent system, benefits from examiners applying the correct definition of "on sale" prior art. Without clear guidance from this Court on the most basic boundaries of "on sale" prior art, the PTO may allow or reject applications due to a misunderstanding of the law. Whatever the correct interpretation of "on sale" is under the AIA, it is critical that the PTO be given that guidance as soon as possible.

Further, individuals and businesses are impacted by the uncertainty. Without clear guidance on the scope of "on sale" prior art, businesses cannot determine how

to structure inter-company agreements in a manner that avoids creating invalidating prior art. This can lead to inefficiencies as businesses either forgo beneficial collaboration with other businesses or reduce their participation in the patent system because the uncertainty reduces the value of patents. Either result ultimately hurts the patent system's ability to promote innovation.

CONCLUSION

For the foregoing reasons, the BPLA respectfully requests the Court grant the petition for rehearing *en banc*. The BPLA respectfully encourages the Court to take this opportunity to clarify what effect, if any, the AIA had on the term "on sale," as used in 35 U.S.C. § 102(a).

Dated July 14, 2017

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Robyn Cocho, being duly sworn according to law and being over the age of 18, upon my oath depose and say that:

Counsel Press was retained by NUTTER MCCLENNEN & FISH, LLP, Attorneys for Amicus Curie Boston Patent Law Association to print this document. I am an employee of Counsel Press.

On **July 14, 2017**, counsel has authorized me to electronically file the foregoing **Brief of Amicus Curiae** with the Clerk of Court using the CM/ECF System, which will serve via e-mail notice of such filing to all counsel registered as CM/ECF users, including the following principal counsel for the parties:

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Eighteen paper copies will be filed with the Court within the time provided in the Court's rules.

July 14, 2017

/s/ Robyn Cocho
Robyn Cocho
Counsel Press

CERTIFICATE OF COMPLIANCE

1. This brief complies with the page limit of Federal Circuit Rule 35(g). The brief does not exceed 10 double-spaced pages and contains 2,124 words, excluding the parts of the brief exempted by rule.
2. This brief complies with the typeface and typestyle requirements of the Federal Rules of Appellate Procedure and the Federal Circuit Rules. The brief has been prepared in a proportionally spaced typeface using Microsoft Word 2013 in a 14 point Times New Roman font.

Dated July 14, 2017

Respectfully submitted,

/s/ Ronald E. Cahill

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