2014-1469, -1504

United States Court of Appeals for the Federal Circuit

THE MEDICINES COMPANY,

Plaintiff-Appellant,

v.

HOSPIRA, INC.,

Defendant-Cross-Appellant.

*Appeals from the United States District Court for the District of Delaware in No. 1:09-cv-00750-RGA, Judge Richard G. Andrew*s.

EN BANC BRIEF FOR INTELLECTUAL PROPERTY OWNERS ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF NEITHER PARTY

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<u>CERTIFICATE OF INTEREST</u>

The Medicines Company v. Hospira, Inc.
Nos. 2014-1469, -1504

Counsel for the Amicus Curiae, Intellectual Property Owners Association certifies the following (use "None" if applicable; use extra sheets if necessary):

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

Intellectual Property Owners Association

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INTERESTS OF AMICUS CURIAE[1]

Amicus curiae Intellectual Property Owners Association (IPO) is a trade association representing companies and individuals in all industries and technology fields who own or are interested in intellectual property. IPO's members include over 200 companies and 12,000 individuals involved in the association through their companies or as inventor, author, executive, law firm, or attorney members. Founded in 1972, IPO represents the interests of all intellectual property owners. IPO regularly represents its members' interests before Congress and the United States Patent and Trademark Office (Patent Office) and has filed amicus curiae briefs in this and other courts on significant intellectual property issues. The Appendix lists IPO's Board of Directors, which approved filing this brief.[2]

Many of IPO's members, large and small corporations alike, frequently contract with third parties for a wide range of research, development, and manufacturing services in the normal course of their businesses. These members are concerned that the panel's decision will expose their inventions to the on-sale bar under 35 U.S.C. § 102(b) before they have received a commercial benefit for

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[1] No counsel for a party authored any portion of this brief. Only amicus curiae or its counsel contributed monetarily to its preparation or submission. A Motion is being filed with this brief. The parties do not oppose the filing of this brief.

[2] IPO procedures require approval of positions in briefs by a two-thirds majority of directors present and voting.

their invention, and place them at a competitive disadvantage to those who are able to manufacture the products of their inventions in-house. IPO accordingly has a substantial interest in the question presented by this proceeding, and believes that this brief will be helpful to the Court in rehearing this case *en banc*.

SUMMARY OF ARGUMENT

The *en banc* Court should hold that merely outsourcing commercial manufacturing activity does not trigger the on-sale bar—at least when, as here, there is no transfer of title or property rights, and where the parties' agreement makes clear that it is a contract for manufacturing services, rather than for the sale of goods. Under these circumstances, there is no unfair term extension involved in pre-commercialization activities that merely involve a patentee preparing prototypes or building an inventory that might not be commercialized for years. A contrary holding—that the on-sale bar is triggered by outsourcing manufacturing services—would create significant concerns for innovators, most notably smaller enterprises and individual inventors who lack in-house prototyping, testing, and manufacturing capabilities. The "supplier exception" is not implicated by this case because no "sale" of the invention occurred, but to the extent the Court determines otherwise, it should overrule *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353 (Fed. Cir. 2001) and find that contract manufacturing services are not subject to the on-sale bar.

ARGUMENT

A. This Court Should Clarify That Contract Manufacturing Is Not a "Commercial Sale" Subject to the On-Sale Bar.

The *en banc* Court should hold that merely outsourcing commercial manufacturing activity does not trigger the on-sale bar—at least where, as here, (1) there is no transfer of title or property rights and (2) the parties' agreement makes clear that it is a contract for manufacturing services rather than for the sale of any product. Unlike cases concerning the application of a so-called "supplier exception," which address situations where there has been a "commercial sale" of a product embodying the invention, here no commercial "sale" took place. Rather, the invention was privately manufactured for the inventor, with no transfer of title or ownership, just as if it were being manufactured by a large corporation's in-house facility. Because the invention was never the "subject of a commercial offer for sale," as the Supreme Court and Circuit precedent requires, this Court should clarify that such contract manufacturing activity does not trigger the on-sale bar.

The on-sale bar applicable to claims that issued prior to March 16, 2013, provides that a person may obtain a patent unless "(b) 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." 35 U.S.C. § 102(b) (2010).[3] The Supreme Court interpreted that bar to apply when (1) the invention at issue had become the "subject of a commercial offer for sale" more than one year before the filing of the patent application; and (2) the invention was ready for patenting. *Pfaff v. Wells Elecs.*, 525 U.S. 55, 67 (1998). The Court's rationale was to promote certainty and predictability in the patent laws: By requiring that "the product . . . be the subject of a commercial offer for sale," "[a]n inventor can both understand and control the timing of the first commercial marketing of his invention…." *Id.* (emphasis added); *see also General Elec. Co. v. United States*, 654 F.2d 55, 61 (Ct. C1. 1981) (on-sale bar designed to provide an inventor with "a reasonable amount of time following sales activity to determine whether a patent is a worthwhile investment"). The *Pfaff* court thus equated the date an invention "is the subject of a commercial offer for sale" as the day it was "first marketed commercially." 525 U.S. at 67.

[3] The America Invents Act, Pub. L. 112-29, which became effective on March 16, 2013 (18 months after the Act's passage), substantially revised the "on-sale" bar. The provision now makes clear that any offer to sell or other disclosure must be publicly accessible. *See* 35 U.S.C. § 102(a)(1) (person not entitled to a patent when "the claimed invention was . . . in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention"); H.R. Rep. No. 112-98, at 42–43 (2011) (purpose of revision was "to emphasize the fact that [invention] must be publicly accessible").

In light of *Pfaff*'s rationale and its requirement of a "commercial offer for sale," this Court should clarify that an invention is not "marketed commercially" or the "subject of a commercial offer for sale" when a company merely contracts for manufacturing services, without transferring title or rights to the invention, and where only a sale of services is involved. Indeed, this Court suggested that when an "individual inventor takes a design to a fabricator and pays the fabricator for its services in fabricating a few sample products," the on-sale bar should not apply. *See Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 182 F.3d 888, 891 (Fed. Cir. 1999). This Court should extend that rationale to situations where, as here, the inventor uses a third-party manufacturing service instead of manufacturing in-house.

It is true that the on-sale bar is meant both to encourage inventors to promptly enter the patent system, thereby leading to the widespread disclosure of inventions to the public, as well as to prevent what essentially constitutes an extension of patent term by allowing an inventor to commercially exploit the invention prior to filing the patent application. *See W. Marine Elecs., Inc. v. Furuno Elec. Co.*, 764 F.2d 840, 845 (Fed. Cir. 1985). But neither of those concerns is implicated here, where the inventor did not commercially exploit the product embodying the invention and filed a patent application within one year of the time the product was first offered for sale. There is no risk of unfair term extension in instances of pre-commercialization activities like preparing prototypes or building an inventory that might not be commercialized for years. Indeed, these activities are routinely undertaken internally by large corporations.

The so-called "supplier exception" is not implicated by this case because there was no "commercial sale." The cases in which this Court previously addressed the "supplier exception" involved circumstances where there was a "commercial" offer or sale under *Pfaff*. For example, in *Brasseler*, the patentee agreed to buy from its exclusive manufacturer 3,000 surgical saws embodying the claimed invention. After noting that the saws were ordered "in large quantity for resale," the Federal Circuit concluded that "[t]he transaction at issue undisputedly was a 'sale' in a commercial law sense." 182 F.3d at 890. Only after concluding there was a commercial sale did the Federal Circuit reject the assertion that the relationship between the supplier and the patentee somehow prevented the sale from triggering the on-sale bar. *Id.* Likewise, in *Special Devices*, the patentee conceded that its pre-critical date activities were commercial offers for sale, and then asked the Court to excuse the commercial activities under a supplier exception to 35 U.S.C. § 102(b). 270 F.3d at 1355. In refusing to create such an exception, this Court emphasized the literal text of § 102(b) and noted that OEA had the option to file its patent application in a timely manner to preserve its rights, thereby obviating any need for a patentee-supplier exception to the on-sale bar. *Id.* at 1335.

Here, in contrast, the patented product was not "subject of a commercial offer for sale" under *Pfaff*, *Brasseler*, or *Special Devices*. Rather, the business arrangement mirrored the manufacturing services that a large corporation would typically perform in-house. The patentee hired a third party manufacturer in order to determine whether the invention worked for its intended purpose and whether a patent would be a worthwhile investment. *See Honeywell Int'l Inc. v. Universal Avionics Sys. Corp*., 488 F.3d 982, 998 (Fed. Cir. 2007); *Brasseler*, 182 F.3d at 891 (The on-sale bar is not triggered when an "inventor takes a design to a fabricator and pays the fabricator for its services in fabricating a few sample products."). Furthermore, the private agreement in this case provided for manufacturing *services*, not the *sale* of any product embodying the invention. *Cf. Pfaff*, 525 U.S. at 67 (equating a "commercial sale" with the day the invention was "first marketed commercially" to the public). Finally, there was no transfer of title or property between the patentee and third party manufacturer that would indicate that a "sale" had occurred in the commercial sense. *Special Devices*, 270 F.3d at 1355 (explaining that a "sale" occurs only when "rights of property" are transferred); *Trading Techs. v. eSpeed, Inc*., 595 F.3d 1340, 1361 (Fed. Cir.

2010) (same); *see also* U.C.C. § 2-106(1) (defining a "sale" as "the passing of title from the seller to the buyer for a price").

In sum, in assessing an on-sale bar, this Court should focus on whether the patentee's activities constitute a "commercial" offer for sale or sale under *Pfaff*, regardless of the corporate relationship (or lack thereof) between the parties. Hiring a third-party contract manufacturer under a confidential arrangement (because the patentee has no in-house manufacturing capabilities) should not be viewed as a "commercial sale" under 35 U.S.C. § 102(b). Under circumstances like these, the Court should find that there is no "commercial sale" triggering an on-sale bar—no different from how such activities would be assessed if they took place solely within a single, larger corporation.

B. Finding the On-Sale Bar Triggered in This Case Would Penalize Companies That Cannot Manufacture Products in Their Own Facilities.

A contrary holding—that the on-sale bar is triggered by simple contract manufacturing activities, when no title or rights to the invention itself are transferred, and the agreement specifies that the contract is for services rather than the invention itself—would create significant concerns for innovators, most notably smaller enterprises and individual inventors who lack in-house prototyping, testing, and manufacturing capabilities. *Cf. Monon Corp. v. Stoughton Trailers, Inc.*, 239 F.3d 1253, 1258-61 (Fed. Cir. 2001) (concluding that the sale was non-commercial where the patentee had a third party test its patented trailer because it lacked in-house testing capabilities). Whenever the development process requires those smaller entities to manufacture working prototypes or pre-mass-production samples, they often have no choice but to reach out to third-party contract manufacturers. Sweeping these activities within the scope of section 102(b) to encourage "the inventor to enter the patent system promptly" would harm these innovators. *Woodland Trust v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1370 (Fed. Cir. 1998). It would mean that companies large enough to have internal testing and manufacturing capabilities would be entitled to an effectively longer patent term than companies that are forced to use third-party contract manufacturers. As a result, companies with the ability to manufacture products in-house would have a significant competitive advantage; the on-sale bar would not apply to their pre-filing manufacturing activities, while conversely companies that outsource manufacturing would be held to a different on-sale bar standard. *See* Leah C. Fletcher, *Equal Treatment Under Patent Law: A Proposed Exception to the On-Sale Bar*, 13 TEX. INTELL. PROP. L.J. 209, 231-234 (2005) (recognizing the disadvantages smaller entities face in patenting and bringing a product to market, particularly in the absence of a supplier exception for outsourced manufacturing).

To illustrate the disproportionality under the current law, consider the following example. *See* Jeffrey R. Kuester & N. Andrew Crain, *Beware of Back Door On-Sale Activities*, 14 INTELL. PROP. & TECH. L.J. 1 (2002). Big Co. is a large global corporation with thousands of employees, including its own internal research and development and manufacturing divisions. Products invented by Big Co.'s research and development division are manufactured by Big Co.'s manufacturing division. Big Co.'s manufacturing division made one million units of its latest product, which will be highly marketed, and stored the products in a warehouse—all before the first offer for sale or sale to the public. Once the one million units were made and warehoused, Big Co. released its marketing campaign in time for the holidays and sold the one million units to retailers. Big Co. subsequently filed a patent application on the invention on the day before the one-year anniversary of the first sale or offer for sale to the public.

In comparison, Small Co. is a family-owned company with approximately 50 employees, trying to bring that same product to market. Products invented by Small Co. must be outsourced for manufacturing because Small Co. has no internal manufacturing capabilities. Small Co. engaged Third Party, Inc., a third party manufacturer, to manufacture the product embodying the invention for Small Co.'s sale to the public. Third Party, Inc. agreed to provide its manufacturing services and for Small Co. to retain title to the manufactured products. Third Party, Inc.

then manufactured one million units and Small Co. stored the units in a rented warehouse prior to the first sale or offer for sale to the public. In time for the holiday season, Small Co. made its first offer for sale or sale to the public. Small Co. thereafter filed its patent application on the invention on the day before the one-year anniversary of Small Co.'s first offer for sale or sale to the public.

If the mere outsourcing of manufacturing services is held to trigger the on-sale bar, Small Co.'s patent would most likely be barred under section 102(b), while Big Co.'s patent would not. Small Co.'s patent would be invalid even though its pre-filing activity is essentially the same as that of Big Co., whose patent is not affected by its own internal manufacturing and product stockpiling—simply because Small Co. had to outsource its manufacturing operations. Without a contract manufacturer exception, a small inventor like Small Co. would face a Catch-22: file early and risk the possibility that the patent application will not cover all aspects of the marketed product, or file later and risk the loss of patent rights based solely on a decision to contract out manufacturing services.

There is no sound basis to permit such a biased application of the on-sale bar or to mandate such an uneven competitive playing field. To promote uniform treatment of all innovators—large and small—the Court should decline to find a "commercial" offer or sale where an inventor merely outsources manufacturing or development work to a third party. *See* Leah C. Fletcher, 13 TEX. INTELL. PROP. L.J. at 231 (recognizing that "[o]utsourced manufacturing allows small inventors, who otherwise do not have manufacturing capacity, to compete with larger companies [and] …to provide products for certain niche markets….").

C. To the Extent This Court Cannot Distinguish *Special Devices*, It Should Be Overruled.

As noted above, the "supplier exception" rejected in *Special Devices* is not implicated in this case because there was no commercial sale of the invention itself. To the extent this Court nevertheless concludes that contract manufacturing relationships ordinarily would be subject to the on-sale bar, amicus respectfully suggests that the Court overrule *Special Devices* and recognize such a "supplier exception"—at least under circumstances like in this case, perhaps more-accurately termed the "contract-manufacturer exception."

The Federal Circuit previously rejected a "supplier exception" because the text of section 102(b) itself "makes no room for" such an exception. *Special Devices*, 270 F.3d at 1357. This Court, however, has previously created two exceptions to the on-sale bar in order to fully effectuate congressional intent and prevent absurd results, even though neither exception is found explicitly in the text of the statute. First, it is well-established that experimental use of an invention does not trigger the on-sale bar, even when there has been a sale of the invention. *See, e.g.*, *Honeywell*, 488 F.3d at 998 ("[T]his court has consistently distinguished permitted experimental uses from barred public or commercial uses”); *RCA Corp. v. Data General Corp.*, 887 F.2d 1056, 1061 (Fed. Cir. 1989) (“Such an offer may not constitute a bar because of policy considerations which allow an inventor to engage in experimentation to develop his invention.”). Second, the Court has also carved out an exception for offers to “license” an invention. *See, e.g., In re Kollar*, 286 F.3d 1326, 1331 (Fed. Cir. 2002) (“[M]erely granting a license to an invention, without more, does not trigger the on-sale bar.”). Neither of these exceptions has explicit support in the statutory language, yet this Court recognized implicitly that such exceptions are necessary to promote the competing policy goals of section 102(b)—to allow an inventor to understand and control the timing of the first commercial marketing of his invention, and to permit him or her a reasonable amount of time to determine whether his patent is a worthwhile investment. *General Elec.*, 654 F.2d at 61.

Consistent with the statutory language and the policies underpinning the on-sale bar, there is nothing to prevent the Court from recognizing that, at least where the invention is never subject to a “sale,” 35 U.S.C. § 102(b), a “supplier exception” should permit small companies to compete with large ones on an equal footing. A patent owner should be allowed to contract with a third party to develop and manufacture a product without having to rush to file a patent application. The third party is simply doing the same acts as the patentee would do itself in developing a product, and that is not putting the product commercially "on-sale" for purposes of section 102. Thus, to the extent this Court finds that *Special Devices*'s rejection of a "supplier exception" controls the outcome of this case, it should be overruled.

CONCLUSION

For these reasons, the *en banc* Court should clarify that merely outsourcing manufacturing services to a third party under the circumstances of this case does not trigger the on-sale bar. In the alternative, the Court should overrule *Special Devices* and recognize a "supplier exception" to the on-sale bar, at least in the "contract manufacturing" scenario presented here.

Dated: February 5, 2016

Respectfully submitted,

/s/ Emily C. Johnson

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APPENDIX

APPENDIX

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On **February 5, 2016**, counsel for Amicus 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 any of the following counsel registered as CM/ECF users:

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Two copies will also be mailed to the above counsel on this date.

Any counsel for Amici Curiae, appearing at the time of this filing, will also be served only via CM/ECF email notice.

Additionally, thirty one copies will be sent to the Court within the time provided by the Court's rules.

Dated: February 5, 2016

<u>/s/ Robyn Cocho</u>
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CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION, TYPEFACE REQUIREMENTS AND TYPE STYLE REQUIREMENTS

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7). The brief contains 3,280 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii) and Federal Circuit Rule 32(b).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6). The brief has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point Times New Roman type style.

Dated: February 5, 2016

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