2014-1469, -1504

IN THE
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, Judge Richard G. Andrews

BRIEF OF *AMICUS CURIAE* AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION IN SUPPORT OF NEITHER PARTY

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January 19, 2016

CERTIFICATE OF INTEREST

In accordance with FED. CIR. R. 47.4, counsel for the Amicus Curiae the American Intellectual Property Law Association certifies the following:

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

   American Intellectual Property Law Association

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:

   N/A

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:

   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 are:

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January 19, 2016

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STATEMENT OF INTEREST OF AMICUS CURIAE

The American Intellectual Property Law Association ("AIPLA") is a national bar association of approximately 14,000 members who are primarily lawyers engaged in private and corporate practice, in government service, and in the academic community. AIPLA members represent a wide and diverse spectrum of individuals, companies, and institutions involved directly or indirectly in the practice of patent, trademark, copyright, and unfair competition law, as well as other fields of law affecting intellectual property. Our members represent both owners and users of intellectual property. AIPLA's mission includes providing courts with objective analysis to promote an intellectual property system that stimulates and rewards invention while balancing the public's interest in healthy competition, reasonable costs, and basic fairness.

AIPLA has no stake in any of the parties to this litigation or in the result of this case.[1] AIPLA's only interest is in seeking correct and consistent interpretation of the law as it relates to intellectual property issues.[2]

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[1] Pursuant to Fed. R. App. P. 29(c)(5), AIPLA states that this brief was not authored in whole or in part by counsel to a party, and that no monetary contribution to the preparation or submission of this brief was made by any person or entity other than AIPLA and its counsel. Specifically, after reasonable investigation, AIPLA believes that (a) no member of its Board or Amicus Committee who voted to prepare this brief, or any attorney in the law firm or corporation of such a member, represents a party to this litigation in this matter, (b) no representative of any party to this litigation participated in the authorship of this

(continued…)

SUMMARY OF THE ARGUMENT

By statute, a person is not entitled to a patent if the invention was "on sale in this country, more than one year prior to the date of application for patent in the United States." 35 U.S.C. § 102(b).[3] As explained by the Supreme Court in *Pfaff v. Wells Elecs. Inc.*, the on-sale bar protects the public's right to retain knowledge already in the public domain while also protecting an inventor's right to control whether and when he patents his invention. 525 U.S. 55, 64-65 (1998). The statute's purpose is to promote the prompt filing of patent applications and ensure that the patent owner's exclusive rights are appropriately limited in time.

Pfaff's framework for the on-sale bar was designed to strike a balance between the interests of the public and the patent owner by applying it when the claimed invention was (1) the subject of a "commercial offer for sale"; and (2) "ready for patenting." *Id. at* 67-68. While the Supreme Court in *Pfaff* held that both prongs of this test were satisfied, *id.* at 68, its analysis focused mostly on the

(…continued)
brief, and (c) no one other than AIPLA, its members who authored this brief, and their law firms or employees, made a monetary contribution to the preparation or submission of this brief.

[2] AIPLA files this brief as amicus curiae in response to the Court's invitation in its November 13, 2015 Order ("Order").

[3] All references to Title 35 of the U.S. Code refer to the pre-America Invents Act ("AIA") version. AIPLA addresses only pre-AIA law and takes no position on how the AIA would affect the issues raised in this brief.

second prong and whether the invention was sufficiently developed at the time of the commercial offer for sale to warrant application of the on-sale bar, *id.* at 65-67. In performing this analysis, the Supreme Court adopted a "ready for patenting" standard over this Court's previous "substantially complete" standard. *Id.* at 67-68.

While the *Pfaff* test was intended to bring greater certainty to the application of the on-sale bar, this Court's post-*Pfaff* cases lack clarity on what constitutes a patent-defeating "commercial offer for sale." That precedent illustrates the complexity of industry transactions and the grave risks of invalidity that outsourcing product development or production can create when viewed as a commercial offer for sale. Put differently, this Court has applied the on-sale bar to supplier-to-inventor transactions involving activities that would not result in a patent-barring event if performed in-house by the inventor. The application of the on-sale bar should not turn on whether inventors need or choose to commercially contract with third parties to develop or produce their inventions.

With no sound justification, however, the current state of this Court's precedent restricts the innovation process and hinders inventors from bringing their inventions to market. These harsh results interfere with an inventor's ability to develop and produce his invention, and, even worse, do so without advancing the purpose of the statutory on-sale bar.

In response to question (a)(i) posed by the Court for briefing, AIPLA asserts that transfer of title to the invention can evidence a commercial offer for sale, but maintains that the absence of transfer of title does not necessarily demonstrate that no commercial offer for sale took place. The Supreme Court in *Pfaff* showed that a commercial offer for sale can occur without a transfer of title, finding that the acceptance of a purchase order satisfied the first prong of the analysis. *Pfaff*, 525 U.S. at 67. In any event, the Court should avoid a bright-line rule regarding transfer of title. Such a rule would exalt form over substance and remove the flexibility necessary to address the various types of scenarios that can arise in deciding whether a commercial offer for sale occurred.

In response to question (a)(ii), a supplier-to-inventor transaction is not necessarily a commercial offer for sale under *Pfaff*. As stated there, the on-sale bar was intended to strike a balance between motivating innovation with patent protection, on the one hand, and preventing public ideas from becoming the subject of patent protection, on the other. A supplier-to-inventor transaction, like an experimental use, is not a commercial offer for sale where the transaction shows no indication that the inventor is exploiting the commercial value of the invention.

Although "[t]his court, following pre-*Pfaff* decisions, has stated on several occasions, post-*Pfaff*, that the experimental use doctrine cannot provide an exception to the on-sale bar once an invention is reduced to practice,"[4] there are certainly activities that occur after a reduction to practice that fall short of commercial exploitation of the invention. A supplier-to-inventor transaction is such an activity. To be sure, a supplier-to-inventor transaction does not necessarily involve a commercial offer for sale. Because it is not commercial, applying the on-sale bar to a supplier-to-inventor transaction does nothing to deter the premature commercial exploitation of the invention to the detriment of the public. But it can significantly interfere with innovation and the product development process.

Finally, to the extent this Court's decision in *Special Devices* is inconsistent with the positions stated above, AIPLA urges the Court to overrule it and recognize that certain supplier-to-inventor transactions are not patent-barring commercial offers for sale. This recognition would appropriately put all inventors—those who can develop and produce their inventions in house and those who cannot—on the same footing.

I. ARGUMENT

Section 102, including the on-sale bar, "serves as a limiting provision, both excluding ideas that are in the public domain from patent protection and confining

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[4] *Atlanta Attachment Co. v. Leggett & Platt, Inc.*, 516 F.3d 1361, 1368 (Fed. Cir. 2008) (Prost, J., concurring).

the duration of the monopoly to the statutory term." *Pfaff*, 525 U.S. at 64 (citing *Frantz Mfg. Co. v. Phenix Mfg. Co.*, 457 F.2d 314, 320 (7th Cir. 1972)). Thus, the policies underlying and defining the on-sale bar provide guideposts for determining whether it should apply. *RCA Corp. v. Data Gen. Corp.*, 887 F.2d 1056, 1062 (Fed. Cir. 1989) ("As we have stated a number of times, the policies or purposes underlying the on-sale bar, in effect define it.").

A. The Commercial Offer for Sale Prong Should Not Turn Solely on Transfer of Title Though Transfer of Title Can Evidence an Offer for Sale If Tied To a Product or Process

This Court asked whether a § 102(b) sale can occur absent transfer of title. AIPLA asserts that transfer of title to the invention can show that a commercial offer for sale occurred. But not all transfers of title invoke the on-sale bar. The transfer must relate to a claimed physical product or process and not to patent rights or patent application rights alone. Likewise, the absence of transfer of title does not necessarily immunize an event from an on-sale bar, which can be found even when no transfer of title occurred. Transfer of title, therefore, should not be a touchstone in the on-sale bar analysis. Too much focus on transfer of title could lead to gamesmanship, with parties structuring relationships to avoid transfer of title and thus the on-sale bar, even though the substance of the transaction is effectively a commercial offer for sale of the invention.

1. A Commercial Offer for Sale Under *Pfaff* Does Not Necessarily Require Transfer of Title

Pfaff itself demonstrates that a commercial offer for sale can occur without transfer of title. After construing the statutory term "on sale" to include mere "offers for sale," the *Pfaff* Court concluded that the acceptance of a purchase order satisfied its first prong. *Pfaff*, 525 U.S. at 67. The *Pfaff* Court's reliance on acceptance of a purchase order also shows that courts can rely on post-offer events as evidence that an offer for sale occurred at an earlier point in time. *Linear Tech. Corp. v. Micrel, Inc.*, 275 F.3d 1040, 1048 (Fed. Cir. 2001) (explaining that one can infer from the acceptance of a purchase order that "an offer for sale had been made at some point before that") (citing *Pfaff*, 525 U.S. at 67).

This Court's other precedent on this point is similarly flexible, applying the on-sale bar in many cases without proof that title had been transferred. *See, e.g.*, *Cargill, Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359, 1370 (Fed. Cir. 2007) (finding an offer for sale without the recipient paying for the product because "[t]here is no requirement that the sale be completed"); *Scaltech, Inc. v. Retec/Tetra, LLC*, 269 F.3d 1321, 1328 (Fed. Cir. 2001) (finding an offer for sale even though no sale ultimately occurred because "[a]n offer for sale does not have to be accepted to implicate the on sale bar"); *Abbott Labs. v. Geneva Pharm., Inc.*, 182 F.3d 1315, 1318-19 (Fed. Cir. 1999) (finding on-sale bar when a third-party offered to sell inventor's product). In sum, transfer of title is best viewed as a post-offer event showing that an offer for sale had previously occurred, and nothing more. Transfer of title can thus support but is not necessary for an on-sale bar finding.

2. The Nature of the Offer for Sale Is Key, Irrespective of Whether There Is Transfer of Title

In analyzing whether a prohibited offer for sale occurred, the nature of the transaction in question is key. *Group One, Ltd. V. Hallmark Cards, Inc.*, 254 F.3d 1041, 1048 (Fed. Cir. 2001); *Linear Tech.*, 275 F.3d at 1050. For example, offers to sell a claimed product or process can trigger the on-sale bar, but offers to sell patent rights or patent application rights cannot. *In re Kollar*, 286 F.3d 1326, 1331-1332 (Fed. Cir. 2002); *Elan Corp. v. Andrx Pharm., Inc.*, 366 F.3d 1336, 1341 (Fed. Cir. 2004) (citing *Group One* at 254 F.3d at 1048). In *Kollar*, this Court stated that, "[w]hen money changes hands as a result of the transfer of title to the tangible item, a sale normally has occurred." *Kollar*, 286 F.3d at 1332. In contrast, a transaction concerning the assignment of a patent (i.e., patent application rights) is not a patent-defeating transaction under § 102(b). *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1267 (Fed. Cir. 1986), *abrogated on other grounds by Egyptian Goddess, Inc. v. Swisa, Inc.*, 543 F.3d 665 (Fed. Cir. 2008). Likewise, "[a]n offer to enter into a license under a patent for future sale of the invention covered by the patent when and if it has been developed . . . is not an offer to sell the patented invention that constitutes an on-sale bar." *Elan*, 366 F.3d at 1341 (quoting *Kollar*, 286 F.3d at 1331).

Not all licenses and assignments, however, are immune from an on-sale challenge. Again, the focus is on what is being transferred: patent rights or the product or process itself. For example, a "license" or "lease" of a product or device "may be tantamount to a sale (e.g., a standard computer software license), whereupon the bar of § 102(b) would be triggered." *Kollar*, 286 F.3d at 1330 n.3. In this situation, the product is "just as immediately transferred to the 'buyer' as if it were sold." *Id.* (citing *Group One*, 254 F.3d at 1053 (Lourie, J., concurring)). Thus, "simply disguise[ing] a sales price as a licensing fee . . . would not avoid triggering the on-sale bar." *Elan*, 366 F.3d at 1341; *but see Mas-Hamilton Grp. v. LaGard, Inc.*, 156 F.3d 1206, 1217 (Fed. Cir. 1998) (conveyance of "production rights in the invention" and/or "the exclusive right to market the invention" is not "a sale or offer to sell the devices themselves").

This Court's focus on whether the subject matter of an offer for sale is a claimed product or process, as opposed to a patent or patent application rights, limits potential gamesmanship by parties attempting to avoid the on-sale bar. Under this standard, parties cannot escape the on-sale bar by merely applying a particular label to a transaction (e.g., lease, license, no transfer of title). Thus, this Court should continue to focus on the substance of the transaction—rather than on its form—when addressing the first prong of *Pfaff*.

B. A Transaction Is Not a Commercial Offer for Sale If It Was Solely from a Supplier to the Inventor in Producing the Claimed Invention

1. The Focus of the Panel Decision on Whether There Was a "Sale" Improperly Collapsed the *Pfaff* Inquiries, Short-Circuiting the Required Analysis

Under the first prong of *Pfaff*, a patent-barring offer for sale must be commercial. 525 U.S. at 67. By requiring a commercial offer for sale, *Pfaff* specifically qualifies which sales activities will trigger a patent-invalidating on-sale bar. Defining "commercial" too broadly ensnares sales for experimental purposes and sales that are *not* commercial marketing of the invention—sales *Pfaff* expressly exempts from the on-sale bar. *Id*. Here, the Panel Decision[5] deemed the transaction "commercial," and concluded that "because the invention was sold," it was reduced to practice. 791 F.3d at 1371-72. By zeroing in on the fact that a sale occurred and equating that sale to a reduction to practice, the Panel collapsed the two-prong *Pfaff* test into one question: was there a sale? *Id*. at 1372. That is not the standard. And by finding that the existence of a sale alone satisfied both prongs of *Pfaff*, the Panel Decision foreclosed consideration of facts and weighing of policies that may have established that the supplier-to-inventor transaction was not "commercial." Such an analysis is mandated by *Pfaff* and is fundamental to

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[5] "Panel Decision" refers to *The Medicines Co. v. Hospira, Inc.*, 791 F.3d 1368 (Fed. Cir. 2015).

evaluating whether certain conduct is subject to the on-sale bar. AIPLA asserts that under the appropriate analysis, a supplier-to-inventor transaction is not necessarily "commercial" under *Pfaff*.

2. The On-Sale Bar Limits Only Certain Sales Activity

The on-sale bar is defined by the policies that underlie it. *RCA Corp.*, 887 F.2d at 1062 ("As we have stated a number of times, the policies or purposes underlying the on-sale bar, in effect define it."). The bar encourages prompt disclosure of inventions to the public. *Woodland Trust v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1370 (Fed. Cir. 1998); *In re Caveney*, 761 F.2d 671, 676 (Fed. Cir. 1985); *Gen. Elec. Co. v. U.S.*, 654 F.2d 55, 61 (Ct. Cl. 1981). It precludes commercialization for longer than the statutory term. *Netscape Commc'ns. Corp. v. Konrad*, 295 F.3d 1315, 1323 (Fed. Cir. 2002). The on-sale bar prohibits the withdrawal of inventions from the public domain that the public has justifiably come to believe are freely available due to commercialization. *Abbott Labs.*, 182 F.3d at 1319; *King Instrument Corp. v. Otari Corp.*, 767 F.2d 853, 860 (Fed. Cir. 1985); *In re Caveney*, 761 F.2d at 676; *Gen. Elec.*, 654 F.2d at 61. And the on-sale bar gives an inventor a reasonable period of time following a commercial offer for sale to determine whether a patent is worthwhile. *Gen. Elec.*, 654 F.2d at 61.

When a sale or offer for sale is commercial under *Pfaff*, the inventor relinquishes control of the invention and profits by placing it into the hands of the public. *Pfaff*, 525 U.S. 67. To allow a patent that was sought more than one year after such conduct occurred would contravene the policies underlying the on-sale bar. By contrast, however, a supplier-to-inventor transaction does not undermine those policies. Such transactions are typically confidential and controlled by the inventor. In addition, in a supplier-to-inventor transaction, the inventor does not place the invention on sale to the general public, and as a result, does not profit from the invention. Because a supplier-to-inventor transaction does not run afoul of the on-sale bar's underlying policies, it should not prevent patent protection. *City of Elizabeth v. Am. Nicholson Pavement Co.*, 97 U.S. 126, 135-36 (1877) ("So long as he does not voluntarily allow others to make it and use it," "so long as it is not on sale for general use," and so long as "[h]e did not let it go beyond his control," the inventor will not "lose his title to a patent.").

3. Facts Beyond Whether There Is Sales Activity Are Key To Ensuring the Appropriate Balance is Preserved

When this Court has considered whether a sale is "commercial," it has examined (and should examine) facts beyond whether a sale or offer for sale occurred. In cases that implicate experimental use, for example, this Court considers whether the inventor sought to develop and modify the invention, test it in actual use conditions, meet regulatory hurdles, or obtain sufficient information to comply with the other statutory requirements. *E.g.*, *City of Elizabeth*, 97 U.S. at

133-36; *EZ Dock, Inc. v. Schafer Sys., Inc.*, 276 F.3d 1347, 1352-53 (Fed. Cir. 2002); *TP Labs., Inc. v. Prof. Positioners Inc.*, 724 F.2d 965, 968 (Fed. Cir. 1984). Beyond experimentation, this Court also considers: the confidential or public nature of the transaction; what was being sold; whether the inventor maintained control over the invention; whether the inventor had the requisite skills to produce the invention; and to what extent, if any, the inventor commercially exploited the invention. *E.g.*, *City of Elizabeth*, 97 U.S. at 133-36; *EZ Dock*, 276 F.3d at 1352-53; *Dey, L.P. v. Sunovion Pharm., Inc.*, 715 F.3d 1351, 1353-54 (Fed. Cir. 2013) ("*Sunovion*"); *Trading Techs. Int'l, Inc. v. eSpeed*, 595 F.3d 1340, 1361 (Fed. Cir. 2010); *Dey, L.P. v. Teva Parenteral Meds., Inc.*, 6 F. Supp. 3d 651, 672 (N.D.W.Va. 2014) *aff'd* 600 Fed. Appx. 773 (Fed. Cir. 2015) ("*Teva*"). Only after weighing *all* of these factors can a determination of "commercial" be made.

This Court has provided guidance on how to distinguish between permissible transactions and patent-barring commercial offers for sale, and which facts tip the scale in one direction or another. For example, in *EZ Dock*, this Court concluded that the inventors' actions surrounding the sale of their floating dock did not constitute a commercial offer for sale under *Pfaff*. *EZ Dock*, 276 F.3d at 1352-53. There, the inventors sold their invention to someone for use in a heavily trafficked and turbulent area of the Mississippi river. *Id*. at 1349. The inventors installed the dock for free, visited it on several occasions, and made no-cost repairs. *Id*. at 1349, 1353. This Court concluded that, notwithstanding the sale, "[t]hese facts show that the inventors were still working to detect and correct flaws in their invention," which evinced an experimental purpose for the sale and belied any purpose of commercially exploiting the value of the invention. *Id*. at 1353.

This Court considered other important facts in *EZ Dock* that demonstrated the inventors were not prematurely exploiting the invention for commercial gain: when the transaction occurred, the inventors were not selling any docks—there were no "for sale" signs, brochures, or "any other markings to indicate that the docks" in the "office supply store were for sale." *EZ Dock*, 276 F.3d at 1352. Instead, the purchaser initiated the sale. *Id*. Also the inventors did not charge the "full market price" for the dock, and they added in free equipment and installation for the lower-than-market-value sale price. *Id*. This Court concluded that such additional facts raised questions about whether the inventors "offered their invention for a commercial sale under market conditions in accordance with the first part of the *Pfaff* test." *Id*. at 1352.

In *Trading Technologies*, this Court concluded that an inventor's contract with a third-party-supplier software company did not cause an on-sale bar. One of the inventors of the patented trading software and method entered into a consulting agreement with a software development firm. 595 F.3d at 1361. The supplier agreed to "build a new trading window according to specifications provided [by the inventor].” *Id*. The supplier delivered and the inventor paid for the “custom software.” *Id*. This Court noted that the inventor “lacked the technical expertise” to “develop trading software,” and stated that “[i]nventors can request another entity’s services in developing products embodying the invention without triggering the on-sale bar.” *Id*. at 1361-62. As a result, the transaction for the inventor’s “own secret, personal use could not constitute a sale under 35 U.S.C. § 102(b).” *Id*. at 1362.

Courts also note the importance of distinguishing activity that places the invention “on sale for general use” from activity maintained under the inventor’s “own control.” *City of Elizabeth*, 97 U.S. at 135. In *City of Elizabeth*, there was no patent-barring activity even though the invention, a roadway, was “used in the premises of another” with some benefit to that other party and to the public. *Id*. The inventor maintained strict control over the invention, limiting the test road to a single strip in front of a tollhouse. *Id*. at 136. The inventor did not consent to the use of the inventive road anywhere else. *Id*. And the road was made at the inventor’s expense. *Id*. The Supreme Court concluded that such facts established that the inventor had not sold the invention for “general use,” even though he benefited from the tolls he recovered for use of the road. *Id*.

Further, this Court has already condoned the use of a supplier to meet regulatory requirements. *Sunovion* and its companion case, *Teva*, demonstrate that a sale for clinical trials does not run afoul of the on-sale bar. These cases involved two patent families—in *Teva*, the First Patent Family; in *Sunovion*, the Second Patent Family. *See Teva*, 6 F. Supp. 3d at 672; *Sunovion*, 715 F.3d at 1354. In *Teva*, Lot 3501 was provided by a supplier after the filing of the First Patent Family but before the filing of the Second Patent Family. *See Teva*, 6 F. Supp. 3d at 672; *Sunovion*, 715 F.3d at 1354. That same lot was used in a clinical trial. *Sunovion*, 715 F.3d at 1354. The prior sales transaction did not invalidate the patents of the Second Patent Family. In fact, in *Teva*, the district court concluded that batches of the drug product supplied before the filing of the First Patent Family did not invoke the on-sale bar because, *inter alia*, the supplier-to-inventor transaction was not commercial. *Teva*, 6 F. Supp. 3d at 671-72, *aff'd* 600 Fed. Appx. 773 (Fed. Cir. 2015).

Thus, this Court has declined to apply the on-sale bar based on an inventor's efforts to produce his invention—even publicly and when money changes hands—provided that the inventor maintains control over the invention, limits the public's access to the invention, and does not profit by commercially exploiting the invention. The outcome should be no different if an inventor requires the assistance of a supplier. To conclude otherwise "would severely restrict the rights of inventors to conduct ongoing work on an invention; they could do so only in private without using outside resources that may be necessary." *Atlanta Attachment*, 516 F.3d at 1369 (Fed. Cir. 2008) (Prost, J., concurring).

4. The Premise of *Auld* Is Inapplicable in the Context of a Supplier-to-Inventor Transaction

The Panel Decision relied on *D.L. Auld Co. v. Chroma Graphics Corp.*, 714 F.2d 1144 (Fed. Cir. 1983), in finding an on-sale bar. Panel Decision, 791 F.3d at 1370-71. The patent-barring activity in *Auld*, however, was significantly different from a supplier-to-inventor transaction.

In both *Auld* and its predecessor case, *Metallizing Engineering*, the courts concluded that an inventor's secret use of a process to make a product that was sold to the public before the critical date was a statutory bar to a process patent. *D.L. Auld*, 714 F.2d at 1151; *Metallizing Eng'g Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516 (2d Cir. 1946). Both cases involved claimed processes that the inventors practiced in private. The public never became aware of the later-claimed processes. But in both cases, the inventors used the secret processes to make products sold to customers before to the critical date. *Auld*, 714 F.2d at 1147-48; *Metallizing Eng'g*, 153 F.2d at 517-18. Consistent with *City of Elizabeth*, therefore, there was a "sale for general use." 97 U.S. at 135. The commercial exploitation and benefit from the sale to customers implicated the on-sale bar. *Metallizing Eng'g*, 516 F.2d at 518; *Gen. Elec.*, 654 F.2d at 61 ("The 'on sale' bar forces the inventor to choose between seeking patent protection promptly following sales activity or taking his chances with his competitors without the benefit of patent protection.") (quoting Barrett, *New Guidelines for Applying the On Sale Bar to Patentability,* 24 Stanford L.R. 730, 734 (1972)).

Contrary to the conclusion in the Panel Decision, there is, however, a "principled distinction" between the transactions in *Auld* and *Metallizing Engineering*, in which a product was made available to customers, and a supplier-to-inventor transaction, in which the product is not. Panel Decision, 791 F.3d at 1371. For this reason, the underlying premise of both *Auld* and *Metallizing Engineering* is very different from that of *City of Elizabeth*, *EZ Dock*, *TP Laboratories*, *Trading Technologies*, and *Teva*, where this Court has permitted some commercial activity while developing and producing the invention. These latter cases support the proposition that an inventor should not be barred from patent protection when his or her efforts involve assistance from a third party. *See Atlanta Attachment*, 516 F.3d at 1361 (Prost, J., concurring).

While such third-party assistance may benefit the inventor, Panel Decision, 791 F.3d at 1371, that benefit it is not the commercial exploitation that resulted in the patent bars in *Auld* and *Metallizing Engineering*. Under the more factually analogous cases, control and confidentiality trump commercial activity. To hold differently risks penalizing those inventors and their assignees who, on their own, cannot do what their bigger and more fully integrated counterparts can. The Panel

Decision starts the on-sale bar clock when a supplier, for a fee, validated the claimed invention and provided the product to the inventor. For inventors who do not have the capacity, skills, or funds to develop and produce their inventions, the Panel Decision unnecessarily time limits inventors who hire others to perform those activities. This is so even if the very same activities would not have barred patentability had the inventor not used a supplier. This result conflicts with the carefully-crafted balance of spurring innovation while at the same time giving the public a full, working knowledge of the invention so that it can be freely practiced after the patent expires.

C. To the Extent Necessary, This Court Should Overrule *Special Devices* and Recognize that Certain Supplier Transactions Do Not Implicate the On-Sale Bar

Based on *Pfaff's* requirement of a "commercial offer for sale," AIPLA urges this Court to recognize that supplier-to-inventor transactions do not implicate the on-sale bar, so long as those transactions remain under the inventor's control before the critical date. Such a recognition is consistent with the statute and Supreme Court precedent, and is supported by strong policy interests in patent law.

1. The "No-Supplier-Exception" Rule Originates from Pre-*Pfaff* Precedent Applying a Different On-Sale Bar Standard

Currently, supplier transactions are not recognized as falling outside of the on-sale bar. *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353, 1357 (Fed. Cir.

2001); *Hamilton Beach, Inc. v. Sunbeam Prods., Inc.*, 726 F.3d 1370, 1375 (Fed. Cir. 2013) (citing *Special Devices* for the proposition that "it is of no consequence that the commercial offer for sale" was made by the patentee's supplier to the patentee itself). This rule traces back to a pre-*Pfaff* case, *Buildex Inc. v. Kason Indus., Inc.*, 849 F.2d 1461, 1465 (Fed. Cir. 1988), which held that no joint-development exception existed for the on-sale bar. That case used the "totality of the circumstances" standard in applying the on-sale bar: "[T]his court has never recognized a 'joint development' exception to the 'on sale' bar. We have deliberately resisted rigid formulas and per se exceptions in applying § 102(b), instead considering the totality of the circumstances in each case." *Buildex*, 849 F.2d at 1465.

The Supreme Court in *Pfaff* overruled the totality of the circumstances standard applied in *Buildex* and adopted the present two-prong test. *Pfaff*, 525 U.S. at 67-68; *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 424 F.3d 1374, 1379 (Fed. Cir. 2005) ("Following the Court's guidance in *Pfaff*, this court rejected the totality of the circumstances test in the context of statutory bar disputes.") (citing *EZ Dock*, 276 F.3d at 1351 (explaining that the Supreme Court in *Pfaff* replaced the "totality of the circumstances" test with a "two-part test")). But after *Pfaff*, this Court again declined to adopt a joint-development exception. *See Brasseler U.S.A. I, L.P. v. Stryker Sales Corp.*, 182 F.3d 888, 890 (Fed. Cir. 1999) (citing *Buildex* and concluding that "we have 'never recognized a "joint development" exception to the "on sale" bar'").

This Court in *Special Devices* expressly rejected a supplier exception for the on-sale bar. 270 F.3d at 1356-57. Relying on *Brasseler*, which in turn relied on *Buildex*, the basis for rejecting the exception originated with the now-discarded totality of the circumstances standard. *Id.* While *Special Devices* relied on *Pfaff's* abandonment of the "totality of the circumstances" standard to find that there can be no supplier-to-inventor exception, in fact, such an exception is more urgently needed after *Pfaff* than before. Nothing in the *Pfaff* opinion requires a strict construction of the on-sale bar, and the supplier-to-inventor exception is justified for the reasons given above.

2. This Court Should Recognize that Supplier Transactions Are Not Commercial Offers for Sale to Prevent Prejudice to Companies Without Resources to Develop Products In House

Continuing to apply a no-supplier-exception rule after *Pfaff* produces inconsistent results that conflict with the two-prong test *Pfaff* introduced. For example, a company having the resources to develop and produce an invention "in house" can avoid an on-sale bar because there is no commercial activity relating to the invention outside of the company. But a company needing—or even just wanting—to hire (and pay) a third party to perform those same activities risks potential loss of patent rights. Application of the on-sale bar should not turn on whether activities are performed in house or through a transaction with a third party. It should also not force companies to create or ramp up in-house operations where third-party assistance is a more viable option. Recognizing that not all supplier transactions are commercial offers for sale would place on equal footing those patentees who perform all activities in house and those who do not or cannot. And it would appropriately place the focus on whether the invention was on sale for general use or beyond the inventor's control before the critical date.

As Judge Reyna explained in his *Hamilton Beach* dissent, a supplier exception is necessary to give meaning to the "Supreme Court's requirement that the offer be a 'commercial' one." *Hamilton Beach*, 726 F.3d at 1379 (Reyna, J., dissenting). Judge Reyna criticized the majority in that case for not analyzing whether the offer was commercial in nature, thus extending the no-supplier-exception-rule "without considering whether the purchase order was placed for purely experimental purposes." *Id*. at 1380. Judge Reyna emphasized the negative impact that a no-supplier-exception rule has on "small enterprises and individual inventors who lack in-house prototyping and fabricating capabilities." *Id.* at 1381.

Recognizing that supplier-to-inventor transactions are not commercial offers for sale would not impact the typical on-sale bar situation in which the patentee offers its own product on sale for general use or cedes control of the invention. Nor would it impact the situation in which a third party sells an invention to someone other than the inventor. Such recognition would be consistent with the policy rationales identified by this Court in *Kollar*, when it held that the on-sale bar was not implicated in a patent licensing arrangement, notwithstanding royalty payments. 286 F.3d at 1329. There, as with a confidential supplier-to-inventor transaction, the public would not "justifiably believe that [the] invention is freely available" particularly "with an accompanying confidentiality obligation." *Id*. at 1334. Also as in *Kollar*, in a supplier-to-inventor transaction, "the objective of making inventions available to the public" is furthered "by enabling inventors to place their inventions into the hands of parties that are in a better position to commercialize the invention and thus disclose it to the public." *Id*. Moreover, "[m]any inventors do not have the resources to produce commercial embodiments of their inventions." *Id.* As a result, "the ability to license or assign" as in *Kollar* or the ability to enter into limited commercial relationships in a supplier-to-inventor transaction, "without fear of triggering the on-sale bar" would facilitate the efforts of inventors in "providing the public with the benefit of their inventions under circumstances in which they might not otherwise have the ability or the incentive to do so." *Id*. And finally, as in *Kollar*, "although an inventor may economically benefit somewhat" from being allowed to enter into a commercial relationship with a third party, "the real benefit from commercializing an invention occurs when the invention is actually utilized commercially or made available to the public." *Id.* The transaction with the supplier, albeit accompanied by some payment, would only be "part of the pre-commercialization process aimed at making the invention commercial." *Id*. The policies outlined in *Kollar* align squarely with and equally support a recognition that certain supplier-to-inventor transactions do not trigger the on-sale bar.

II. CONCLUSION

AIPLA urges the Court to recognize that: (1) transfer of title is not required for an on-sale bar but can evidence an offer for sale if tied to a product or process; (2) a transaction is not a commercial offer for sale if it was solely from a supplier to the inventor in producing the claimed invention; and (3) to the extent *Special Devices* is contrary to point (2), it should be overruled.

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