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. Andrews

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AMICUS CURIAE BRIEF OF MILLER, PATTI, PERSHERN PLLC IN SUPPORT OF APPELLANT THE MEDICINES COMPANY

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February 3, 2016

CERTIFICATE OF INTEREST

The undersigned counsel certify the following:

1. The full name of every party or *amicus curiae* we represent: None. Our law firm, Miller Patti Pershern PLLC, has chosen to write this brief, with no involvement of any other person or entity.

2. The name of the real party in interest we represent: Not applicable.

3. All parent corporations and any publicly held companies that own 10% or more of the stock of the party or *amicus curiae* represented by me are: None.

Dated: February 3, 2016

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STATEMENT OF IDENTITY, INTEREST, AND AUTHORITY

Pursuant to Rule 29(c)(4), the undersigned counsel states that this Brief was authored solely by the members of the law firm Miller Patti Pershern PLLC, *i.e.*, Anthony P. Miller, John J. Patti, and S. Scott Pershern. No other person or entity participated in the preparation of the Brief or provided any kind of funding in support of the Brief. No consent was obtained or required to file this brief under this Court's November 13, 2015 Order.

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ARGUMENT

I. This Court Should Overrule the No-Supplier-Exception Rule of *Special Devices*.

The no-supplier-exception rule of *Special Devices*[1] (the "**NSE Rule**") should be overruled.

A. The NSE Rule of *Special Devices* Is the Sort of "Flaw in the System" that the America Invents Act Was Designed to Prevent.

In 2011, Congress passed the "America Invents Act" (the "**AIA**")—the first comprehensive patent reform in nearly sixty years.[2] The purpose of the AIA was to modernize patent law in order "to correct flaws in the system that have become unbearable, and to accommodate changes in the economy

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[1] *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353, 60 U.S.P.Q.2D 1537 (Fed. Cir. 2001).

[2] "America Invents Act," House Judiciary Committee, June 29, 2011, H.R. Rep. No. 112-98, at 38, available at http://www.uspto.gov/sites/default/files/aia_implementation/crpt-112hrpt98-pt1.pdf, accessed February 3, 2016; *see also* Press Release, The White House, President Obama Signs America Invents Act, Overhauling the Patent System to Stimulate Economic Growth, and Announces New Steps to Help Entrepreneurs Create Jobs (Sept. 16, 2011), available at http://www.whitehouse.gov/the-press-office/2011/09/16/president-obama-signs-america-invents-act-overhauling-patent-system-stim (accessed February 3, 2016).

and the litigation practices in the patent realm."[3] According to the House Judiciary Committee Report,[4] "[i]f the United States is to maintain its competitive edge in the global economy, it needs a system that will support and reward all innovators with high quality patents."[5] The principle in *Special Devices*—*i.e.*, that there is no "supplier exception" to the on-sale bar of Section 102(b)—is precisely the sort of "flaw in the system that ha[s] become unbearable" given "changes in the economy" in the sixty years since the last overhaul of patent law.

One of the key components of the AIA was its modernization of the definition of "prior art," including the removal of private sales from the scope of the term. According to AIA cosponsor Senator John Kyl:

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[3] H.R. Rep. No. 112-98, at 38-39.

[4] "[C]ourts generally place committee reports at the apex of their hierarchy of legislative history." Matal, J., *A Guide to the Legislative History of the America Invents Act: Part I of II*, 21 Fed. Cir. Bar J. 435, 436 (2012) (citing *Zuber v. Allen*, 396 U.S. 168, 186, 90 S. Ct. 314, 24 L. Ed. 2d 345 (1969) ("A committee report represents the considered and collective understanding of those Congressman involved in drafting and studying the proposed legislation."); *Bingham & Taylor Div., Va. Indus., Inc. v. United States*, 815 F.2d 1482, 1485 (Fed. Cir. 1987) ("Although not decisive, the intent of the legislature as revealed by a committee report is highly persuasive.")).

[5] H.R. Rep. No. 112-98, at 40.

> [O]ne of the bill's clear improvements over current law is its streamlined definition of the term 'prior art.' Public uses and sales of an invention will remain prior art, but only if they make the invention ***available to the public***. An inventor's confidential sale of his invention, his demonstration of its use to a private group, or a third party's unrestricted but private use of the invention will no longer constitute private art. ***Only the sale or offer for sale of the invention to the relevant public or its use in a way that makes it publicly accessible will constitute prior art***.[6]

The House Judiciary Committee Report states that "the phrase 'available to the public' [wa]s added to clarify the broad scope of relevant prior art, as well as to emphasize the fact that it ***must be publicly accessible***."[7] The goal was to remedy the fact that, under the current law, the "forfeiture doctrines [including the on-sale bar and public-use bar] ha[d] become traps for unwary inventors and impose[d] ***extreme results to no real purpose***," such

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[6] Senator Kyl (AZ), "America Invents Act," Congressional Record 157:130 (September 6, 2011), at S5320, available at https://www.congress.gov/crec/2011/09/06/CREC-2011-09-06-pt1-PgS5319-3.pdf, accessed February 3, 2016; *see also Kenna v. U.S. Dist. Court for the C.D. Cal.*, 435 F.3d 1011, 1015 (9th Cir. 2006) ("Floor statements are not given the same weight as some other types of legislative history, such as committee reports, because they generally represent only the view of the speaker and not necessarily that of the entire body. However, floor statements by the sponsors of the legislation are given considerably more weight than floor statements by other members...").

[7] H.R. Rep. No. 112-98, at 42-43 (emphasis added).

as where a patent was invalidated because the inventor had demonstrated the invention to "several guests at a party in her own home."[8]

In addition to avoiding pointlessly harsh results, the revised definition of "prior art" was intended to reduce the time and expense of patent litigation and proceedings before the USPTO:

> The main benefit of the AIA public availability standard of prior art is that it is relatively inexpensive to establish the existence of events that make an invention available to the public. ***Under current law, depositions and litigation discovery are required in order to identify all of the inventor's private dealings with third parties and determine whether those dealings constitute a secret offer for sale or third party use that invalidates the patent under the current law's forfeiture doctrines.*** The need for such discovery is eliminated once the definition of "prior art" is limited to those activities that make the [invention] accessible to the public. This will greatly reduce the time and cost of patent litigation and allow the courts and the [USPTO] to operate much more efficiently.[9]

Unfortunately, the AIA does not apply to this case. The law has been fixed going forward, but the patent in this case is five years too old to benefit from

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[8] Senator Kyl (AZ), "Patent Reform Act of 2011," Congressional Record 157:34 (March 8, 2011), at S1371, available at https://www.congress.gov/crec/2011/03/08/CREC-2011-03-08-pt1-PgS1360-2.pdf, accessed February 3, 2016*Id*. at S1371 (emphasis added) (quoting *Bruckelmyer v. Ground Heaters, Inc*., 335 F.3d 1374, 1378, 78 U.S.P.Q.2D 1684 (Fed. Cir. 2006)).

[9] Congressional Record 157:130, at S5320 (emphasis added).

the AIA's comprehensive remediation of existing law. If this Court chooses to uphold the no-supplier-exception principle of *Special Devices*, the patent at issue will just have to be one that fell through the cracks to become a victim of "extreme results to no real purpose."

B. The *Special Devices* Decision Was Based on a Myopic View of the Policy Underpinnings of Section 102(b).

The determination of whether a Section 102(b) sale occurred is an "exercise of judgment, taking into account a variety of facts in light of the policies behind the statute."[10] There are, according to this Court, four policies underlying the on-sale bar, including "giv[ing] the inventor a reasonable amount of time following sales activity … to determine whether a patent is a worthwhile investment."[11] The Supreme Court has stated the

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[10] *Lough v. Brunswick Corp.*, 103 F.3d 1517, 1518, 41 U.S.P.Q.2D 1385 (Fed. Cir. 1997).

[11] *See*, *e.g.*, *UMC Elecs. Co. v. United States*, 816 F.2d 647, 652, 2 U.S.P.Q.2D 1465 (Fed. Cir. 1987) (setting out four separate policies that underlie Section 102(b), including "giv[ing] the inventor a reasonable amount of time following sales activity … to determine whether a patent is a worthwhile investment.") (citations omitted); *W. Marine Elecs., Inc. v. Furuno Elec. Co.*, 764 F.2d 840, 845, 226 U.S.P.Q. 334 (Fed. Cir. 1985) ("Public policy favors prompt and widespread disclosure of inventions to the public, while giving the inventor a reasonable amount of time (1 year, by statute) to determine whether a patent is worthwhile, but precluding attempts by the inventor or

policies in broader terms: "The patent laws … seek both to protect the public's right to retain knowledge already in the public domain and the inventor's right to control whether and when he may patent his invention."[12] The panel in *Special Devices*, however, appears to have taken a much more narrow view of the policy underpinnings of the statute, noting only that its decision was consistent with only one—"the primary policy of the on-sale bar; namely, the policy of 'encouraging an inventor to enter the patent system promptly'"—and concluding that "the on-sale bar would apply even if a patentee's commercial activities took place in secret."[13] That, however, is exactly the sort of "extreme result" that the AIA was designed to prevent, particularly given the profound changes—in both the economy and in how businesses operate—that have come to pass in the six decades since the current Section 102(b) was promulgated.

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his assignee from commercially exploiting the invention more than a year before the application for patent is filed.").

[12] *Pfaff v. Wells Elecs.*, 525 U.S. 55, 65, 119 S.Ct. 304, 142 L. Ed. 2d 261 (1998).

[13] *Special Devices, Inc.*, 270 F.3d at 1357.

C. The NSE Rule of *Special Devices* Is Outdated Given the Current Economy.

Having no supplier exception to Section 102(b) might make sense in an economy where the majority of companies are fully integrated, with research, development, manufacturing, and sales all carried out by or within the same entity. In fact, integrated companies were the norm back in 1952, when the current version of Section 102(b) was passed.[14] That is no longer the case, however. Today, contract manufacturers—whose resources are devoted solely to manufacturing—can produce commercial volumes of products at a lower cost than those whose resources have to be spread out between research, design, marketing, sales, and manufacturing, particularly in industries such as semiconductors and pharmaceuticals, where complex and sophisticated manufacturing processes demand huge amounts of capital.

Texas Instruments ("**TI**") is a good example of this phenomenon. TI is the third largest semiconductor manufacturer in the world and was a

[14] Handfield, Dr. Robert, "A Brief History of Outsourcing," NC State Poole College of Management, SCRC Articles Library, dated June 1, 2006, available at https://scm.ncsu.edu/scm-articles/article/a-brief-history-of-outsourcing, accessed February 3, 2016.

pioneer in the field. The company designed and manufactured the first transistor radio in 1954, and one of its employees, Jack Kilby, actually invented the integrated circuit, winning the Nobel Prize in physics for his invention.[15] TI started out as an integrated company and, as recently as 2007, was named a "Manufacturer of the Year."[16] Yet over the past decade, TI has been forced to outsource more and more of its manufacturing.[17] The costs associated with developing manufacturing processes for ever-smaller chips are in the billions, and growing.[18] Not even the huge product demand enjoyed by companies as big as TI can sustain multi-billion-dollar capital

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[15] *See* "Texas Instruments," Wikipedia, last updated January 28, 2016, available at https://en.wikipedia.org/wiki/Texas_Instruments, accessed February 3, 2016.

[16] *See id*.

[17] *See* "TI bares details of new 'hybrid' fab strategy," EET Times-Asia, dated May 22, 2007, available at http://www.eetasia.com/ART_8800465321_480200_NT_36558d3c.HTM, accessed February 3, 2016 ("Nearly half of TI's logic chip production is outsourced to the foundries today, but that figure could jump to 70 percent over time, according to analysts.").

[18] Korczynski, Ed., "Design and Manufacturing Technology Development in Future IC Foundries," Semiconductor Manufacturing & Design Community, dated September 16, 2014, http://semimd.com/blog/2014/09/16/design-and-manufacturing-technology-development-in-future-ic-foundries/, accessed February 3, 2016.

investments every few years.[19] So now, even the number three semiconductor manufacturer in the world uses outside manufacturers that are able to consolidate the product demand of multiple semiconductor companies to make manufacturing economically viable.[20]

This same phenomenon has affected both manufacturing and research and development ("**R&D**") in the pharmaceutical industry. According to one report, "the outsourcing of R&D and manufacturing processes has become increasingly prevalent, and is now a major trend in the pharmaceutical industry."[21] In fact, "[t]he pharmaceutical/biotech industry has the highest levels of R&D outsourcing across hi-tech industries," and as of 2015, pharmaceutical companies reported "that 40% or more of their R&D

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[19] *Id*.

[20] *See supra* Note 17.

[21] "How can pharmaceutical and life sciences companies strategically engage global outsourcing?" PricewaterhouseCoopers, Global Pharmaceutical and Life Sciences Industry Group, dated 2015, available at https://www.pwc.com/gx/en/pharma-life-sciences/pdf/pwc-pharma-outsourcing.pdf, accessed February 3, 2016 ("Over the past two decades, the outsourcing of R&D and manufacturing processes has become increasingly prevalent, and is now a major trend in the pharmaceutical industry.").

spend will be outsourced in the near future and that clinical operations functions will eventually be outsourced entirely."[22]

Judge Reyna, in his dissent in the *Hamilton Beach* case, worried about the impact that this Court's application of the NSE Rule would have on "future innovators, most notably small enterprises and individual inventors who lack in-house prototyping and fabricating capabilities."[23] The outsourcing trend, however, is not limited to small companies and individual inventors. It is instead a phenomenon driven by economic realities that even the very largest companies cannot ignore. The NSE Rule is therefore an anti-business anachronism, which has the effect of forcing

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[22] "R&D outsourcing in hi-tech industries: A research study," PricewaterhouseCoopers, Global Pharmaceutical and Life Sciences Industry Group, dated 2014, available at http://www.pwc.com/gx/en/pharma-life-sciences/assets/pwc-r-and-d-outsourcing-in-hi-tech-industries.pdf, accessed February 3, 2016 (citing "Pharma and biotech firms are rethinking their approach to outsourcing," Tufts Centre for the study of Drug Development (CSDD), dated October 26, 2010, available at http://csdd.tufts.edu/news/complete_story/rd_pr_oct_2010, accessed February 3, 2016).

[23] *Hamilton Beach Brands, Inc. v. Sunbeam Prods.*, 726 F.3d 1370, 1379, 107 U.S.P.Q.2D 1901 (Fed. Cir. 2013); *cf. Monon Corp. v. Stoughton Trailers, Inc.*, 239 F.3d 1253, 1258-61, 57 U.S.P.Q.2D 1699 (Fed. Cir. 2001) (reversing summary judgment of invalidity and 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).

companies to have to choose between the economic impetus to outsource their R&D and manufacturing, on the one hand, and participating in a patent system that punishes prudent business practices with "extreme results [that serve] no real purpose," on the other.

This Court's Section 102(b) law should not punish innovators who are only acting in accordance with the dictates of the current economic climate. Nor should it be based on nitpicking supplier sales to determine how many units were sold, whether it was few enough to be "experimental," or whether the volume was sufficient to cross some arbitrary threshold and thereby merit the label "commercial." Rather, this Court's focus in applying Section 102(b) should be on preventing "the removal of inventions from the public domain which the public justifiably comes to believe are freely available."[24] The Court should therefore eliminate the NSE Rule of *Special Devices* in favor of the simpler and more logical AIA approach, which just requires a

[24] *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 549, 16 USPQ2d 1587 (Fed. Cir. 1990); *see also Ferag AG v. Quipp Inc.*, 45 F.3d 1562, 1566, 33 USPQ2d 1512 (Fed. Cir. 1995) (Where the seller is a parent company of the buyer company, but the President of the buyer company had "essentially unfettered" management authority over the operations of the buyer company, the sale was a statutory bar.).

determination as to whether the invention was actually "available to the public."[25]

II. Even Without a Supplier Rule, There Was No 102(B) Event.

A. The Trial Court's Factual Findings Were Entitled to Deference.

The Section 102(b) on-sale determination comprises a two-part test.[26] First, a court is to determine whether the patented invention was the subject of a commercial sale or offer for sale.[27] Second, the court decides whether the invention was ready for patenting at the time of the sale or offer.[28] Each step requires proof by clear and convincing evidence.[29]

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[25] The briefing in this case and the Panel Opinion do not contain much discussion of whether the claimed invention was available to the public or what steps were or were not taken to preserve the patented method's confidentiality. The undersigned *amici* therefore offer no opinion as to whether the AIA, publicly-available standard would have been met here, and respectfully submit that remand would be appropriate to make that determination.

[26] *See Pfaff*, 525 U.S. at 66-67.

[27] *See id*.

[28] *Id*.

[29] *See Honeywell Int'l Inc. v. Universal Avionics Sys. Corp.*, 488 F.3d 982, 996, 82 U.S.P.Q.2D 1886 (Fed. Cir. 2007).

Each of these inquiries involves a question of law, which is in turn based on underlying factual determinations.[30] For example, the question of whether the invention was the subject of a commercial sale involves underlying factual determinations such as:

> [W]hether the action in question was undertaken for commercial purposes, whether members of the public viewed the invention without any bond of confidentiality to the inventor, whether the nature of the invention was discernible by observation, whether any precautions were taken to exclude outsiders, etc.[31]

Each legal determination is reviewed *de novo*, while the underlying factual determinations are entitled to deference and are only to be overturned where the factfinder committed clear error.[32]

"A finding [of fact] is 'clearly erroneous' when although there is evidence to support it, the reviewing court on the entire evidence is left with

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[30] *See*, *e.g.*, *Merck & Co., Inc. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1369, 73 U.S.P.Q.2D 1641 (Fed. Cir. 2005); *Lough*, 103 F.3d at 1518; *KeyStone Retaining Wall Sys. Inc. v. Westrock, Inc.*, 997 F.2d 1444, 1451, 27 U.S.P.Q.2D 1297 (Fed. Cir. 1993).

[31] *See Lough*, 103 F.3d at 1518.

[32] *See Braintree Labs., Inc. v. Novel Labs., Inc.*, 749 F.3d 1349, 1358, 110 U.S.P.Q.2D 1525 (Fed. Cir. 2014); *Ferag AG*, 45 F.3d at 1566.

the definite and firm conviction that a mistake has been committed."[33] Under this standard, a court of appeals cannot simply substitute its own view of the facts:

> If the district court's account of the evidence is plausible in light of the record viewed in its entirety, the court of appeals may not reverse it even though convinced that had it been sitting as the trier of fact, it would have weighed the evidence differently.[34]

Once the fact questions have been answered, a trial court is supposed to "exercise [its] judgment, taking into account a variety of facts in light of the policies behind the statute," to answer the legal question of whether a commercial sale occurred.[35] Here, the Panel recited the deferential-review standard, but then failed entirely to apply it.

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[33] *Am. Pelagic Fishing Co., L.P. v. United States*, 379 F.3d 1363, 1371 (Fed. Cir. 2004), *cert. denied*, 545 U.S. 1139, 125 S. Ct. 2963, 162 L. Ed. 2d 887 (2005); *see also Union Pac. Res. Co. v. Chesapeake Energy Corp.*, 236 F.3d 684, 693, 57 U.S.P.Q.2D 1293 (Fed. Cir. 2001) ("This court reviews these underlying factual findings for clear error, and will not reverse without a 'definite and firm conviction that a mistake has been committed.'") (quoting *Elk Corp. v. GAF Bldg. Materials Corp.*, 168 F.3d 28, 31, 49 U.S.P.Q.2D 1853 (Fed. Cir. 1999)).

[34] *Anderson v. City of Bessemer City, N.C.*, 470 U.S. 564, 573-74, 105 S. Ct. 1504, 84 L. Ed. 2d 518 (1985).

[35] *Id*.

B. The Trial Court's Factual Findings Received No Deference.

In order to support its position that '727 and '343 patents, Hospira asserts that there were two on-sale events by The Medicine Company.[36] The first is the Validation Batch Transaction, and the second is the Distribution Agreement.[37]

Regarding the Validation Batch Transaction, the trial court—acting as the trier of fact—concluded that "Hospira admits that the batches [which are the subject of the Validation Batch Transaction] were for validation purposes," that "[t]he Medicines Company paid Ben Venue to manufacture validation batches," and that TMC's "payment to Ben Venue for the validation batches was for experimental purposes."[38] The trial court also found that validation was to "to confirm that the [manufacturing] process worked as intended," and that, "[a]t the time of the transaction, the intent

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[36] *See* Appellee's Original Brief at 50.

[37] *See* Appellee's Orig. Br., September 26, 2014, at 49.

[38] *See* Appellant's Orig. Br., Addendum, March 31, 2014 Trial Opinion, at A21, A24. The trial court erroneously labeled its conclusion that TMC's "Distribution Agreement with ICS was not an offer for sale" as a fact determination. *See id*.

was experimental."[39] These are findings of fact which this Court is supposed review under the deferential, clear-error standard.[40] There is nothing in the panel decision, however, that suggests that there was any error in any of these factual findings—let alone clear error.[41] Thus, the initial assumption should be that the batches that are the subject of the Validation Batch Transaction were purchased for validation purposes.

This initial assumption is critical to the ultimate finding that the purchases were subject to the experimental use exception. With experimental use, the ultimate question is "whether the primary purpose of the inventor ***at the time of the sale***, as determined from an objective evaluation of the facts surrounding the transaction, was to conduct experimentation."[42] To the extent that there is any commercial exploitation, "it must be merely incidental to the primary purpose of the experimentation

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[39] *See id.* at A19, A24, A21.

[40] *See Braintree Labs.*, 749 F.3d at 1358; *Ferag AG*, 45 F.3d at 1566.

[41] *See generally* Panel Opinion at 4-8.

[42] *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1354, 63 U.S.P.Q.2D 1769 (Fed. Cir. 2002) (internal quotation omitted) (emphasis added).

to perfect the invention."[43] Here, the trial court's explicit findings that the intent at the time of the purchase was "to confirm that the [manufacturing] process worked as intended" is dispositive without a finding of clear error.[44] The Panel Opinion, which simply concludes that "the sale of manufacturing services here provided a commercial benefit to the inventor,"[45] just ignores the standard of review, and sets the stage for virtually any third-party involvement before the priority date to give rise to invalidation under Section 102(b). This, the undersigned *amici* submit, was the consequence of the current 102(b) standard migrating toward a focus on inventors' efforts to commercialize their inventions, without regard to whether "the invention[s] remain[ed] out of the public's hands."[46]

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[43] *LaBounty Mfg. v. U.S. ITC*, 958 F.2d 1066, 1071, 22 U.S.P.Q.2D 1025 (Fed. Cir. 1992) (internal quotation omitted).

[44] Appellant's Original Brief at A19. As the trial court noted in footnote 11, the subsequent commercial treatment of the pharmaceuticals is irrelevant because the question is what the inventor's intent was at the time of the transaction. *See Allen Eng'g Corp.*, 299 F.3d at 1354.

[45] Panel Opinion at 5.

[46] *Ferag AG*, 45 F.3d at 1566 (Where the seller is a parent company of the buyer company, but the President of the buyer company had "essentially unfettered" management authority over the operations of the buyer company, the sale was a statutory bar.).

C. The *Pfaff* Court Appears Not to Have Equated Using a Third-Party Manufacturer with Villainy.

The *Pfaff* decision, which set out the current two-part test for the on-sale bar, actually appears to have involved—but not to have turned on—the use of a third-party manufacturer.[47] The Supreme Court noted that the inventor "prepared detailed engineering drawings that described the design, the dimensions, and the materials to be used in making the [invention]," and "sent those drawings to a manufacturer" a month or two prior to the priority date.[48] The Supreme Court's conclusion that there was a commercial sale, however, was based on the existence of "a written confirmation of a previously placed oral purchase order" from the inventor.[49] In particular, the court wrote that "[i]n this case the acceptance of the purchase order prior to April 8, 1981, makes it clear that such an offer had been made, and there is no question that the sale was commercial rather than experimental in character."[50] The fact that the invention was shared

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[47] *See Pfaff*, 525 U.S. at 66-67.

[48] *Id*. at 58.

[49] *Id*.

[50] *Id*. at 67.

with the manufacturer was only discussed in the initial recitation of facts and in the context of analyzing whether the invention had been reduced to practice.[51] The reality is that the question—*i.e.*, whether delivery of the design to the manufacturer constituted a sale for purposes of Section 102(b)—was not before the Supreme Court. It is ironic, however, that facts similar to the facts here, which seem not to have irked the Supreme Court, were the basis of the panel's invalidation of the patent at issue in this case.

CONCLUSION

For all of the above and foregoing reasons, the undersigned *amici* respectfully submit that this Court should (1) overrule or revise the principle in *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353 (Fed. Cir. 2001), that there is no "supplier exception" to the on-sale bar of 35 U.S.C. § 102(b), and (2) reverse the panel's ruling that there was a commercial sale in this case.

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[51] *Id.* at 57.

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CERTIFICATE OF COMPLIANCE

This Brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B). It contains 3890 words, according to the word processing system used to prepare it, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii) and Fed. Cir. R. 32(b).

This Brief also complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the style requirements of Fed. R. App. 32(a)(6). The Brief written with Microsoft Word, using a proportionally-spaced font called "Book Antiqua."

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CERTIFICATE OF SERVICE

I certify that I served a copy of the foregoing *Amicus Curiae* Brief Of Miller, Patti, Pershern PLLC in Support of Appellants and Urging Reversal on counsel of record on February 3, 2016 by filing it using the Court's CM/ECF system.

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