14-1469, -1504

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

THE MEDICINES COMPANY,

Plaintiff-Appellant,

v.

HOSPIRA, INC.

Defendant-Appellee.

On Appeal from the United States District Court for the District of Delaware
Judge Richard G. Andrews
1:09-CV-00750

BRIEF OF *AMICUS CURIAE,* BIOTECHNOLOGY INNOVATION ORGANIZATION (BIO) IN SUPPORT OF PLAINTIFF-APPELLANT THE MEDICINES COMPANY

ERIC J. MARANDETT
IRENE OBERMAN KHAGI
CHOATE HALL & STEWART LLP
Two International Place
Boston, MA 02110
Tel. 617.248.5000
emarandett@choate.com

Counsel for Amicus Curiae Biotechnology Innovation Organization

March 2, 2016

CERTIFICATE OF INTEREST

Counsel for *Amicus Curiae* Biotechnology Innovation Organization (BIO) hereby certifies the following, pursuant to Federal Circuit Rule 47.4:

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

Biotechnology Innovation Organization (BIO)

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% 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 are expected to appear in this court are:

CHOATE, HALL & STEWART LLP: Eric J. Marandett, Irene Oberman Khagi

Dated: March 2, 2016

/s/ Eric J. Marandett
Eric J. Marandett

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Rules

Other Authorities

INTEREST OF THE AMICUS CURIAE

Biotechnology Innovation Organization ("BIO") is the world's largest biotechnology trade association, representing over 1,000 biotechnology companies, research institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO members research and develop biotechnological healthcare, agricultural, environmental, and industrial products. BIO members range from startup entities and university spinoffs to Fortune 500 multinational corporations, though the majority of BIO members are small companies that have yet to bring products to market or attain profitability, and thus depend on venture capital and other private investment for their growth.

Modern pharmaceutical and biotechnology products typically require lengthy, costly, and resource-intensive development periods before they reach the marketplace. BIO members devote many years and millions of dollars in direct investment and sweat equity to develop innovative new products that cure diseases, improve food security and/or create alternative energy sources, among other things. The ability to maintain and enforce strong patents covering these innovations provides critical incentive to justify this investment. Increasingly, BIO members, large and small, engage third party contract resources to perform research and manufacturing services to reduce development costs, streamline resources, and enhance efficiency. BIO members therefore are especially

vulnerable to the misapplication and inconsistent application of standards that lead to the invalidation of patents.

The Panel Decision[1] needlessly expands the on-sale bar to discriminate against pharmaceutical manufacturers who choose to take advantage of the economic efficiencies of outsourcing clinical manufacturing or other aspects of the drug development process. Applying the on-sale bar to a contract between a patent holder and a contract manufacturer who confidentially provides manufacturing services conflicts with established precedent and Congressional intent. The decision has wide-ranging economic implications for the pharmaceutical and biotechnology industry as a whole and risks chilling investment in research, development, and commercialization of new products that heal, feed, and fuel the world. BIO and its members have a substantial interest in the Court's resolution of the questions raised by the Panel Decision.

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

BIO has no stake in any of the parties to this litigation or in the result of this case. [2] No party to this appeal has contributed financially or substantively to the preparation of this brief.[3]

PRELIMINARY STATEMENT

The on-sale bar precludes patent protection for an invention that 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).[4] The purpose of the on-sale bar is to promote timely filing of patent applications and prevent inventors from unduly extending the statutory monopoly of patent protection or removing knowledge the public already believes is in the public domain. *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 64 (1998).

---

[2] Pursuant to Fed. R. App. P. 29(c)(5), BIO 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 BIO and its counsel.

[3] BIO files this brief as *amicus curiae* in response to the Court's invitation in its November 13, 2015 Order.

[4] The America Invents Act (AIA) revised 35 U.S.C. § 102 to render an invention ineligible for patent protection if it was "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). Accordingly, the post-AIA 35 U.S.C. § 102(a) makes clear that the sale must make the invention available to the public to be "on sale." MPEP 2152.02(d). The post-AIA on-sale bar is also not limited in geographic scope and applies regardless of where the sale took place.

Increasingly, biotechnology companies are moving toward a model where at least some research and development and manufacturing work often is performed by third party service providers in order to streamline resources and enhance efficiencies in quality, expertise, capacity, and time to market. The ability to obtain such services from independent contract manufacturing organizations ("CMOs") has become crucially important to the economic viability of many companies in the biotechnology industry, especially smaller, development-stage companies that simply cannot maintain in-house operations to do the required wide range of specialized production, testing, and validation work. But even the very largest companies in the biopharmaceutical industry rarely maintain their own internal resources to conduct all manufacturing and to fill and finish products[5] because even for large companies it often is more efficient to use CMOs to perform these services.

The fundamental policies of the on-sale bar are not served by applying the bar in a way that preserves patent rights for companies that perform their own in-house manufacturing while invalidating patent rights for companies otherwise engaging in the very same economic activity, but who seek to operate in a nimble and efficient manner by engaging the services of third party CMOs. The Panel

[5] Fill and finish manufacturing is used in injectable drug manufacturing and commonly involves services including filling vials and syringes.

Decision, if it stands, would undermine, rather than advance the policies behind the on-sale bar of uniformly encouraging all innovators to promptly file for patent protection. It would treat the *very same conduct* – ramp-up production, process validation, and pre-commercialization manufacturing - differently depending on how a patent-holder structures its business (*i.e.*, vertically-integrated manufacturing versus third party subcontracting). The panel decision therefore discriminates against companies with specialized expertise or who choose to take advantage of the capital and resources of CMOs and instead encourages inefficiency and delay in bringing important pharmaceutical products to market.

En banc review of the Panel Decision presents an opportunity for the Court to clarify that confidential contract manufacturing services provided to a patent holder, when an invention is not sold to the public more than one year before filing a patent application, does not constitute a commercial "sale" for purposes of the on-sale bar provided in 35 U.S.C. § 102(b), and should not fall within the scope of the *Special Devices* holding rejecting a "supplier exception" to the on-sale bar.

ARGUMENT

I. Treating Contracts for Pre-Filing Confidential Manufacturing Services as a "Sale" Does Not Promote the Policies Behind the On-Sale Bar.

This Court long has recognized that the on-sale bar serves to promote several precisely articulated policies:

> (1) discouraging removal of inventions from the public domain which the public justifiably comes to believe are freely available due to commercialization; (2) favoring prompt and widespread disclosure of inventions to the public; (3) giving the inventor a reasonable amount of time following the sales activity to determine the value of a patent, and (4) prohibiting an extension of the period for exploiting the invention.

See King Instruments Corp. v. Otari Corp., 767 F.2d 853, 860 (Fed. Cir. 1985); *In re Caveney*, 761 F.2d 671, 676 (Fed. Cir. 1985); *see also RCA Corp. v. Data Gen. Corp.*, 887 F.2d 1056, 1062-63 (Fed Cir. 1989) ("[A]n on-sale bar cannot be determined by ascribing a label to certain activity so as to make it appear to be commercial, in lieu of considering whether the activity runs counter to the policies of the on-sale bar that are to be effectuated."); *In re Kollar*, 286 F.3d 1326, 1334 (Fed. Cir. 2002) (noting that exempting licenses from the on-sale bar "does not conflict with the policies underlying the on-sale bar."). The Panel's holding that a contract for the confidential supply of third party manufacturing services to a patent holder constitutes a commercial "sale" thereby triggering the on-sale bar under Section 102(b) does not further any of these underlying policies. Rather, the Panel Decision only serves to strip patent protection from companies, large and small, that choose to take advantage of the efficiencies of outsourcing or that lack the capability to manufacture in-house while exempting companies that engage in *the same* conduct using in-house resources or wholly owned subsidiaries.

Applying the on-sale bar to a pre-filing contract for confidential third party manufacturing of a patented product does not in any way further the policy of discouraging removal of the invention from the public in circumstances where "the public justifiably comes to believe are freely available *due to commercialization.*" *In re Caveney*, 761 F.2d at 676 (emphasis added); *see also City of Elizabeth v. Am. Nicholson Pavement Co.*, 97 U.S. 126, 135-36 (1877) (non-secret use was not a "public use" where the inventor did not put invention "on sale for general use" and "did not let it go beyond his control"); *Dey, L.P. v. Sunovion Pharms., Inc.* ("*Sunovion*"), 715 F.3d 1351, 1355 (Fed. Cir. 2013) ("[E]ven in the case of third-party uses, being 'accessible to the public' still requires public availability; secret or confidential third-party uses do not invalidate later-filed patents [under § 102(b)]."); *TP Labs., Inc. v. Prof'l Positioners, Inc.*, 724 F.2d 965, 972 (Fed. Cir. 1984) ("[A] pledge of confidentiality is indicative of the inventor's continued control [over the invention]."). To the contrary, this type of confidential contract manufacturing transaction necessarily *precedes* the inventor making the invention freely available to the public.

Treating a confidential CMO manufacturing contract as a commercial "sale" under Section 102(b) also could frustrate the policy of promoting timely public disclosure of the invention. The specter of the on-sale bar will create a dilemma by forcing companies to choose between prematurely filing patent applications with

the barest minimum of technical disclosure, or delaying development of inventions until companies have available internal manufacturing capability. If companies choose to wait until they have acquired costly internal capacity, this will result in a corresponding delay of the filing of patent applications directed to those products and delay the introduction of innovative products to the market. Thus, upholding the Panel Decision could actually undermine the policy goals of the on-sale bar. In contrast, allowing inventors to engage CMOs to provide confidential manufacturing services prior to filing a patent application allows companies without internal manufacturing capacity or expertise to be in a position to get to market more quickly. Use of CMOs therefore could result in companies filing patent applications sooner to coincide with earlier marketing.

Further, a purpose of the on-sale bar is to encourage prompt filing of patent applications by *all* innovators. As discussed above, the Panel Decision likely will have the opposite effect. It encourages only some market participants (those with available internal manufacturing resources) to file early, while discouraging those who choose to rely on third party contractors for the same purpose. *See* Leah C. Fletcher, *Equal Treatment Under Patent Law: A Proposed Exception To The On-Sale Bar*, 13 TEXAS INTELLECTUAL PROPERTY LAW JOURNAL 209, 234-35 (Winter 2005).

Also, a patent holder's engagement of a CMO to confidentially practice a potentially patentable process, or manufacture a potentially patentable product for pre-commercial or confirmatory purposes does not improperly extend the patent holder's monopoly on the invention. The fundamental purpose of the on-sale bar is to prevent an inventor from gaining an "undue advantage over the public by delaying to take out a patent, inasmuch as he thereby preserves the monopoly to himself for a longer period than is allowed by policy of the law." *Pfaff*, 525 U.S. at 64. This policy necessarily implies that the patentee "commercially exploited the invention before the critical date" by selling it to members of the public. *Hospira, Inc.*, 791 F.3d at 1371. *D.L. Auld Co. v. Chroma Graphics Corp.* – the case the *Hospira* Panel relied upon for its holding that the Medicines Company's payment for Ben Venue's services constituted a "sale" – exemplifies this rationale. In *D.L. Auld Co.*, the court found an improper extension of the patentee's monopoly where the patentee received profit from a sale to an ultimate *customer of the patented product* prior to the critical date. *See D.L. Auld Co. v. Chroma Graphics Corp.*, 714 F.2d 1144, 1148 (Fed. Cir. 1983) (patentee attempted to market patented invention to "prospective customers" before the critical date); *see also Metallizing Eng'g Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516, 517-18 (2d Cir. 1946). *D.L. Auld* is simply not analogous to the facts here. The Medicines Company never offered to sell inventions embodying the patented process to

customers prior to the critical date. *The Medicines Co. v. Hospira, Inc.*, 2014 U.S. Dist. LEXIS 43126, at *34-40 (D. Del. Mar. 31, 2014). And the Medicines Company did not profit from the contract for services from Ben Venue. Rather, it was Ben Venue who profited from the contract at issue via receipt of payment from the Medicines Company for its services. *Hospira, Inc.*, 791 F.3d at 1369-70 (noting that the Medicines Company "hired Ben Venue to prepare three batches of bivalirudin" and that the "invoice for these services identifies a 'charge to manufacture Bivalirudin lot'"); Brief for Defendant-Appellee at 7, *The Medicines Co. v. Hospira, Inc.*, No. 14-1469 (Fed. Cir. Jan. 11, 2016), ECF No. 73 ("In late 2006 and early 2007, MedCo paid BVL $347,500 to manufacture and deliver the first three commercial batches using the revised process.").

The *Hospira* Panel concluded that the contract between the Medicines Company and Ben Venue constituted a commercial "sale" because "the sale of the manufacturing services [by Ben Venue to the Medicines Company] provided a commercial benefit to the inventor more than one year before a patent application was filed." *Hospira, Inc.*, 791 F.3d at 1371. But, taking this rule to its logical extreme, *any* step in the commercial development and manufacturing process provides a "commercial benefit" to the inventor – even if the invention is never *actually* commercialized. For example, a product might be manufactured to test batch consistency pursuant to FDA requirements and marked with commercial

product codes, but never actually brought to market. Under the Panel Decision, *any* step taken by a patent holder that indicates preparation for commercial activity (even if that step, for example, occurs before FDA approval) could constitute a "sale" for purposes of the on-sale bar, even in the common situation where the drug never actually reaches the commercial stage.

Furthermore, holding that a contract for third party manufacturing services constitutes a "sale" penalizes companies that choose to take advantage of the efficiencies and flexibilities of contract manufacturing. Under the Panel's logic, the on-sale bar would apply to a company that makes the cost-efficient decision to avail itself of the capital, expertise, or greater resources offered by using a third party contractor – but not to another company that engages in the very same conduct using internal resources. Such a focus on the *form* of the manufacturing relationship without regard to the *economic substance* of the transaction does nothing to further the policies underlying the on-sale bar. Rather, as fully explained in Section III, *infra*, this application of the on-sale bar serves only to make the drug development process even more costly by punishing efficient and quality-enhancing innovation and by deterring future business investment in such innovation.

The panel's decision marks a significant departure from current precedent and portends potentially enormous consequences for many patent holders and their

existing supplier and manufacturing relationships. A confidential contract between a third party manufacturer and a patent holder, where no sale was made to the public prior to the critical date, should not constitute a commercial "sale" under the on-sale bar.

II. The Court Should Revise The Broad Scope of *Special Devices* Holding That There Is No "Supplier Exception."

Special Devices, Inc. v. OEA, Inc. established the principle that no "supplier exception" to the on-sale bar exists where a patent holder had contracted with a supplier to "have the patent's commercial embodiment mass-produced" prior to the critical date. *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353, 1354 (Fed. Cir. 2001).[6] As an initial matter, as stated above, BIO urges the court to find that the confidential provision of pre-commercial third party manufacturing services to a patent holder does not constitute a commercial "sale", which obviates the need to determine whether *Special Devices* applies. To the extent the court continues to apply the on-sale bar to such transactions, BIO urges the court to, at minimum, revise the scope of the *Special Devices* holding to carve out from the on-sale bar contracts between third party manufacturers and patent holders where (1) the

[6] The parties in *Special Devices* conceded that the transactions were "commercial." *Id.* at 1355, 1356. Accordingly, the issue of whether the contracts for production of the patented invention were commercial "sales" was not before the court.

patented product (or a product manufactured by the patented process) was not offered for sale to any potential customer more than one year prior to filing the patent application; (2) the invention was not made available to the public more than one year prior to filing patent application; and (3) the entity who performed the patented process did so pursuant to a confidential contract for manufacturing or related services.

In *Special Devices*, the court confronted a situation where the patent holder had contracted with a supplier to mass-produce a commercial embodiment of the patented invention more than one year before filing a patent application. *Id.* at 1355. The parties in *Special Devices* entered into a requirements contract in which the supplier agreed to meet at least half of the patent holder's needs and the patent holder ordered 20,000 units of the claimed invention for delivery beginning on a date over one year prior to filing the patent application. *Id.* at 1354. In rejecting the "supplier exception," the court made clear that its main concern was that such an exception would allow inventors to "stockpile commercial embodiments of their patented invention via commercial contracts with suppliers" over one year prior to filing a patent application. *Id.*

The *Special Devices* rejection of a "supplier exception" fails to take into account the fact-dependent nature of the on-sale bar inquiry. Courts interpreting *Special Devices* have interpreted its holding as a bright line rule that contracts

between patent holders and suppliers automatically trigger the on-sale bar. *See, e.g., Hamilton Beach Brands, Inc. v. Sunbeam Prods.*, 726 F.3d 1370, 1375 (Fed. Cir. 2013) ("[T]here is no 'supplier exception' to the on-sale bar. Thus, it is of no consequence that the 'commercial offer for sale' at issue in this case was made by Hamilton Beach's own supplier and was made to Hamilton Beach itself."); *Bone Care Int'l, LLC v. Pentech Pharms., Inc.*, 2012 U.S. Dist. LEXIS 43187, at *32 n. 16 (N.D. Ill. Mar. 29, 2012) ("[T]he Court also notes that the Federal Circuit *does not* recognize a 'supplier' exception to the on-sale bar….Thus, it does not matter that the Hauser sales were between a supplier (Hauser) and the patentee (Bone Care)."). Such an interpretation of the "supplier exception" fails to take into account the unique facts and circumstances of each case that do not pose the same concerns as the supplier relationship in *Special Devices*. In many cases, companies who use CMOs as part of the drug development process may not ever commercialize the product or obtain FDA approval. And, to the extent "stockpiling" is a concern, the Panel Decision has no effect on the ability of companies with the in-house capability to manufacture stockpiles. *See* Fletcher, at 235-36 ("The unchallenged ability of the in-house manufacturer to stockpile strongly suggests that, in fact, the on-sale bar is not really intended to deter stockpiling."). In the biotechnology sector, companies would have little to gain, and too much to lose, by delaying patent filings. No rational biotechnology

company would consciously risk losing exclusivity for a new product to an intervening prior art event just to build up a pre-launch stockpile.

This Court need not completely overrule *Special Devices* by establishing a broad unbounded "supplier exception" to the on-sale bar if the Court considers the facts of the particular relationship in question in determining whether a particular transaction constitutes a "commercial sale". Rather, the analysis should be flexible enough to encompass scenarios where the on-sale bar should apply – for example where a "supplier" sells goods to a distributor or marketer. But, at a minimum, BIO urges the Court to revise the scope of the *Special Devices* holding to make clear that the on-sale bar would not apply to a contract between a patent holder and a third party contractor who performs a portion or portions of the drug development and manufacturing process where the following factors are present: (1) the patented product was not offered for sale to any potential customer more than one year prior to filing patent application; (2) the invention was not made available to the public more than one year prior to filing patent application; and (3) the entity who performed the patented process did so pursuant to a confidential contract for manufacturing or related services.

III. The Panel Decision Is Overly Broad and Damaging to Innovation.

The Panel Decision broadly discriminates against the use of third party contractors to manufacture patented inventions. It has a far reach. Applying the

on-sale bar to *any* contract for manufacturing or other production services in which the third party contractor practices the patented method as a part of the manufacturing process significantly affects the reasonable, investment-backed expectations of innovators and undermines future incentives for efficiency and innovation in the biotechnology industry.

In recent years, pharmaceutical and biotechnology companies have increasingly relied on third party contractors to produce their drug substances. These third party contractors – or CMOs – may perform a wide variety of steps of the drug development process, including: active pharmaceutical ingredients (API) manufacturing, finish and/or filling processing, final dosage formulations (FDF) manufacturing and packaging, and preclinical studies. TRANSPARENCY MARKET RESEARCH, HEALTHCARE CMO MARKET: GLOBAL INDUSTRY ANALYSIS, SIZE, SHARE, GROWTH, TRENDS AND FORECAST 2013-2019, Chapter 1, 1.1 (2014). Biopharmaceutical CMOs provide a variety of services, including: cell line development, analysis and characterization of molecules, cell culture and fermentation production technology, purification, final dosage formulations manufacturing and packaging, and assistance with preclinical studies. William Downey, *Trends in Biopharmaceutical Contract Manufacturing*, 31 CHIMICA OGGI – CHEMISTRY TODAY, January/February 2013, at 2, *available at*

http://www.teknoscienze.com/articles/chimica-oggi-chemistry-today-trends-in-biopharmaceutical-contract-manufacturing.aspx#.VsYIu_krIdU.

Subcontracting portions of the drug development and production process to CMOs allows pharmaceutical companies to focus on perfecting their own core competencies while simultaneously partnering with another company whose expertise can complement their own. As a result, both companies can continue to perfect their own manufacturing processes, resulting in better product quality and fewer deviations in each production batch. *See* STUART O. SCHWEITZER, PHARMACEUTICAL ECONOMICS AND POLICY 68 (2007). Such collaborations allow both companies to achieve economies of scale that neither could accomplish on its own. *Id.* Using CMOs yields many other advantages, including reduction of costs and time to market, access to expensive capital and technology, and increased flexibility and commercial capacity. *Id.* at 69. Importantly, outsourcing portions of the manufacturing process avoids the need to invest in expensive technology when a drug may never be approved. *Id.* at 70. Consequently, outsourcing to CMOs is crucially important to small startups and firms without access to capital or production capacity. William Downey, *Trends in Biopharmaceutical Contract Manufacturing*, at 2.

Even larger companies with in-house capacity are increasingly utilizing CMOs to take advantage of the flexibility and efficiencies of production that they

might not otherwise possess. *Id.* In the industry as a whole, an average of 42% of pharmaceutical companies and service providers surveyed outsourced over 50% of their commercial (final dosage) manufacturing; 46% of companies outsourced over 50% of their clinical manufacturing; and 56% of companies outsourced over 50% of their API manufacturing. *2015 Outsourcing Survey*, CONTRACT PHARMA, 40, 44 (May 2015), *available at* contractpharma.com. Over 50% of mid-sized pharmaceutical companies used CMOs, followed by small pharma (38%), big pharma (31%), small biopharma (31%) and big biopharma (21%). *Id.* at 44. The global healthcare CMO market was valued at $97.66 billion in 2012 and is estimated to reach a value of $246.50 billion by 2019. *Healthcare CMO Market is Expected to Reach USD 246.50 Billion Globally in 2019*, MEDGAGET (June 30, 2015), *available at* http://www.medgadget.com/2015/06/healthcare-cmo-market-is-expected-to-reach-usd-246-50-billion-globally-in-2019-2.html.

The *Hospira* Panel held that the on-sale bar was triggered by a contract between CMO and a patent-holder in which the CMO manufactured batches using the patented process. By its terms, this decision would apply to *any* contract in which a patent-holder uses a CMO to assist in producing a product made by a patentable process. Such an interpretation of the on-sale bar discourages use of CMOs and, accordingly, promotes an inefficient and costly method of production of valuable pharmaceuticals. Furthermore, the panel decision needlessly penalizes

companies who choose to manufacture in-house, instead of subcontracting to take advantage of all the flexibilities and technological capabilities of CMOs. The unequal application of the on-sale bar to companies based on the *form* of the manufacturing process they choose to use (*i.e.*, vertically integrated manufacturing instead of subcontracting) and not its *economic substance* does not serve the purposes of the on-sale bar – it only serves to incent inefficient, costly, and irregular manufacture of life enhancing pharmaceutical and biopharmaceutical products.

Given the wide-ranging and growing use of CMOs in the biopharmaceutical industry – widely considered to be essential to the continued growth and development of pharmaceutical drugs and biologics – the decision has dangerous consequences for a large number of existing patent holders in the industry. Thousands of manufacturing transactions involving patented methods have been based on the reasonable belief that the on-sale bar would not be triggered by the decision to outsource a portion of the manufacturing to a CMO. And, going forward, the panel's decision will only encourage "clever" drafting of contracts which do nothing to further the purposes of the on-sale bar and only further increase the costs for companies to develop new products. Thus, the Panel Decision both upends current expectations and assumptions and discourages future

investment and innovation in products essential to the health and well-being of thousands of individuals.

CONCLUSION

For the reasons set forth above, *amicus curiae* BIO urges the court to (1) recognize that a contract for the confidential third party manufacturing services where no sale is made to the public prior to the critical date does not constitute a commercial "sale" within the meaning of the on-sale bar and; (2) clarify that confidential CMO services where no sale is ever made to the public should not fall within the scope of the supplier exception articulated in *Special Devices.*

Respectfully submitted,

March 2, 2016

/s/ Eric J. Marandett

ERIC J. MARANDETT
IRENE OBERMAN KHAGI
CHOATE HALL & STEWART LLP
Two International Place
Boston, MA 02110
Tel. 617.248.5000

Counsel for Biotechnology Innovation Organization

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the appellate CM/ECF system on March 2, 2016.

I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

Dated: March 2, 2016

/s/ Eric J. Marandett
Eric J. Marandett

CERTIFICATE OF COMPLIANCE

I certify that the foregoing BRIEF OF *AMICUS CURIAE* BIOTECHNOLOGY INNOVATION ORGANIZATION (BIO) IN SUPPORT OF PLAINTIFF-APPELLANT THE MEDICINES COMPANY complies with the type-volume limitation of Rule 32(a) of the Federal Rules of Appellate Procedure because it contains 4410 words.

Dated: March 2, 2016

/s/ Eric J. Marandett
Eric J. Marandett