Nos. 14-1469, -1504

IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

THE MEDICINES COMPANY,
Plaintiff-Appellant,

v.

HOSPIRA, INC.,
Defendant-Cross-Appellant.

On Appeal from the United States District Court for the District of Delaware
Case No. 1:09-CV-00750, Judge Richard G. Andrews

BRIEF OF *AMICUS CURIAE* PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA IN SUPPORT OF THE MEDICINES COMPANY

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CERTIFICATE OF INTEREST

In accordance with Federal Circuit Rule 47.4, counsel for Amicus Curiae Pharmaceutical Research and Manufacturers of America certifies the following:

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

   Pharmaceutical Research and Manufacturers of America

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:

   Pharmaceutical Research and Manufacturers of America is a trade association with no parent corporation and with no publicly held company owning 10 percent or more of its stock.

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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Dated: March 2, 2016

Respectfully submitted,

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INTEREST OF *AMICUS CURIAE*

The Pharmaceutical Research and Manufacturers of America ("PhRMA") represents biotechnology and pharmaceutical companies that are devoted to discovering and developing medicines.[1] Those efforts produce the cutting-edge treatments that save, prolong, and improve the quality of the lives of countless individuals around the world every day. Over the past decade, PhRMA's members have secured Food and Drug Administration ("FDA") approval of more than 300 new medicines. In view of the significant failure rate of biopharmaceutical research and development, and the substantial requirements of the FDA to demonstrate safety and efficacy of new products, those results are not obtained cheaply. In 2014 alone, PhRMA members invested roughly $51 billion in discovering and developing new medicines.

PhRMA seeks to advance public policies that foster innovation in new medicines, including by ensuring adequate patent protection to enable and incentivize its members' substantial investments in research and development. To those ends, PhRMA seeks to remove barriers that may arise in the nation's

[1] A complete list of PhRMA members, which includes The Medicines Company and Hospira's parent (Pfizer Inc), is available at http://www.phrma.org/about/member-companies (last visited Mar. 2, 2016). This amicus brief was not authored in whole or in part by a party's counsel, and no individual or entity other than PhRMA and its counsel made any monetary contribution for its preparation or submission.

systems, including the patent laws, for protecting the intellectual property of its members — including as *amicus curiae* before this Court.

INTRODUCTION AND SUMMARY

Nothing in the patent law favors vertically integrated patentees over any other. But that is the result of the erroneous panel decision below. Vertically integrated patentees are free to produce inventory of products embodying the invention before the critical date, but companies that outsource product manufacturing run afoul of the on-sale bar of 35 U.S.C. § 102(b) according to the panel decision. Neither the text nor the policies underlying Section 102(b) — keeping commercialized products in the public domain, incentivizing the prompt disclosure of inventions, and giving an inventor time following sales activity to file for patent protection — justify such divergent treatment or the rigid rule espoused in the decision.

Section 102(b) of the Patent Act[2] bars the obtaining of a patent for an "invention" that was "on sale" more than one year before the filing of a patent application. 35 U.S.C. § 102(b). The Supreme Court has held that this bar requires the invention to be "the subject of a commercial offer of sale." *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 67 (1998). This Court looks to contract principles in determining when a "sale" is offered, and a sale (in keeping with the Uniform

[2] This brief addresses the on-sale bar as it existed before the enactment of the Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011).

Commercial Code) requires a transfer of title for a price. The panel is correct that this definition need not be inflexibly applied, and transactions that are the economic equivalents of sales, but do not involve transfer of title (for example, commercial software licenses or sham transactions), may still be covered by the on-sale bar.

But an extension of the on-sale bar to the economic equivalents of commercial sales does not mean that every contractual transaction involving delivery of product from Entity A to Entity B for consideration constitutes a sale. This Court should clarify that there is a fundamental difference between a bar-triggering sale of goods and a contract for manufacturing services where the manufacturer is not the owner of the goods (and thus has no title to convey). Companies without appropriate (or any) manufacturing facilities, with capacity constraints, or without a given manufacturing expertise, for example, may find it more efficient to contract the manufacturing of the patentee's design, exclusively for the patentee's inventory, to a third party. Not only is such a transaction not literally a "sale" in the absence of a transfer of title, but denying patentability by extending the definition of a sale is unnecessary to vindicate the policies underlying Section 102(b). In this circumstance, the patentee has not itself offered the good for sale, or otherwise attempted to exploit the invention commercially, when it pays for manufacturing services and builds inventory. Nor is this a case

where a third party has offered the invention for public sale for over a year, and acceptance of the patent would claw back inventions already in the public domain. To the extent that *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353 (Fed. Cir. 2001), compels the contrary result, it should be overruled or revised.

The panel decision generally disfavors smaller companies, including smaller pharmaceutical and biotech companies and start-ups, as well as individual inventors — all of whom often lack the assets to internalize manufacturing and distribution. The panel decision's rule is particularly deleterious in the biopharmaceutical industry because it penalizes companies that choose to focus on research and development and outsource manufacturing and distribution. Many such companies are smaller pharmaceutical companies that rely on the assistance of third parties, such as contract research organizations, contract manufacturing organizations ("CMOs"), and contract sales organizations ("CSOs"), because they lack the expertise or means to do all of the work needed for new drug discovery and development within their facilities. But the panel's decision also impacts larger pharmaceutical companies that are looking to focus their efforts on research and reduce the massive investment required to manufacture and distribute new drugs. This is especially important in the current economic environment, where costs stemming from drug research and discovery, competition from generic drug companies, and litigation are all increasing. An inflexible rule creating an on-sale

bar in circumstances involving third-party supply of a patented invention to a patentee or licensee could deter research and discovery of new drugs and new drug treatments.

The on-sale bar is not meant to interfere with manufacturing efficiency, or to discriminate between different classes of patentees. The *en banc* Court should reject the panel opinion's unwarranted extension of the on-sale bar rule to contract manufacturing of a company's own products, which is neither a sale nor tantamount to a sale.

BACKGROUND

Research and development are the lifeblood of innovation in the United States, particularly in the pharmaceutical industry. Much of that work is performed by pharmaceutical and biotechnology companies with particular expertise, who focus their energy on discovering important pharmaceutical breakthroughs, while outsourcing other aspects of the manufacturing and distribution process. *See* Mannching Sherry Ku, *Recent Trends in Specialty Pharma Business Model*, 23 Journal of Food and Drug Analysis (2015) (noting that, as opposed to traditional, vertically integrated pharmaceutical companies, specialty companies focus on certain core activities and rely on a network of contract organizations to accomplish their goals) ("Ku"); *see also* Andrew Moore, *The Big and Small of Drug Discovery*, 4 EMBO Reports 114, 116 (2003). Indeed,

over the past two decades, FDA data show that the share of new molecular entity approvals going to small- and mid-size biotechnology companies has increased. *See* Steven M. Paul et al., *How to improve R&D productivity: The pharmaceutical industry's grand challenge*, 9 Nature Reviews, Drug Discovery 203 (2010). Smaller pharmaceutical companies are important to this country's healthcare industry, and the law should not be lightly interpreted to disadvantage their contributions to the industry.

The pure cost of drug development has forced companies with fewer assets to focus their efforts on research. Even the process for obtaining FDA approval is lengthy and difficult, requiring an estimated 10 years and $2.6 billion.[3] As such, smaller pharmaceutical companies — and, more recently, some larger companies — contract with third parties like CMOs and CSOs to conduct certain manufacturing and distribution-related activities. By externalizing the manufacturing process and/or establishing future distribution and marketing networks, those companies can utilize existing facilities, at less than full capacity, to avoid or delay the significant capital and operating costs required to bring their product to market. Costs are lowered because the company does not need to start from square one, but can take advantage of the existing skill and investment of the

[3] *See* PhRMA, *Biopharmaceutical Research & Development: The Process Behind New Medicines*, at 1 (2015), *available at* http://www.phrma.org/sites/default/files/pdf/rd_brochure_022307.pdf (last visited Mar. 2, 2016).

third party. Without that help, smaller companies in particular would face hardships inventing new medicines and bringing them to the public. *See, e.g.*, Ku at 596.

With their attention solely on innovation, smaller pharmaceutical and biotechnology companies have an important role in the innovation ecosystem. As a result, research-focused pharmaceutical and biotechnology companies should be protected and allowed to concentrate on what they do best. Even generic drug companies depend on those efforts: Without the introduction of new drugs, there would be nothing to copy. Indeed, while a specific generic drug company may have an interest in invoking the on-sale bar to invalidate a particular patent in a given case, generic manufacturers collectively benefit from measures that incentivize drug research and development. Reducing the incentive for innovation inherently reduces the eventual availability of all drugs, both branded and generic. Furthermore, the policy reasons for creation of the on-sale bar, such as keeping commercialized products in the public domain and incentivizing the prompt disclosure of inventions, are not jeopardized where, as here, an innovator contracts for the manufacture of its own product for its own development work.

ARGUMENT

A. Outsourcing Transactions Do Not Constitute Commercial Sales under 35 U.S.C. § 102(b)

In *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55 (1998), the Supreme Court adopted a two-part test for the application of Section 102(b)'s on-sale bar: "the product must be the subject of a commercial offer for sale" and "the invention must be ready for patenting." *Id.* at 67. Animating the Court was a desire to prevent an applicant from (i) putting his invention into public use before seeking patent protection and (ii) removing existing knowledge, gained through the sale of an article, from public use. *Id.* at 64. In other words, "it is a condition upon an inventor's right to a patent that he shall not exploit his discovery competitively after it is ready for patenting," thereby improperly extending his statutory period of exclusivity. *Id.* at 68 (citing *Metallizing Eng'g Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516, 520 (2d Cir. 1946)).

1. A "Sale" Should Presumptively Require Transfer of Title or an Economically Equivalent Commercial Transaction

A threshold question for application of Section 102(b) is what constitutes an invalidating "sale" for purposes of the on-sale bar. This Court looks to the Uniform Commercial Code ("U.C.C.") for guidance as to whether certain conduct rises to the level of a commercial sale or offer for sale. *Grp. One, Ltd. v. Hallmark Cards, Inc.*, 254 F.3d 1041, 1047 (Fed. Cir. 2001); *Linear Tech. Corp. v. Micrel, Inc.*, 275 F.3d 1040, 1048-50 (Fed. Cir. 2001). Under Article 2 of the U.C.C., a

"'sale' consists in the passing of title from the seller to the buyer for a price." Section 2-106. This Court, consistent with the U.C.C., has long defined a sale for purposes of Section 102(b) as "a contract between parties to give and to pass rights of property for consideration which the buyer pays or promises to pay the seller for the thing bought or sold." *In re Caveney*, 761 F.2d 671, 676 (Fed. Cir. 1985). In *Group One*, the Court noted that "[a]pplying established concepts of contract law, rather than some more amorphous test, implements the broad goal of *Pfaff*, which, in replacing this court's 'totality of the circumstances' test with more precise requirements, was to bring greater certainty to the analysis of the on-sale bar." 254 F.3d at 1047.

Accordingly, this Court has abandoned the concept, announced in cases decided under the now-discarded totality-of-the-circumstances test, that something less than a formal offer of sale might suffice: "Only an offer which rises to the level of a commercial offer for sale, one which the other party could make into a binding contract by simple acceptance (assuming consideration), constitutes an offer for sale under § 102(b)." *Grp. One*, 254 F.3d at 1048; *Linear Tech.*, 275 F.3d at 1048-50; *Minn. Mining & Mfg. Co. v. Chemque, Inc.*, 303 F.3d 1294, 1307-08 (Fed. Cir. 2002) (noting that an offer must be something the acceptance of which "would create a contract," *i.e.*, "'the manifestation of willingness to enter into a bargain, so made as to justify another person in understanding that his assent to

that bargain is invited and will conclude it'") (quoting Restatement (Second) of Contracts § 24 (1981)).

Even in establishing this bright-line rule, the Court in *Group One* recognized that, in unique circumstances, an economic equivalent of a sale might also qualify as a "sale" for purposes of Section 102(b). Judge Lourie, in additional remarks, pointed out that software products, by their nature, are typically offered commercially through licenses, yet a license contract should be regarded as "tantamount to a sale" under the statute:

> There may be instances in which a license is tantamount to a sale, and in which a bar may arise from a license. When a product, such as a computer program, is transferred to a customer in a transaction that is tantamount to a sale, the transaction may under commercial law nevertheless still be a license. The transaction is structured as a license (a "shrink wrap" license) so that the seller can restrict what the "buyer" does with the program, in particular, to ensure that it is not duplicated and distributed to others who have not paid the seller for the product. The product is, however, just as immediately transferred to the "buyer" as if it were sold. Notwithstanding the provisions of such a license, it is not contemplated that the product will ever be returned to the seller.

Grp. One, 254 F.3d at 1053 (Lourie, J., additional remarks). The *Group One* majority, albeit in *dicta*, embraced the concept that certain transactions would be deemed tantamount to a sale and included within Section 102(b): "a sale of an interest that entitles the purchaser to possession and use of the machine, unrelated

to any patent present or future, could be couched as a 'license'; such labeling would not prevent the transaction from triggering the on-sale bar, all other requirements being met." 254 F.3d at 1049 n.2; *see also In re Kollar*, 286 F.3d 1326, 1330 n.3 (Fed. Cir. 2002) ("In certain situations, a license . . . may be tantamount to a sale (*e.g.*, a standard computer software license), whereupon the bar of § 102(b) would be triggered because the product is . . . just as immediately transferred to the buyer as if it were sold.") (internal quotation marks and citations omitted). Similarly, the transfer of expensive capital goods might be structured as a long-term lease rather than as an outright sale for tax, financing, or legal purposes, but in economic terms the transaction might be deemed tantamount to a sale. Finally, parties should not be able to evade Section 102(b) with sham transactions; the panel voiced legitimate concerns that allowing transfer of title to be the principal factor in determining whether a sale has occurred could result in the doctrine being easily circumvented. Panel Op. at 4; *Elan Corp. v. Andrx Pharm., Inc.*, 366 F.3d 1336, 1341 (Fed. Cir. 2004) ("simply disguis[ing] a sales price as a licensing fee . . . would not avoid triggering the on-sale bar.").

Thus, this Court should adopt a rule that, under Section 102(b), the "sale" of a product embodying an invention presumptively requires transfer of title, while allowing an exception for economically equivalent commercial transactions tantamount to a sale that do not involve a title transfer where possession and use of

property of the transferor are conveyed to the transferee for a price. But a flexible rule encompassing such transactions within the Section 102(b) bar does not mean that every transaction involving the delivery of products from Entity A to Entity B constitutes a sale, even where there is no transfer of title and no economic equivalence to a sale.

In particular, a distinction should be made between a sale of goods and a contract for manufacturing services where the producer is not the owner of the patented goods (and thus has no title to convey and no power to conduct a sale). Indeed, this Court has previously recognized this delineation, observing that the on-sale bar would not apply when "an individual inventor takes a design to a fabricator and pays the fabricator for its services in fabricating a few sample products." *Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 182 F.3d 888, 891 (Fed. Cir. 1999). It is not the quantity of goods that determines whether there was a sale; it is the nature of the economic transaction. *See id.* at 890-91 (finding a "sale" where: "[t]he transaction at issue undisputedly was a 'sale' in a commercial law sense"; the entities were separate; and "[t]he transaction was invoiced as a sale of product, and the parties understood the transaction to be such"). The producer in the outsourcing context does not have any property rights in the goods and therefore cannot sell them; it simply contracts to provide manufacturing services.

A rule that the economic-equivalence exception cannot be invoked for outsourcing contracts where the producer is not the owner of the goods embodying the invention would provide clear guidance to market participants on what type of conduct would be invalidating (a concern discussed by the Court in *Pfaff*, 525 U.S. at 65-66, and by the panel here, Panel Op. at 4). At the same time, such a rule would still allow for flexible application of the statutory bar where owners of goods engage in commercial transactions tantamount to sales.

Here, the record established that title to the batches produced by Ben Venue Laboratories always remained with The Medicines Company. Principal Br. and Resp. Br. of Hospira at 51. Ben Venue had no freedom to carry out the process, create the product outside of The Medicines Company's authorization and control, or enjoy the product's use after it was made. *See En Banc* Br. of The Medicines Co. at 9-11.

Nor is there any evidence that the agreement was structured as a sham transaction to avoid a commercial sale. Instead, the transaction was one where an inventor without the equipment to create the final product hired another to do so at his direction; in essence, The Medicines Company leased equipment and operating know-how from Ben Venue so that The Medicines Company could manufacture its invention. There was no agreement to transfer "rights of property," *Caveney*, 761 F.2d at 676, but rather a reservation of rights to the assembled products, Resp. and

Reply Br. of The Medicines Co. at 37-38. It cannot be that the offer of payment for services was sufficient to trigger the bar, since the Court has previously held that the exchange of money does not necessarily make a transaction commercial (much less a sale). *Mas-Hamilton Grp. v. LaGard, Inc.*, 156 F.3d 1206, 1217 (Fed. Cir. 1998). Indeed, the mere presence of a contract does not necessarily give rise to an offer for sale.[4] *E.g.*, Trial Op. at 22-23. And, contrary to the panel decision's conception, the inventor did not commercially exploit his invention: *i.e.*, "profit from commercial use of an invention for more than year before an application for patent is filed."[5] Panel Op. at 4. Under the more flexible on-sale bar test articulated above, The Medicines Company's conduct would not rise to the level of an invalidating sale since there was no commercial sale or exploitation of the invention.

2. This Court Should Overrule or Revise the No "Supplier Exception"

To make way for a more flexible rule, the Court should revisit its rigid standard in *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353 (Fed. Cir. 2001), that the on-sale bar is triggered whenever there is delivery of product from a supplier to

[4] For example, there is no definite sale or offer for sale when two parties agree to future distribution channels for potential future sales, the use of which is subject to some condition precedent (*e.g.*, satisfying FDA-approval requirements).

[5] Ben Venue was not in the business of selling products embodying the claimed invention to potential users, *see Caveney*, 761 F.2d at 676, but instead was providing a service exclusively to The Medicines Company.

another entity for consideration.[6] As discussed above, a more adaptable approach that addresses the nature of the transaction between the parties is the correct rule. While certain transactions between a third party and an inventor can give rise to the on-sale bar, the sole fact that a third party created an embodiment of the invention should not by itself trigger the bar. In other words, an inventor should have the freedom to outsource certain activities without risking forfeiture of potential patent rights.

Special Devices misapprehended Section 102(b) when it found that there was "no room for a 'supplier' exception" merely because the law was silent regarding sales from suppliers. 270 F.3d at 1355. PhRMA is not advocating an exception from the "commercial offer of sale" doctrine established in *Pfaff*; it is simply pointing out that not all contracts outsourcing the production of goods involve commercial offers of sale of the invention. It is undisputed that the on-sale bar may be triggered where a third party has commercially offered the product for sale. *Zacharin v. United States*, 213 F.3d 1366, 1370-71 (Fed. Cir. 2000). But contracting with a third-party vendor — one that has never previously produced the product and has no property right therein — to manufacture an invention on the

[6] While instructive, *Special Devices* is arguably not direct precedent for the present case. The *Special Devices* patentee conceded that the transactions at issue were commercial in nature. 270 F.3d at 1355. That is not the case here, however, where the transaction between Ben Venue and The Medicines Company (irrespective of whether it was experimental) was not commercial in nature. *See infra*, Section B.

inventor's behalf does not remove it from the public domain (because it was never placed there). Nor does such outsourcing promote delays in the filing of patent applications. Rather, it puts the inventor in the same position as if it were manufacturing the invention in-house.

Instead of performing that analysis, the panel decision here (like the one in *Special Devices*) created a fixed rule that any transaction with a third party "supplier" that results in a product that is ultimately sold is an invalidating sale. That is inappropriate for several reasons. First, whether the product supplied is eventually sold should not color the transaction between the supplier and the inventor. A manufacturing transaction that does not rise to the level of a commercial sale should not be relevant to whether an invalidating sale potentially could occur downstream, as such a downstream transaction must be considered separately, with respect to the time and manner of the transaction, from the manufacturing service transaction. Second, a supplier whose sole role is to fabricate a product according to instructions provided by the inventor would invoke Section 102(b) under the panel decision's reasoning, but should be clear of the bar under this Court's *Brasseler* decision. 182 F. 3d at 891 (reasoning that commercial exploitation of an invention before the critical date does not occur if "an individual inventor takes a design to a fabricator and pays the fabricator for its services in fabricating a few sample products"). This Court has not articulated

how the goals underpinning the on-sale bar are furthered by the fabricator exception in *Brasseler*, yet thwarted by a supplier exception in *Special Devices*.[7]

At a minimum, this Court may leave open the case of whether a supplier that makes a commercial offer to sell products designed by the inventor back to the inventor is subject to the on-sale bar. *See Brasseler*, 182 F.3d at 890-91 (explaining that "[t]he transaction at issue undisputedly was a 'sale' in a commercial law sense" and was "invoiced as a sale of product"); *Hamilton Beach Brands, Inc. v. Sunbeam Prods., Inc.*, 726 F.3d 1370, 1375 (Fed. Cir. 2013) (purchase order of 2,000 units). But it should adopt the economic-equivalent rule proposed here and clarify that a straightforward contract for manufacturing services is not a commercial sale or offer of sale of a product-by-process invention within the meaning of Section 102(b).

B. Sales of Third-Party Manufacturing Services Are Not Sales of the "Invention" for Product Patents

The panel acknowledged that, because The Medicines Company "paid Ben Venue for performing services that resulted in the patented product-by-process . . . a 'sale' of services occurred," rather than a sale of products embodying the

[7] As discussed below in Section B, it cannot be that the number of units produced is determinative. Whether 10 or 10,000 products are made does not impact whether they are placed into the public domain. At the same time, if such a consideration were relevant, a company could stockpile inventory if the market is such that sales are large and infrequent, all without running afoul of *Special Devices*.

invention. Panel Op. at 5. Nonetheless, the Court found that the on-sale bar applied equally to the patentee's sale of a product embodying (or produced by) an invention and to a third-party's sale of services to the patentee. *See id.*

The panel decision's statement that *D.L. Auld Co. v. Chroma Graphics Corp.*, 714 F.2d 1144 (Fed. Cir. 1983), compelled this result is incorrect. Panel Op. at 5. And to the extent any language in *D.L. Auld* could be construed as compelling such a result, the *en banc* Court now has an opportunity to clarify the law. The *D.L. Auld* Court, in a case involving a method claim, emphasized that, despite the parties' reliance on "numerous cases involving 'on sale' considerations in respect of product inventions under 35 U.S.C. § 102(b)," "[t]he focus of inquiry here . . . is on the method." *Id.* at 1147. The Court then pronounced (and applied) an unexceptional rule for applying the on-sale bar to method claims: Where a "sale is made by the applicant for patent or his assignee," "a party's placing of the product of a method invention on sale more than a year before that party's application filing date must act as a forfeiture of any right to the grant of a valid patent on the method to that party if circumvention of the policy animating § 102(b) is to be avoided in respect of patents on method inventions." *Id.* at 1147-48.

The panel decision's reliance on *D.L. Auld* is mistaken for two reasons. First, it characterized *D.L. Auld* as a case where "the inventor did not transfer title

to the commercial embodiment of the invention." Panel Op. at 4. But that fact is irrelevant. The on-sale bar does not require an actual sale or actual title transfer, but only a "commercial offer for sale," *Hamilton Beach*, 726 F.3d at 1374 ("An actual sale is not required for the activity to be an invalidating commercial offer for sale."), which is ordinarily a definite offer to transfer title to a good for a price. *Supra*, Section A.1. The patentee in *D.L. Auld* was found to have made at least one such offer. *See* 714 F.2d at 1148 (noting that, before the critical date, "Auld quoted pricing and delivery dates in writing, for an order of more than 150,000 emblems, to International Crest"). Nothing in *D.L. Auld* casts doubt on the presumptive rule that a commercial offer for sale consists of an offer to transfer title to a good for a price.

Second, the panel decision declared that there is "no principled distinction between the commercial sale of products prepared by the patented method at issue in *D.L. Auld* and the commercial sale of services that result in the patented product-by-process here." Panel Op. at 5. But the distinction is drawn in Section 102(b) itself, which denies a patent only 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) (emphasis added); *see Pfaff*, 525 U.S. at 67 (noting that the on-sale bar of Section 102(b) is measured "against the date when *an*

invention that is ready for patenting is first marketed commercially") (emphasis added).

In product-by-process claims of the kind at issue here, the services that are used to perform the process do not themselves constitute the invention (even if they may be part of it) and do not embody the invention (which is a product). Thus, simply offering or selling manufacturing services that can be used to make an invention does not place the invention itself on sale. Significantly, the panel decision is also so broadly phrased as to apply potentially to pure product claims as well. By contrast, for a patented method, either a commercial offer to perform the method for a price, or to sell a product produced by the method, are deemed to be an offer to sell the invention (*i.e.*, the method). *See Kollar*, 286 F.3d at 1333. Because *D.L. Auld* involved the patentee's commercial offer to sell (and transfer title to) a product produced by the invention, the on-sale bar served there to "preclude attempts by the inventor or his assignee to profit from commercial use of [that] invention for more than a year before an application for patent [was] filed." 714 F.2d at 1147.

Here, there was no commercial offer for sale (or sale) by the patentee or a third party of goods embodying the invention. The record instead showed a purchase of unclaimed manufacturing services to produce such goods on behalf of the inventor. Nor did The Medicines Company earn a profit simply by paying a

supplier to produce goods according to its specification. Nothing in Section 102(b) precludes a patentee from building an internal inventory of patented goods embodying an invention in anticipation of later making future offers for sale (or for future non-commercial purposes, such as the process required for regulatory approval) before filing a patent application. *See Pennock v. Dialogue*, 27 U.S. 1, 18-19 (1829) (in applying a predecessor statutory bar, holding that the legislature could not have sought to prohibit "employ[ing] others to assist in the original structure or use by the inventor himself" of his invention). It is only when the patentee makes a commercial offer of sale of the products embodying the invention that patent rights will have been exploited, which, a year from that point, will trigger the on-sale bar.

The governing authority is not *D.L. Auld*, but *Trading Technologies International, Inc. v. eSpeed, Inc.*, 595 F.3d 1340 (Fed. Cir. 2010). In *Trading Technologies*, this Court concluded that an inventor's contract with a third-party-supplier software company did not meet the requisites for triggering the on-sale bar. An inventor of patented trading software (who "lacked the technical expertise" to develop the software himself) entered into a consulting agreement with a software development firm. *Id.* at 1361. The supplier agreed to "'build a new trading window according to specifications provided [by the inventor],' and the inventor "agreed to pay [the supplier] for the custom software." *Id.* The

contract, however, was one "for providing hourly programming services to" the patentee, who "did not sell or offer for sale anything embodying the invention." *Id.* This Court agreed that "the invention had not been offered for a commercial sale," for "[i]nventors can request another entity's services in developing products embodying the invention without triggering the on-sale bar." *Id.* at 1361-62.

The panel opinion attempted to distinguish *Trading Technologies*, but instead has created confusion and conflict in the law. In both that case and the present appeal, the inventors lacked the ability on their own to create an embodiment of the claimed invention. Both inventors contracted with a third-party vendor to create the embodiment according to specifications provided by the inventor. And in both cases, the inventor "did not sell or offer for sale anything embodying the invention" by operation of that services contract. *Trading Techs.*, 595 F.3d at 1361. The opinion nonetheless attempted to draw a distinction between the software in *Trading Technologies* that was prepared for the inventor's "secret, personal use," *id.* at 1362, and the batches here that "were prepared for commercial exploitation" — with that commercial exploitation being presumed and at some unknown point in the future, including after patent filing. Panel Op. at 6 (emphasis omitted).

The on-sale bar, however, is triggered by *actual* commercial exploitation, not preparation for that exploitation. Indeed, the entire research process is,

hopefully, preparation for commercial exploitation. As this Court stated, "[i]t is not a violation of the on-sale bar to make preparations for the sale of a claimed invention—an actual sale or offer to sell must be proved." *Intel Corp. v. Int'l Trade Comm'n*, 946 F.2d 821, 830 (Fed. Cir. 1991); *cf. Poly-America, L.P. v. GSE Lining Tech., Inc.*, 383 F.3d 1303, 1309 (Fed. Cir. 2004) (explaining that a pre-critical date sale of a machine usable in a patented process is not an offer of sale of the process and does not trigger the on-sale bar).

The decision also attempted to distinguish *Trading Technologies* based on the amount of product produced here and its eventual market value, Panel Op. 6,[8] but such facts are irrelevant. The holding of *Trading Technologies* is that a contract for services was not a sale of products, and that rule does not vary with the size or value of the contract. But even to use the volume of product manufactured and its market value as a proxy for commercial exploitation of the claimed invention misses the point. An inventor does not exploit his invention commercially by outsourcing its manufacture. Indeed, the policy of prohibiting commercial sales has historically been targeted primarily at the inventor himself,

[8] The panel decision presents a discordant view of the commercial activity triggering the on-sale bar. For purposes of the alleged sale, it references the transaction between Ben Venue and The Medicines Company. For purposes of the market value of that transaction, however, it looks several steps downstream, to when the drugs actually were sold to consumers. *See* Combined Pet. for Panel Reh'g and Reh'g En Banc of The Medicines Co. at 7. That lack of consistency in identifying the relevant timeframe underscores its lack of relevance.

not a fabricator selling services to the inventor. *See, e.g.*, *Pfaff*, 525 U.S. at 67 ("An inventor can both understand and control the timing of the first commercial marketing of his invention."). That the inventor makes no revenue on the transaction and retains the economic benefits of the product are yet further support that the inventor has not exploited his invention.

C. The Panel Decision Creates Unequal Patent Rights for Companies Without In-House Manufacturing Facilities

The panel decision creates an unwarranted imbalance between the patent rights of companies large enough to have their own manufacturing and distribution operations and smaller companies that do not. If one corporation owned the intellectual property, the physical manufacturing equipment, and the distribution network, there would be no on-sale bar issue. *See, e.g.*, *Caveney*, 761 F.2d at 676 ("[A] sale or offer to sell under 35 U.S.C. § 102(b) must be between two separate entities."). Instead, under the rule of the decision below, an inventor's reliance on third parties to achieve the same end triggers the statutory bar.

That rule "would disadvantage small pharmaceutical companies who fairly commonly outsource mixing and packaging because of the capital investment and specialized knowledge required to operate the machinery." *Dey, L.P. v. Teva Parenteral Meds., Inc.*, 6 F. Supp. 3d 651, 671 (N.D.W. Va. 2014) (internal quotation marks omitted), *aff'd*, 600 F. App'x 773 (Fed. Cir. 2015); *cf. Monon Corp. v. Stoughton Trailers, Inc.*, 239 F.3d 1253, 1258-61 (Fed. Cir. 2001)

(reversing summary judgment of invalidity and concluding that the sale was non-commercial where the patentee paid a third party to test its patented trailer because it lacked in-house testing capabilities). It makes little sense for the application of the statutory bar to hinge on a company's ability to buy manufacturing equipment or decisions of corporate structure. Outsourced manufacturing at the inventor's direction should not be invalidating when in-house manufacturing is permissible.

Indeed, under the panel's decision, a hypothetical patentee would lose its patent rights even if it supplied all of the components of the claimed invention and directed how they were to be assembled, solely because it lacked the ability within its corporate structure to perform the assembly itself. Like licensing of the invention, which does not trigger the statutory bar, outsourcing of manufacturing and distribution — which would allow a smaller pharmaceutical company to do what its larger counterpart can do — is not inconsistent with the traditional policies underlying the on-sale bar. *See Kollar*, 286 F.3d at 1333-34. In neither circumstance can the public "justifiably believe that an invention is freely available," for such practices usually are protected by confidentiality obligations and do "not involve an embodiment of the invention that is publicly available." *Id.* at 1334. Second, each practice "in fact further[s] the objective of making inventions available to the public 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.* "Many inventors do not have the resources to produce commercial embodiments of their inventions," and a rule that allows patentees to pursue such production "without fear of triggering the on-sale bar facilitates 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.* Lastly, "the real benefit from commercializing an invention occurs when the invention is actually utilized commercially or made available to the public," and (like licensing) contracting for manufacturing services "is only part of the pre-commercialization process aimed at making the invention commercial." *Id.*

The on-sale bar is not implicated by outsourcing contracts any more than by patent licensing or doing externally what another company permissibly can do internally. All inventors, regardless of size, should be treated equally and have the same incentive structures.

CONCLUSION

This Court should reject the panel decision and rule that a contract to provide manufacturing services does not constitute a commercial offer to sell the product-by-process invention at issue in this case.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE
PURSUANT TO FED. R. APP. P. 29(d)

I certify that this brief complies with the type-volume limitation of Fed. R. App. P. 29(d) because this brief contains 6,603 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

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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.

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