No. 14-1469, 14-1504

United States Court Of Appeals for the Federal Circuit

THE MEDICINES COMPANY,

Plaintiff-Appellant,

v.

HOSPIRA, INC.,

Defendant-Cross Appellant,

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE
CASE NO. 09-CV-750-RGA, JUDGE RICHARD G. ANDREWS

BRIEF OF AMICUS CURIAE GILEAD SCIENCES, INC. IN SUPPORT OF PLAINTIFF-APPELLANT

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March 2, 2016

CERTIFICATE OF INTEREST

1. The full name of every party represented by me is: Gilead Sciences, Inc.

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 represented by me are: N/A.

4. The names of all law firms and the partners or associates that appeared for the party now represented by me in the trial court or agency or are expected to appear in this court are:

Fish & Richardson P.C.: Jonathan E. Singer, Craig E. Countryman, and Jared A. Smith

Gilead Sciences, Inc.: Lori Mayall and Tim Marquart

Dated: March 2, 2016

/s/ Craig E. Countryman
Craig E. Countryman

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INTEREST OF AMICUS CURIAE

Gilead Sciences, Inc. is a biopharmaceutical company that discovers, develops, and commercializes medicines to fulfill unmet medical needs, including ground-breaking treatments for HIV/AIDS, liver diseases, cancer, and serious respiratory and cardiovascular conditions. Gilead created the first complete HIV treatment in a once-daily tablet and the first Hepatitis C treatment to provide a complete regimen in a single tablet that can potentially cure the most common form of the disease.

Gilead relies on patents to protect its investment in developing these new treatments. Gilead has invested billions in research and development, and it has obtained approximately 500 U.S. patents. Gilead is a small company within the biopharmaceutical field of only about 8,000 employees. As such, it must partner with contract manufacturers to efficiently make and supply large enough quantities of many of its drugs, both for FDA testing and for eventual commercial sale. But the panel's decision in this case makes this practice extremely risky, as it raises the specter of creating a § 102(b) bar when the manufacturer transfers the drug to Gilead, even though Gilead is still testing whether the drug will be safe and effective in humans and, as a result, might not yet have filed a patent application.

Gilead has a strong interest in preventing this threat to the patent incentive, as it relies on patents to fund its research, and, without patents, many of its potential products could never make it to market. Gilead certifies under Rule 29(c)(5) that no one else authored this brief or contributed money to its preparation.

INTRODUCTION

The panel's decision, if allowed to stand, will impair the ability of patents to protect investments in developing new drugs. Before a new drug may be marketed, extensive testing is required for FDA approval. Nearly all pharmaceutical companies rely on third-party manufacturers to make the large quantity of product needed for FDA testing. As a small company within the biopharmaceutical field, Gilead in particular must rely upon contract manufacturers during this development process to bring its products to market as rapidly and efficiently as possible. As such, Gilead and other innovators might not be able to file for a patent before it must go to a contract manufacturer. But the panel's approach makes this salutary practice extremely risky—an innovator's payment for manufacturing services constitutes an invalidating "sale," blocking it from obtaining a patent well before an innovator could actually sell the patented invention to the intended consumer.

The *en banc* Court should eliminate this problem by returning the on-sale bar to the statutory text. Section 102(b) states that only a sale of the patented "invention" will bar a patent, and the claimed invention here is a drug product. The patentee's payment for manufacturing services is not a sale of the product and thus cannot be an invalidating sale of the "invention," especially where the patentee always holds title to the product itself. Moreover, any "sale" of a product necessarily requires two separate parties—a buyer and a seller. But here the patentee and its manufacturer were effectively functioning as one, because the patentee directed and controlled the

manufacturer's activity. Tort law principles thus justify treating the manufacturing as if it were conducted by the patentee itself, meaning there could be no arm's length "sale" of the "invention." Applying those principles here makes perfect sense, as it avoids the asymmetry of treating a patentee's in-house manufacturing differently than a patentee's use of an agent to manufacture on its behalf. The two types of conduct are economically equivalent—and the law should treat similar conduct similarly.

The *en banc* Court should also restore the experimental use doctrine to the proper position required by Supreme Court precedent. The Supreme Court has never required a patentee who has made an invention to either forgo the experiments or forfeit its patent rights, especially in an industry like pharmaceuticals, where an innovator cannot commercially exploit its invention without conducting FDA trials that require large scale production of its products. Nor has it permitted a patentee's subsequent sale of the invention to convert prior experimentation into invalidating activity. Yet the panel, building on a line of precedent, has adopted both ill-founded rules. The *en banc* Court should eliminate this artifice that has been layered onto the *Pfaff* test, as it is inconsistent with both the statute and Supreme Court precedent.

The panel's rules are particularly problematic because penalizing innovator drug companies for relying on manufacturers advances no interest protected by the on-sale bar. The practice does not improperly extend patent term or slow disclosure of new inventions. If anything, a rule that prevents innovators from using third-parties will make it more difficult to test and bring new drugs to market, to the public's detriment.

ARGUMENT

I. The Circumstances Here Do Not Trigger the On-Sale Bar of § 102(b).

A. A Payment for Manufacturing Services Is Not a "Sale" of the Patent Invention Where Product-by-Process Claims Are Involved.

This case can be resolved based on a simple issue of statutory construction, so the analysis "begins and ends" with the statutory text. *Octane Fitness, LLC v. Icon Health & Fitness, Inc.*, 134 S. Ct. 1749, 1755 (2014). Section 102(b) bars patent protection where "the invention" was "in public use or on sale in this country" more than a year before the filing date. 35 U.S.C. § 102(b). The "invention" is, of course, defined by the patent's claims. *See* 35 U.S.C. § 112, ¶ 2. And, in the case of a "product-by-process" claim like the ones at issue here, this Court and its predecessor have repeatedly held that the "invention" is the product, not the process by which it is made. *See, e.g.*, *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1317 (Fed. Cir. 2006) ("Regardless of how broadly or narrowly one construes a product-by-process claim, it is clear that such claims are always to a product, not a process."); *In re Lyons*, 364 F.2d 1005, 1016 (1966) ("[A] product-by-process claim is a product, not a process."). The reason is simple—product-by-process claims were "developed in response to the need to enable an applicant to claim an otherwise patentable product that resists definition by other than the process by which it is made," yet they still claim the product itself as the invention. *In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1985). So an invalidating § 102(b) "sale" of the "invention" covered by a product-by-

process claim must be of a ***product*** itself, not a sale of services for manufacturing the product, because the manufacturing process is not the claimed invention.

No sale of the patented "invention"—*i.e.*, a product—occurred in this case. The district court instead made an explicit factual finding that the manufacturer (Ben Venue Laboratories) sold only the performance of manufacturing services, not the product itself. (A21 ("The Medicines Company paid Ben Venue to manufacture validation batches.").) The court's finding was well-supported, as the invoices for the transaction stated that they were for a "[c]harge to ***manufacture*** Bivalirudin lot," not a charge for the product itself. (A17177-78; A24.) The absence of any transfer of title underscores that the payment was for manufacturing services, not the product—Ben Venue could not have been selling the product, because it had no legal rights to it. *See, e.g.*, Uniform Commercial Code § 2-106(1) (defining a "sale" as "the passing of title from the seller to the buyer for a price").

The panel recognized as much, acknowledging that "the district court is correct that Ben Venue invoiced the sale as manufacturing services," and treating the transaction as "the commercial sale of services." *The Medicines Co. v. Hospira, Inc.*, 791 F.3d 1368, 1370-71 (Fed. Cir. 2015). That should have been the end of this case under the text of 35 U.S.C. § 102(b). The claimed "invention" was not a manufacturing process but a product, and neither the district court nor the panel found that the sale of a product occurred.

The panel nevertheless departed from the statutory text by pointing to prior cases—*D.L. Auld Co. v. Chroma Graphics Corp.*, 714 F.2d 1144 (Fed. Cir. 1983) and *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983)—that addressed whether a sale of the performance of a patented method was invalidating under § 102(b). Neither purported to address whether claims to a product would be invalid by a paying another to manufacture the product. Both cases instead distinguished between method and product claims.

For example, in *D.L. Auld*, the Court stressed that the "invention is a method," rejected the parties' citations to "considerations in respect of product inventions," and emphasized that "[t]he focus of inquiry here, however, is on the method." *See* 714 F.2d at 1147. The plaintiff had commercially exploited the patented method to make emblems that it distributed to potential customers, such as Ford, GM, and the National Football League. *Id.* at 1148-49. As a result, the plaintiff was selling the "invention"—it was performing the patented method to generate emblems for outside customers in exchange for money—thus triggering the on-sale bar of § 102(b). The decision there simply reflects the fact that the only way for the patentee to monetize its invention (a method of making emblems) was to charge people for emblems produced by that method.

By contrast, in *W.L. Gore*, the Court dealt with a situation where a third-party had secretly used the patented process to produce tape, and then sold the tape to others. *See* 721 F.2d at 1549-50. This did not render the claims invalid, because "[i]f

[the third-party] offered and sold anything, it was only tape, not whatever process was used in producing it." *Id.* at 1550. That underscores that the on-sale bar applies to a sale of the "invention," and that a sale of a product (which was not claimed) differs from selling the performance of a method (which was claimed). The Court added that, if the third-party had itself tried to obtain a patent, its sale of the tape might have prevented it from doing so because, as in *D.L. Auld*, it would have been commercially exploiting the patented method by selling the result of that method. But this case presents the opposite situation—the manufacturer is not selling a product at all; it is simply charging for carrying out a process that is not the patented invention.

So the panel had no basis for departing from the statutory text, and that departure is particularly unwise as it undermines the easy-to-follow bright-line rule the statute sets forth. Under the statutory text, an inventor can know that a sale of the "invention" starts the clock for seeking patent protection but that payments for other things that are not the "invention" do not. *See, e.g.*, *Trading Techs. Int'l, Inc. v. eSpeed, Inc.*, 595 F.3d 1340, 1362 (Fed. Cir. 2010) (no § 102(b) bar based on a "contract for providing hourly programming services" where the claimed inventions were software methods). The panel, by contrast, has created a trap for unwary innovators by holding that a payment for something other than the invention can nevertheless be invalidating if, years later, a court determines it is close enough to constitute "commercial exploitation" of the invention. Such an unpredictable standard is more difficult to apply in practice and is contrary to the Supreme Court's admonition that

there should be "a definite standard for determining when a patent application must be filed." *Pfaff v. Wells Elecs., Inc.,* 525 U.S. 55, 65 (1998). It will also likely upset the settled expectations of pharmaceutical companies who sought patents to products while relying on the statutory text to conclude that payments for third-party manufacturing services were not a sale of the "invention." And it discourages companies from manufacturing their products in the most economically efficient manner—*i.e.*, by outsourcing the task to a specialist firm—because they now run the risk that doing so will invalidate their patents, while manufacturing in-house triggers no such bar.

B. The Transaction Here Was Experimental at the Time It Occurred, and Subsequent Commercial Resale of the Product Is Irrelevant.

The *en banc* order asks whether the transaction here is commercial or experimental. The answer turns on the time period that one considers. There should be little debate that the three product batches at issue were prepared for experimental purposes when Ben Venue initially sent them to the patentee. The district court found that they were "made in order to verify that the invention worked for its intended purpose," (A24), and, indeed, the batches were prepared in accordance with FDA Guidelines to test whether they had sufficiently eliminated impurities, as contemplated by the patent claims (which require an impurity level of Asp^9–bivalirudin of less than about 0.6%). (*See, e.g.*, A14880, A14884, A14893.) It wasn't certain whether these batches successfully limited the impurities until after these tests

were run—otherwise there would have been no reason to run the tests. The panel made two mistakes in setting aside those findings.

First, the panel erred by focusing on developments occurring well after the transaction between Ben Venue and the patentee. The panel pointed to the fact that each batch, once its composition was validated, could be sold to outside customers for over $10 million. *The Medicines Co.*, 791 F.3d at 1371. But this says nothing about whether the transaction between Ben Venue and the patentee was commercial—the validation experiments might have failed, in which case the batches would have been worthless. The panel also observed that "the inventor was well aware that the batches had levels of Asp^9-bivalirudin well below the claimed levels of 0.6%," *id.* at 1372, but it appears that the inventor had this knowledge only after running the experiments on the first three batches, along with many subsequent ones. (A16894 ("As we heard yesterday in videotaped testimony of Dr. Krishna, who is one of the two inventors of the patents in suit, they didn't realize that they had an invention until they analyzed all 25 batches of what we now refer to as the new Angiomax, and that happened only toward the end of 2007, and sometime after July 27, 2007.").) Neither fact undermines the district court's finding that, at the relevant time, the transaction was experimental. (A24 & n.11.)

Hospira's brief makes much (at 38-39) of the fact that testing was done to "confirm" and provide "verification" of the inventors' hypothesis that they had reduced impurities. (A14883-84.) But this doesn't mean the inventors knew the

outcome ahead of time; they had a hunch that proved right. Indeed, the experimental protocol reflected their uncertainty by noting that additional optimization might yet be required. (A14883 ("In the event that further optimizations are required as testing proceeds, additional lots will be manufactured and tested to ensure that the changes are effective.").) That an inventor can correctly predict the result of his experiment does not make it any less of an experiment.

That the same batches were later sold to outside customers does not convert the initial transaction between Ben Venue and the patentee into a commercial sale. It isn't until the patentee actually sells the batches to an outside customer that it reaps any actual commercial advantage from the invention—internal stockpiling of a drug has no independent value until the patentee is able to sell it and reap a profit. No one disputes that the patentee's eventual sale to an outside customer is a triggering § 102(b) event, but all those sales were well after the critical date and not invalidating.

The panel's rule of retroactively conferring "commercial" status on a transaction based on later facts will encourage waste. A patentee looking to head off an argument that there was a commercial sale of batches that it obtains for experimentation and FDA testing would be well-advised to discard them after the testing, even if they succeed, rather than later trying to re-purpose them by selling to outside customers. The patentee would instead be well-advised to obtain a new batch from its manufacturer and sell those to outside customers, to avoid the appearance of any link between the prior experimental transaction and the subsequent commercial

sale. The law should not require such behavior or elevate form over substance in that way.

Second, the panel further erred by applying the rule from prior precedent that the transaction could not be experimental because the invention had already been reduced to practice. *The Medicines Co.*, 791 F.3d at 1372. The rule conflicts with Supreme Court precedent, which has recognized that experimentation can occur for years after the invention is made, so long as the inventor is still focused on perfecting and refining it. *See City of Elizabeth v. Pavement Co.*, 97 U.S. 126, 133-37 (1877) (inventor's installation of a short stretch of road and continual monitoring for six years was experimental, because he needed to test it under actual operating conditions). This conflict has prompted several judges on this Court to call that rule into question. *See, e.g.*, *Hamilton Beach Brands, Inc. v. Sunbeam Prods., Inc.*, 726 F.3d 1370, 1381 n.3 (Fed. Cir. 2013) (Reyna, J., dissenting) ("[T]he circumstances suggest that Hamilton Beach was in the midst of testing and perfecting its slow cookers under the experimental use exception when the offer was made. This is true—and can be true—even if the invention was ready for patenting at that time."); *Atlanta Attachment Co. v. Leggett & Platt, Inc.*, 516 F.3d 1361, 1369 (Fed. Cir. 2008) (Prost & Dyk, JJ., concurring) ("Assuming a complete invention, ready for patenting, inventors should be able to continue to privately develop any claimed aspect of that invention without risking invalidation, if they conduct development activities in a way that is neither

public nor simply commercial, even if there is some commercial benefit to the inventor in connection with the experimental use.").

Those calls for reform are well-founded. There should be no set point after which a transaction's experimental character must be ignored. Inventors should be encouraged to continue trying to refine and improve upon their inventions, especially where, as here, they do it in secret. The present rule discourages such attempts to refine the invention, because, if the inventor is working with a third-party, he runs the risk that obtaining samples of his own invention for further experimentation will trigger a § 102(b) bar.

The panel's approach also creates the odd disparity that a successful inventor may be punished, while an unsuccessful scientist would be free to keep experimenting. For example, the panel was skeptical that these transactions were experimental because the patentee had previously conducted a successful validation study. *The Medicines Co.*, 791 F.3d at 1371. But this second round of testing became necessary after the patentee scaled up the process, moved it to another facility, and sought to further optimize the manufacturing process for those conditions. (A14883.) The testing was designed to measure whether it was still possible to achieve the claimed invention (*i.e.*, a bivalirudin product with reduced Asp9 impurities) with the new manufacturing protocols. (A14884 ("The second objective of this study is to ensure that the process optimizations indeed minimize the risk of high levels of Asp9 impurity in the final product.").) Present law discourages such efforts to further

improve the invention, while allowing scientists who have not yet had any success free rein to keep experimenting. There is no basis for such asymmetry. The experimental use doctrine should be available to all inventors, including the best, not reserved for only the unsuccessful.

C. Section 102(b) Requires an Arm's Length Sale Between Two Entities, Which Is Absent When, as Here, One Company Directs and Controls Its Manufacturer's Conduct.

The *en banc* order also asks whether it should overrule *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353 (Fed. Cir. 2001), which held that there is no "supplier exception" to the on-sale bar of § 102(b). We think that current doctrine should be modified, but that the resulting rule should not be characterized as an "exception" to § 102(b). The statutory text requires a "sale," and, as noted in *Special Devices*, the text is phrased in the passive voice, so it does not leave room for exceptions based on the identity of the participants involved. Nevertheless, "a sale or offer to sell under 35 U.S.C. § 102(b) must be between two separate entities." *Brasseller USA I, LP v. Stryker Sales Corp.*, 182 F.3d 888, 890 (Fed. Cir. 1998). And where, as here, a patentee directs and controls its manufacturer's activity, the relevant conduct is effectively that of a single entity, negating any potential "sale" that could trigger § 102(b). The contract manufacturer effectively acts as an extension of the patentee.

Such a rule is well-grounded in traditional tort principles, as evidenced by this Court's recent precedent dealing with joint infringement under § 271(a). A single party is responsible for infringement, even if it outsources some parts of the

infringing conduct to another, if that party "directs or controls others' performance" or if "the actors form a joint enterprise." *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020, 1022 (Fed. Cir. 2015) (*en banc*). Direction and control includes situations where the parties have an agency relationship or where one party "contracts with another to perform one or more steps of a claimed method." *Id.* at 1023. A joint enterprise is formed where the parties have formed an agreement, share a common purpose and financial interest, and have an equal voice in direction of the enterprise. *Id.* These circumstances are sufficient under tort law to attribute all the activity to a single entity for liability purposes.

These principles should apply equally in determining whether a "sale" between distinct entities has occurred. A "sale" is traditionally understood to occur between two unrelated parties—a buyer and a seller—acting at arm's length. *See, e.g.*, UNIFORM COMMERCIAL CODE § 2-106(1) ("A 'sale' consists in the passing of title from the seller to the buyer for a price."). Neither of the situations in which one party is responsible for another's acts involves such an arm's length transaction. Each reflects some kind of special relationship—either one party has total authority and is directing and controlling the other, or the parties act as one by working in concert. Either way, the relationship is fundamentally different from the seller-customer transaction that the on-sale bar is intended to cover. Both situations involve private activity, where a patentee is working with another to make or test its invention before putting it on sale

for the public. Neither involves conduct where the parties are reaping a financial benefit from a sale of the "invention" to outside customers.

Precedent has taken a stricter view and treated two entities as separate for purposes of assessing whether there is a "sale" even when they are jointly working toward a common goal. For example, *Brassler* held that two entities (a medical device company and its exclusive manufacturer) were distinct for on-sale bar purposes where they lacked common ownership or control, even though they collaborated on the design and both employed a named inventor. *Brassler*, 182 F.3d at 889-90. The Court focused solely on the corporate relationships, rather than the medical device company's (Brassler's) *de facto* control of its manufacturer, explaining that it did not matter that Brassler "may have retained control over the manufacturing of the patented invention as a result of the alleged exclusive relationship between the two companies," because it "says nothing about the basic corporate relationships." *Id.* at 889.

But this Court's intervening joint infringement decisions require rethinking this strict approach. Tort law has eschewed such formalism when determining whether one entity's actions are legally attributable to another, extending liability in many situations where there is no common ownership. *See, e.g.*, RESTATEMENT (SECOND) OF AGENCY § 220 (1958) (master and servant); RESTATEMENT (FIRST) OF TORTS §§ 876-877 (1939) (direction and control); RESTATEMENT (SECOND) OF TORTS § 491, cmt. c (1965) (joint enterprise). A similar rule should apply in the context of the on-

sale bar—if a patentee would be legally responsible for its manufacturer's conduct in a tort suit, then they should not be said to be two separate entities engaged in an arm's length "sale" for purposes of § 102(b). After all, patent infringement is a tort, and the on-sale bar is an affirmative defense to tortious conduct—it is thus proper to apply tort principles equally to both sides of the calculus. This would not change the fact that any subsequent "sale" by either the manufacturer or the patentee to an outside customer would still be a § 102(b) event; it would just ensure that private transfers between the patentee and its agent could not invalidate the patent.

None of the on-sale bar's related objectives are served by classifying conduct as a "sale" where one entity would be legally responsible for it under tort law. The on-sale bar prevents the improper extension of the patent term, promotes prompt public disclosure of the invention, and reduces the risk that the public will think an unpatented good in commerce can be freely copied only to have a patent filed afterward, while giving the inventor a grace period to assess whether the invention will be successful enough to justify investing in a patent. *See, e.g.*, *In re Kollar*, 286 F.3d 1326, 1334 (Fed. Cir. 2002); *Rotec Indus. v. Mitsubishi Corp.*, 215 F.3d 1246, 1255 (Fed. Cir. 2000); *see also* Francis J. Albert, *Reformulating the On-Sale Bar*, 28 HASTINGS COMM. & ENT. L.J. 81, 94-96 (2005). A patentee's grace period should not begin until it begins selling the invention to outside customers in arm's length transactions—only then does it know whether the product will be well-received, and only then would its activity raise concerns about patent term extension or about others unwittingly

thinking the product is in the public domain. When the patentee merely receives a product from its manufacturer, it is not improperly extending its patent term, because it has not yet reaped any commercial reward, since it has not actually sold anything yet to customers. Indeed, pharmaceutical innovators like Gilead cannot reap any commercial benefit from their technology until after they obtain FDA approval, which in turn necessitates large quantities of products that can be most efficiently be produced through use of a contract manufacturer.

Moreover, the transfer between the patentee and its manufacturer is private—nothing about their interaction puts the product in the public domain, and so it does not implicate § 102(b)'s purpose of preventing the withdrawal of information from the public. In fact, the public benefits from allowing the inventor to iron out any manufacturing problems before the clock to file a patent starts ticking. Because once the inventor solves them, he can disclose both the problem and a refined solution in the specification, enabling others to more readily make and use the invention.

Applying tort law's traditional rules about attributing one party's conduct to another also has the virtue of treating economically equivalent conduct equivalently. There should be no difference between a party that manufactures in-house and a party that contracts with a third-party manufacturer and directs its activity. Both sets of conduct have an identical effect on the policies underlying the on-sale bar—it's not as if using a third-party manufacturer results in any more of an extension of the patent term or delays public disclosure any more than internal manufacturing would. If

anything, the law should encourage parties to manufacture a patented invention in the most economically efficient way possible.

Almost all pharmaceutical companies have determined that using outside manufacturers is the most efficient option. *See, e.g.*, Jonathan M. Barnett, *Intellectual Property As A Law of Organization*, 84 S. CAL. L. REV. 785, 837 (2011) ("The United States enjoys a thriving biotechnology industry, propelled in substantial part by smaller R&D-intensive firms that contract with larger pharmaceutical companies for production and distribution functions."); *cf.* Ronald J. Gilson, *Locating Innovation: The Endogeneity of Technology, Organizational Structure, and Financial Contracting*, 110 COLUM. L. REV. 885, 916-17 (2010) ("[T]he vertical disintegration of the supply chain allows a startup to outsource capital-intensive functions like manufacturing and assembly to contract manufacturers," which "dramatically reduces the amount of capital that must be raised, and thereby provides another source of financing for innovation."); Sean McElligott, *Addressing Supply Side Barriers to Introduction of New Vaccines to the Developing World*, 35 AM. J.L. & MED. 415, 435 (2009) (proposing that innovator firms utilize developing world contract manufacturers to mitigate the pressures of high sunk costs, low profits, high volume, and uncertain demand, in order to increase access to life-saving vaccines in low-income countries). Yet the panel's decision penalizes them for doing so, and puts them to the choice of either risking the loss of their patent rights or bringing their manufacturing in-house, thereby increasing costs and diverting their focus from developing innovative new drugs. *See, e.g.*, *Barnett*, 84 S. CAL. L. REV. at

836 ("[F]ailure to match the cost efficiencies made available by outsourcing supply chain functions to least-cost outside providers inherently results in a competitive disadvantage."). The *en banc* court should reject that approach and hold that where, as here, an innovator drug company directs its manufacturer's conduct, there is no "sale" between two separate entities for purposes of § 102(b).

CONCLUSION

For the reasons above, the Court should affirm the district court's determination that the patent-in-suit is not invalid under 35 U.S.C. § 102(b).

Dated: March 2, 2016

Respectfully submitted,

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CERTIFICATE OF SERVICE AND FILING

I certify that I electronically filed the foregoing document using the Court's CM/ECF filing system on March 2, 2016. All counsel of record were served via CM/ECF on March 2, 2016.

/s/ Craig E. Countryman
Craig E. Countryman

CERTIFICATE OF COMPLIANCE

The undersigned attorney certifies that Appellee's Responsive Brief complies with the type-volume limitation set forth in Fed. R. App. P. 32(a)(7)(B). The relevant portions of the brief, including all footnotes, contain 4,634 words, as determined by Microsoft Word.

Dated: March 2, 2016

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