APPEAL NO. 2014-1469, 2014-1504

IN THE
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

REPLY BRIEF OF DEFENDANT-CROSS-APPELLANT HOSPIRA, INC. IN RESPONSE TO THE COURT'S NOVEMBER 13, 2015 ORDER

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March 14, 2016

CERTIFICATE OF INTEREST

Counsel for Defendant-Cross Appellant Hospira, Inc. certifies the following:

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

Hospira, 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:

None.

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:

Pfizer, Inc., of which Hospira, Inc. became a subsidiary on September 3, 2015.

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:

Jenner & Block LLP: Bradford P. Lyerla, Aaron A. Barlow, Sara T. Horton, and Jamie K. Lord.

Morris James LLP: Richard K. Herrmann and Mary B. Matterer.

Sutherland Ashbill & Brennan LLP: William F. Long and Tara Stuart (subsequently moved to McKenna Long & Aldridge LLP), and Kristin E. Goran.

March 14, 2016 /s/ Bradford P. Lyerla

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"A___"	Appendix page number(s)
"AIA"	Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011)
"BVL"	Ben Venue Laboratories
"FDA"	United States Food and Drug Administration
"Gilead Br."	Brief of Gilead Sciences, Inc. as Amicus Curiae
"Gov't Br."	Brief of the United States as Amicus Curiae
"HIPLA Br."	Brief of the Houston Intellectual Property Law Association as Amicus Curiae
"Hospira Br."	En Banc Brief of Hospira, Inc.
"ICS"	Integrated Commercialization Solutions, Inc.
"MedCo Br."	En Banc Brief of the Medicines Company
"PhRMA Br."	Brief of the Pharmaceutical Research and Manufacturers of America as Amicus Curiae
"UCC"	Uniform Commercial Code

INTRODUCTION

The primary theory advanced in MedCo's brief is that BVL's large-scale manufacture of Angiomax using the revised compounding process was experimental, and that a ruling in Hospira's favor therefore would hamper the development of drug products. But MedCo's effort to shoehorn this case into an "experimental" category has virtually nothing to do with the record below.

- To give the batches an experimental character, MedCo asserts that BVL served only as a "pair of laboratory hands." MedCo Br. 9, 15. The record says nothing of the sort. Although BVL *did* conduct earlier bench-scale experiments for MedCo, the pre-critical date batches at issue here encompassed delivery of tens of thousands of vials of Angiomax "for commercial use." A14884.
- MedCo claims that BVL's activities were intended to determine whether its "invention" worked for its intended purpose. MedCo Br. 17-18, 32, 36. Although the district court stated as much, in fact, the record contains no testimony to this effect.
- MedCo suggests that Hospira admitted that validation was the only purpose of the three batches at issue. MedCo Br. 4. Notwithstanding the district court's comments to this effect, the record makes clear that

Hospira did nothing of the sort—it merely acknowledged that these were "validation batches." A24 (citing A15901).

- To escape the effect of the eight additional pre-critical date batches, MedCo asserts that these too were made "to determine whether the inventions worked for their intended purpose." MedCo Br. 39. For support, MedCo cites nothing.
- MedCo suggests that it placed experimental use at issue below by contending that the transactions at issue were not "commercial." MedCo Br. 36. But the cited portion of the record does not even suggest an argument that BVL's activities were experimental. A16987. Indeed, the word "experimental" appears nowhere in MedCo's opening statement or its on-sale briefing below.

With MedCo's claim of experimental use set aside, there simply is no reason to conclude that these overwhelmingly commercial transactions fell outside the on-sale bar. MedCo and its amici seek to exempt categories of transactions based on the parties involved, the manner in which claims are drafted, or the transactions' legal form—yet this Court has long eschewed such approaches, in recognition that commercial exploitation can take many transactional forms. And while MedCo and its amici worry that a ruling for Hospira will chill innovation, applying the on-sale bar does not prohibit any way of doing business. It simply means that the in-

ventor must apply for a patent within one year of the commercial exploitation that triggered the bar—which MedCo failed to do.

I. A COMMERCIAL SALE TOOK PLACE FOR PURPOSES OF SECTION 102(b).

A. The Transactions Between MedCo And BVL Constituted A Commercial Sale.

In return for payment from MedCo, BVL delivered batches of Angiomax—that is, commercial embodiments of the patented inventions—valued at many millions of dollars. Both parties derived substantial commercial benefit from these transactions: BVL received payment from MedCo, and MedCo replenished its depleted commercial pipeline. Under long-established case law, these transactions constituted a commercial sale under 35 U.S.C. § 102(b)—even if they were not sales of goods under the UCC. Hospira Br. 7-8, 28-30.

MedCo and its amici make a variety of arguments in response. As an initial matter, MedCo repeatedly suggests that the district court's conclusions are subject to clear-error review. MedCo Br. 17, 32. Not so: as explained in Hospira's opening brief, a district court's conclusions regarding whether an invention was "on sale" under Section 102(b), or whether the activities in question were experimental, are legal conclusions subject to de novo review. Hospira Br. 22-23. MedCo nowhere explains why the standard of review should be any different here.

With that point aside, MedCo argues it did not benefit from the transactions prior to the critical date because it did not itself sell the batches until after that date. MedCo Br. 10-11, 17-18, 24. These arguments fall short, for MedCo ignores the important commercial benefit it realized, by virtue of these transactions, prior to the critical date. Twice in the preceding two years, MedCo had ordered BVL to shut down production for long periods of time.[1] *See* A16057, 77:7-21; A16063-64, 83:24-84:14; A16066-67, 86:1-87:22. BVL's manufacture and delivery of tens of thousands of vials (valued at many millions of dollars), allowed MedCo to replenish its depleted stores of Angiomax and confidently enter a new distribution agreement with ICS, which would exclusively govern all sales of Angiomax in North America well into the future. Hospira Br. 48. The date on which MedCo itself later sold those batches is not the point. Nor is the fact that the batches remained in a "quarantine" state until after the critical date. Regardless of whether they were quarantined, they were part of MedCo's inventory, adding immediate value to the company's balance sheet and operations. And, in any event, MedCo has pointed to no reason for the quarantine other than completion of its own review process. *See* A16863, 881:2-12.

To be sure, stockpiling is not *itself* activity that triggers the on-sale bar. But here, MedCo's stockpiling of Angiomax is not the transaction on which Hospira

[1] MedCo accordingly is incorrect to claim (MedCo Br. 26) that there is no evidence that its commercial pipeline had been depleted.

relies. Rather, Hospira relies on the transactions between MedCo and BVL, in which MedCo paid BVL to manufacture and deliver commercial quantities of Angiomax. A17177-78; A17183. MedCo's resultant ability to stockpile Angiomax merely underscores that those transactions constituted commercial exploitation of the claimed invention before the critical date.[2]

Applying the on-sale bar here will not, as MedCo and its amici suggest, deter innovation or disable inventors from using third-party manufacturers. MedCo Br. 2, 44-47; *see also, e.g.*, PhRMA Br. 4-5; HIPLA Br. 23-24. Applying the bar does not mean that particular transactions are prohibited. It means only that, *if* those transactions take place, the inventor should file a patent application—even a provisional one—within one year. Particularly where highly valuable commercial quantities of the invention's embodiment change hands, that is a modest and reasonable requirement.

Trading Technologies does not suggest a different result. There, this Court held that an inventor may "request another entity's services in developing products embodying the invention without triggering the on-sale bar." *Trading Techs. Int'l, Inc. v. eSpeed, Inc.*, 595 F.3d 1340, 1361-62 (Fed. Cir. 2010). Consistent with that principle, the *Trading Technologies* panel held that an inventor did not trigger the

[2] MedCo and its amici are wrong to claim that these activities constituted "pre-commercialization." Angiomax had long been on the market—and as one of the inventors admitted, the only difference between these batches and the earlier ones was the process used to manufacture them. *See* A16483-84, 502:8-503:6.

bar by paying another entity to build software embodying his idea "for his own secret, personal use." *Id.* This case is nothing like *Trading Technologies*: here, MedCo paid BVL not to provide a few sample vials of Angiomax for "personal use," but instead to manufacture and deliver tens of thousands of vials with immediate commercial value, destined for resale to the public. Hospira Br. 7-9. Indeed, the *Trading Technologies* panel was careful to distinguish *Brasseler*, in which the seller had "manufactured over 3,000 products embodying the invention and sold it solely to the buyer," which employed some of the inventors. *Trading Techs.*, 595 F.3d at 1361.

B. The Fact That Title Did Not Pass Is Irrelevant.

Seeking to escape the on-sale bar, MedCo and its amici characterize the transactions with BVL as for "manufacturing services" rather than sales—making much of the fact that title did not pass to the commercial-scale batches that BVL delivered to MedCo. MedCo Br. 18, 20-22; Gov't Br. 5-7. But passage of title is irrelevant here: the on-sale bar's touchstone is commercial exploitation, and case after case has recognized that the bar can apply even where title does not pass to any embodiment of the invention. Hospira Br. 30-32. Indeed, *Pfaff* itself favorably quoted the operative language from *Metallizing*: an inventor "shall not exploit his discovery competitively after it is ready for patenting." *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68 (1998) (quotation marks omitted); *see* Hospira Br. 25.

Insisting upon passage of title, even where the invention has been commercially exploited, would allow inventors to game the system—and prolong their periods of patent exclusivity—by structuring manifestly commercial transactions to avoid the passage of title. For instance, an inventor might structure an arrangement as a license, a long-term lease, or a "sale of services" to avoid the on-sale bar.[3] Particularly where just a few months of pharmaceutical exclusivity can be worth many millions of dollars, this Court should avoid offering inventors that temptation.

MedCo and its amici make little effort to grapple with the mischief that would result from an insistence on title's passage. Nor do they cite any case that has declined to apply the on-sale bar simply because title has not passed. Indeed, MedCo itself disclaims the notion that the passage of title is always a requirement. MedCo Br. 19. Nonetheless, MedCo and its amici offer a variety of reasons why the structure of these transactions warrants a result for MedCo. None has merit.

To begin with, MedCo is wrong to insist that, because there was no sale within the meaning of the UCC, the on-sale bar cannot apply here. MedCo Br. 19-20. As explained in Hospira's opening brief, this Court has repeatedly applied the bar even where there has been no UCC "sale" of the invention. Hospira Br. 30-31,

[3] Indeed, one of MedCo's own amici recognizes this point in proposing a convoluted exception to a rule requiring the passage of title. *See* PhRMA Br. 11-12.

34-35. MedCo's cases do not warrant a contrary result here. In *Enercon GmbH v. ITC*, for instance, this Court deemed the UCC a "useful, *though not authoritative*, source in determining the ordinary commercial meaning of the term 'sale.'" 151 F.3d 1376, 1382 (Fed. Cir. 1998) (emphasis added). The Court did the same in *Group One*—and even there, it consulted the UCC only to determine whether a series of communications was sufficiently definite to constitute an offer for sale, not to determine whether a *consummated* transaction constituted a Section 102(b) "sale." *Group One, Ltd. v. Hallmark Cards, Inc.*, 254 F.3d 1041, 1047-48 (Fed. Cir. 2001).

MedCo and its amici likewise are incorrect that, because its claims purportedly are to a product (or a product-by-process), cases such as *Metallizing Engineering Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516 (2d Cir. 1946), *D.L. Auld Co. v. Chroma Graphics Corp.*, 714 F.2d 1144 (Fed. Cir. 1983), and *Plumtree Software, Inc. v. Datamize, LLC*, 473 F.3d 1152 (Fed. Cir. 2006), should not apply. *See, e.g.*, MedCo Br. 21-22. These cases all stand for the principle that commercial exploitation is the touchstone of the on-sale bar, and none suggests that this principle is limited to process claims. Nor would it be sensible for this Court to so hold. A person can commercially exploit a product without actually selling it; for instance, the inventor of a machine might charge others a fee to use it. Moreover, limiting the *Metallizing* line of cases in this fashion would make it

easy for inventors to avoid its impact altogether: in many cases, the inventor of a process could simply claim a machine or system that performs that process.

Even if passage of title is a requirement in cases of product claims, that would not save MedCo here, because all of its asserted claims have process limitations. Indeed, as explained in Hospira's opening brief, MedCo's revised process not only was central to its "invention" (Example 5 of the patents), but was the *only* feature distinguishing it over the prior art disclosed in Example 4. Hospira Br. 10-12. Unless limited to that process, in other words, the claims would have been invalid as anticipated—as the district court readily apprehended.[4]

To this, MedCo responds that, even without an efficient-mixing limitation, its claimed invention would not exist in the prior art, because the claims are directed to *maximum* Asp^9 levels resulting from a particular compounding process, and the batches of Example 4 had a maximum Asp^9 level above .6%. MedCo Br. 8, 22. MedCo is wrong. Under its logic, its "invention" would have existed in the prior art *until* the previous compounding process yielded Asp^9 levels above .6%, but would have then vanished from the prior art once a single batch exceeded that level. The more sensible conclusion is the one reached by the district court. And

[4] Section 102(b)'s reference to the "invention" being on sale does not mean that, in the case of product (or product-by-process) claims, the on-sale bar requires passage of title. Tying "invention" strictly to the claim language would run headlong into the fact that the literal subject matter of many claims is incapable of itself being sold—and yet this Court has not hesitated to apply the on-sale bar in such circumstances. *See D.L. Auld*, 714 F.2d at 1147; *Plumtree*, 473 F.3d at 1163.

even under MedCo's own construction, the claims have process limitations: they require that the solution's pH be "adjusted by a base," and the "pharmaceutical batches" in question must be produced by a "same compounding process." A35-36; A38-39.

Nor should this Court be led astray by MedCo's suggestion that the batches at issue here constituted a different product from what it had previously sold. Repeatedly, MedCo refers to the Example 4 batches as "Original Angiomax," and refers to subsequent batches as "Improved Angiomax." *E.g.*, MedCo Br. 8-9, 23. The latter batches were "improved" only in that they were made by a different compounding process—the process BVL used to manufacture the batches at issue here. Otherwise, the subsequent batches were indistinguishable from the earlier ones that MedCo had sold. *See* A16483-84, 502:8-503:6.

United States v. Eurodif S.A., 555 U.S. 305 (2009), does not counsel against applying the on-sale bar here, contrary to the government's contention. Gov't Br. 7-8, 22-23. In *Eurodif*, the Supreme Court applied *Chevron* deference to a federal agency's interpretation of the term "sale" in a statute regulating customs duties, not patent validity. 555 U.S. at 316. Reasonableness review under *Chevron* is an entirely different standard and irrelevant to this court's interpretation of "on sale" in Section 102(b). Moreover, *Eurodif* stressed that courts should not focus on "the legal fiction" that the parties had created, but instead on their "substance" and

"economic reality." *Id.* at 317-18 (quotation marks omitted). Particularly where BVL delivered batches that the patents themselves describe as embodiments of the claims, the status of title is not determinative.

C. The Experimental Use Doctrine Does Not Apply.

MedCo also argues that its pre-critical date batches fell outside the on-sale bar because they constituted experimental uses. MedCo Br. 32-39. This argument fails because the record cannot possibly support a conclusion that the "primary" purpose of these batches was experimental, rather than commercial. Indeed, MedCo did not even attempt to argue experimental use at trial—even though it is up to the patentee to produce "convincing evidence" of such use to counter the application of the on-sale bar. *Lisle Corp. v. A.J. Mfg. Co.*, 398 F.3d 1306, 1316 (Fed. Cir. 2005); *U.S. Envt'l Prods. Inc. v. Westall*, 911 F.2d 713, 716 (Fed. Cir. 1990).

1. The "Primary Purpose" Of MedCo's Pre-Critical Date Batches Of Angiomax Was Not Experimentation.

The issue presented by the experimental use doctrine is simple and narrow: "whether the transaction constituting the sale was 'not incidental to the primary purpose of experimentation.'" *Allen Eng'g Corp. v. Bartell Indus.*, 299 F.3d 1336, 1354 (Fed. Cir. 2002) (quoting *EZ Dock v. Schafer Sys., Inc*., 276 F.3d 1347, 1357 (Fed. Cir. 2002) (Linn, J., concurring)). Under this standard, the mere fact that an invention might still be "under development, subject to testing, or otherwise still in

its experimental stage at the time of sale" is not sufficient for the experimental use exception to apply. *Id.*; *see also, e.g., Smith & Griggs Mfg. Co. v. Sprague*, 123 U.S. 249, 254-55, 256 (1887) (invalidating patent where the patented machine was used to make commercial products even while being simultaneously tested and re-designed). The experimental purpose must be primary, with any commercial purpose only incidental.

MedCo's brief nowhere acknowledges this governing legal standard—which thoroughly forecloses any conclusion that the experimental use doctrine applies here. *See generally* MedCo Br. 31-32. There is no dispute that the batches involved commercial-scale volumes of Angiomax. A14959; A15210; A15452. The three pre-critical date batches were filled "for commercial use" and "[r]eleased for commercial . . . packaging" before the critical date. A14884; A14960; A15211; A15453. Those batches also had significant commercial value and were eventually sold to the public. A14598; A14604; A14610.[5] Under these circumstances, it simply cannot be said that the batches were manufactured primarily for experimental purposes, with any commercial purpose merely incidental.

[5] MedCo is wrong that its "commercial" product codes were required by FDA regulations. MedCo Br. 25. The FDA requires a "distinctive code," 21 C.F.R. § 211.80(d), but this need not be a commercial code. The fact that MedCo chose to refer to these codes as "commercial" product codes, even before the critical date, further confirms the significant commercial purpose of these batches.

Tellingly, not once during trial did any witness—or MedCo's counsel—describe the batches as experimental. The only activities of MedCo or BVL that were described as "experimental" or "experiments" were the laboratory-scale experiments that BVL conducted, that BVL invoiced as experimental, and that the patents disclose as Examples 1 through 3.[6]

2. That BVL's Activities Involved Validation Or Testing Does Not Make Them Experimental.

Still, MedCo contends that BVL's validation batches were necessarily "experimental" simply because they were validation batches. MedCo Br. 34-36. As explained in Hospira's opening brief, that is not so. Although validation is necessary to *document* the efficacy of a drug manufacturing process, that does not mean that validation is an experiment to determine whether the invention works. *See* Hospira Br. 42-43. And even assuming that validation is "experimental" in some sense—which it is not—that certainly does not mean that the *primary* purpose of validation batches is experimental; indeed, this Court has previously resisted efforts to muddle patent law with FDA regulatory requirements. *See AstraZeneca LP v. Breath Ltd.*, 603 F. App'x 999, 1003 (Fed. Cir. 2015) (rejecting efforts by patentee "to equate regulatory compliance with evidence of nonobviousness" under

[6] A16073, 93:6-20; A16102, 122:10-20; A16103-104, 123:5-124:9; A16109-110, 129:19-130:11; A16111-113, 131:7-133:8; A16114-15,134:5-135:8; A16117, 137:6-12; A16118, 138:16; A16119-120, 139:12-140:1; A16123, 143:11-15; A16124, 144:7; A16127-28, 147:23-148:9; A16129, 149:9-11; A16130-31, 150:24-160:1; A15988, 8:6-20; A15989, 9:19-24; A15990, 10:3-5.

patent law). Here, MedCo had BVL make tens of thousands of commercial vials of Angiomax that it could ship to its customers when necessary; the fact that it also used those same batches to validate its process does not dilute their commercial purpose.

MedCo's arguments do not establish that validation means experimentation. For example, MedCo asserts that "[t]esting at laboratory scale is inadequate, as it is unknown how the product would scale"—yet it cites nothing to support this assertion. MedCo Br. 36. MedCo cites to FDA requirements that control procedures be established for validating the performance of manufacturing processes that may cause variability in drug products, and that validation must take place under conditions simulating actual use. MedCo Br. 34-35. But this does not mean the commercial purpose of validation batches is purely incidental. It merely shows that commercial processes are always subject to validation obligations.

MedCo is similarly wrong to claim (MedCo Br. 33) that its first three validation batches fall within the experimental use exception because they were manufactured using varying mixing parameters. MedCo cites nothing to support its claim that the varying parameters were used "to determine whether the invention worked for its intended purpose." *Id.* Nor does it explain how varying a process's parameters necessarily implies experimentation. And although MedCo points to language in the validation protocol like "experimental challenge" and "testing

methodology," *id.* at 34, MedCo ignores that this same validation study states that the batches "will be filled for commercial use," A14884—making clear that their commercial purpose was far more than incidental.

Indeed, the only evidence of whether MedCo considered the validation batches to be experimental shows the opposite. MedCo put at risk more than two full batches of commercial grade product, consisting of tens of thousands of vials valued in excess of $20 million. Hospira Br. 7. It would make no sense for MedCo to risk that much commercial product on what it now claims was "experimental"—and MedCo has never offered any explanation to the contrary.

More generally, this Court should reject MedCo and its amici's efforts to expand the experimental use exception to capture commercial production and sales where some testing or refinement is present. *See Smith & Griggs*, 123 U.S. at 254-55 (finding no experimental use despite testing that led to refinement of the invention). Pharmaceutical manufacturers frequently monitor their commercial manufacturing processes, collect data, and make improvements. These efforts do not convert the processes (or the resulting products) into experiments. Recognizing as much does not subject inventors to the on-sale bar for *bona fide* experimentation, like that which is often involved in clinical trials. And even in cases where there

may be some doubt, the inventor can easily protect herself by filing a patent application within one year.[7]

3. MedCo's Claim That Its "Invention" Was Not Ready For Patenting Should Be Rejected.

Alternatively, MedCo insists that the experimental use doctrine applies because it purportedly did not realize it had an invention until it had manufactured 25 batches. MedCo Br. 37-38. That argument fails.

First, MedCo's argument fundamentally concerns whether the invention was ready for patenting; indeed, this is the same argument it made below in connection with the second prong of *Pfaff*. The district court rejected this argument, A23; the panel likewise rejected it, *see Medicines Co. v. Hospira, Inc.*, 791 F.3d 1368, 1372 (Fed. Cir. 2015); and the en banc Court did not include the "ready for patenting" prong in the scope of issues to be briefed anew.

Second, even assuming (implausibly) that MedCo truly did not realize it had an "invention" until after it had made 25 batches, that does not mean its primary purpose until then was experimental. Whatever MedCo subsequently *realized* log-

[7] As for whether reduction to practice necessarily forecloses a claim of experimental use, *see* Gov't Br. 32-33, this question is ultimately irrelevant here, for the record does not support the notion that MedCo's primary purpose in connection with the batches was experimental at *any* time. Holding that reduction to practice forecloses experimental use, moreover, would not leave the experimental use doctrine without meaning, for it could still apply where the invention has become ready for patenting by some avenue other than reduction to practice—as *Pfaff* itself envisioned. *See* 525 U.S. at 67-68.

ically says nothing about what its *purpose* may have been prior to that realization, and certainly cannot render its commercial purpose merely incidental.

Third, MedCo's argument fails on its own terms. MedCo claims that 25 batches were necessary for it to apprehend the "maximum" Asp^9 level associated with its revised process. But even after 25 batches, it would have been possible—at least theoretically—for the next batch to disprove the calculated maximum. MedCo nowhere explains why exactly 25 batches—rather than 10, 50, or 100 batches—were needed to calculate the maximum Asp^9 value.[8] Under MedCo's proposed approach, a drug manufacturer could sell its product for years—reaping hundreds of millions of dollars of commercial gain—and claim that all of those sales were "experimental" because *just one more batch* was needed to definitively determine the "maximum" level of some substance.

Fourth, this Court has previously *rejected* arguments analogous to MedCo's. In *Cargill, Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359 (Fed. Cir. 2007), the Court explained that a patentee "did not need to be aware of the specific characteristics that made the [invention] useful" in order for it to be ready for patenting. *Id.* at 1371. Instead, where an embodiment of the invention is known to have *any* utility—not just the specific utility of the claimed invention—it has been reduced to

[8] MedCo used the prior art process for five years, during which 85 out of 87 batches (97 percent) had acceptable Asp^9 levels. A58, col. 22, Table 6. If the new mixing process were to have a similar failure rate, even 25 batches might not have been adequate to reveal the problem.

practice for purposes of the on-sale bar and therefore is ready for patenting. *Id*. This same principle applies with equal force here. Even if MedCo did not know the specific maximum Asp[9] level that resulted from its revised process, it had sufficient information well before the critical date to know that its revised process was useful.

4. The Eight Non-Validation Batches Had A Significant Commercial Purpose.

Finally, even if this Court were to agree with MedCo that its first three batches were experimental, the experimental use exception still could not save MedCo's patent from invalidation. After the first three batches, MedCo paid BVL to manufacture and deliver to MedCo eight *additional* commercial-scale batches of Angiomax, made with the revised process, all before the critical date.[9]

[9] MedCo claims Hospira should be barred from relying on these eight batches because it failed to adequately raise them at trial. MedCo Br. 28-30. As explained previously, however, Hospira had no need to argue that anything more than the three validation batches triggered the on-sale bar, because MedCo never argued experimental use. *See* Hospira Br. 41 n.10.

In any event, the record on the eight additional batches, on which Hospira relied in support of its ready-for-patenting argument, contains much more than "a conclusory statement" (MedCo Br. 29) regarding those batches. *See, e.g.*, A16661, 679:12-14 ("[A]t least 11 different lots were manufactured using this new process before the critical date."); A16678, 696:18-20 ("So all of this work, those 11 lots, the validations, the master batch records were all significantly before that critical date."); *see also* A16662, 680:13-14; A16678, 696:4-9, 21-24; A16679, 697:1-24.

MedCo claims these eight batches were experimental because they supposedly were part of the effort to determine the new maximum Asp^9 value for the claimed invention. MedCo Br. 38. But, again, this misses the mark. Even assuming *arguendo* that MedCo needed those batches to determine the maximum Asp^9 value, that would not show that their *primary* purpose was experimental and not commercial. And given that those eight batches were valued at more than $80 million collectively, *see* A16055-56, 75:15-76:2, it defies belief to claim that the commercial purpose was merely incidental.

II. THE RULE OF *SPECIAL DEVICES* SHOULD BE LEFT INTACT AND FAVORS HOSPIRA HERE.

Special Devices embodies a clear and straightforward rule: if a transaction otherwise would constitute a barring sale, the fact that it involved an inventor and its supplier does not remove it from the on-sale bar's scope. *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353, 1355 (Fed. Cir. 2001). MedCo, however, asks this Court to "clarify" *Special Devices* to create a new exception for certain supplier transactions. *See* MedCo Br. 41. The Court should decline to do so.

A. *Special Devices* And Its Subsequent Application Are Sound And Fully Consistent With Precedent.

MedCo points to no legal error in the *Special Devices* decision. Indeed, MedCo all but admits that *Special Devices* properly applied *Pfaff* to determine whether a Section 102(b) sale had taken place. *See* MedCo Br. 42 (noting that only

"*[a]fter* finding an invalidating commercial sale" did the panel decline to create a supplier-inventor exception (emphasis in original)). And MedCo does not appear to claim that *Special Devices* was wrongly decided. *See generally* MedCo Br. 41-44.

Unable to point to any legal error in *Special Devices*, MedCo instead argues that subsequent cases have wrongly *applied* that decision. In particular, MedCo asserts that these cases have failed to consider whether an invention was actually the subject of a commercial sale (or offer for sale) and whether the activities at issue were experimental. *See* MedCo Br. 42-44 (citing *Hamilton Beach Brands, Inc. v. Sunbeam Prods., Inc.*, 726 F.3d 1370 (Fed. Cir. 2013), and the panel decision in this case).

MedCo is wrong. In *Hamilton Beach*, the Court carefully assessed both prongs of *Pfaff*. 726 F.3d at 1375-79. And in this case, the transactions between MedCo and BVL before the critical date were commercial sales for purposes of the on-sale bar. *See supra* at 3-19. MedCo does not even try to identify similar errors in the district court cases applying *Special Devices*. *See* Hospira Br. 53 (collecting cases).

But even if MedCo were correct that the no-supplier-exception rule has caused courts to give short shrift to *Pfaff*, this is no reason to overrule or modify *Special Devices*. Instead, the Court could simply remind courts to conduct the

two-step *Pfaff* analysis, even where the transaction is between a supplier and an inventor. Such an approach would avoid the disruption that would result from overturning long-settled case law, while alleviating MedCo's purported concerns.

Relatedly, MedCo suggests that *Special Devices* might lead courts to improperly deem certain transactions commercial, rather than experimental. *See* MedCo Br. 43-44. Even if that problem existed, it would not be a problem with *Special Devices*; instead, it would represent a failure to properly apply the experimental use doctrine. *Special Devices* fully accords with the principle that the on-sale bar applies only to *commercial* sales and offers for sale, and that experimental uses fall outside the bar. Indeed, *Special Devices* itself recognized that pre-critical date sales from a supplier to an inventor for the purpose of testing or developing a prototype will not invalidate a patent. *See Special Devices*, 270 F.3d at 1356. In sum, MedCo points to no legal error in *Special Devices* that would justify overruling the clear rule articulated by that decision.

B. The Court Should Decline To Create A Supplier Exception Or To Limit The On-Sale Bar To Public Sales.

Despite pointing to no actual flaw in *Special Devices*, MedCo proposes a new supplier exception to the on-sale bar. As MedCo would have it, sales from a supplier to the inventor should fall outside the bar only where they are "confidential[], and under the inventor's direction and control." MedCo Br. 42. MedCo also articulates a "broad[er]" version of its proposed exception, applicable when "(1)

the invention is not publicly disclosed by anyone, and (2) the inventor does not commercially sell or offer to sell the invention before the critical date." *Id.* The government, for its part, proposes to limit the on-sale bar to sales made to the public. Gov't Br. 4-19. This Court should decline to adopt any of these approaches.

1. The On-Sale Bar Should Not Be Limited To Public Sales.

The Court should reject suggestions to limit the on-sale bar to "public" sales, or to exclude sales that are confidential. *See* MedCo Br. 42; Gov't Br. 4-19. Neither text nor precedent supports the claim that "confidential" sales should be treated differently from others.

The United States asserts that the Supreme Court "has repeatedly described the statute as addressed to *public* sales." Gov't Br. 11-12. Yet it points to no Supreme Court case holding that *only* public sales will trigger the bar. In *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 152-57 (1989), for instance, the Court addressed whether federal law preempted a state law that gave patent-like protections to unpatented designs that already were in the public domain. In that context, the Court naturally discussed why sales to the public would invalidate a patent. *See id.* at 148-52. But the case did not involve, and the Court did not address, whether *non*-public sales could also be invalidating. Nor did *Pfaff* address the question. There, the Court examined whether an invention must first be "reduced to practice" in order for the on-sale bar to apply. *Pfaff*, 525 U.S. at 63, 67-

68. Although it did link the on-sale bar to a "reluctance to allow an inventor to remove existing knowledge from public use," *id.* at 64, it also linked the on-sale bar to "confining the duration of the monopoly to the statutory term." *Id.* And it did not even consider whether a sale must be public in order to trigger the bar.

Lower courts, by contrast, *have* addressed whether confidential sales fall within the scope of the on-sale bar. For decades, they have rejected the notion that inventors can escape the bar merely by keeping the transactions or the invention confidential. *See, e.g.*, *In re Caveney*, 761 F.2d 671, 675 (Fed. Cir. 1985) (rejecting the proposition that a sale "kept secret from the trade" would not constitute a sale under § 102(b)); *Gould Inc. v. United States*, 579 F.2d 571, 580 (Ct. Cl. 1978) ("[A] sale . . . pursuant to a secret military contract . . . was still held to be a sale proscribed by 35 U.S.C. § 102(b)." (citing *Piet v. United States*, 176 F. Supp. 576 (S.D. Cal. 1959))); *Hobbs v. U.S., Atomic Energy Comm'n*, 451 F.2d 849, 860 (5th Cir. 1971) ("We cannot attach any relevance to any conditions of secrecy which may have existed at the time the [invention] was placed 'on sale.'").[10] Even in *Atlanta Attachment*, on which MedCo heavily relies, the parties "agreed to keep the development [of the invention] confidential." *Atl. Attachment Co. v. Leggett &*

[10] The United States also acknowledges that the Manual of Patent Examining Procedure (MPEP) interprets pre-AIA Section 102(b) to apply to both confidential and public sales. *See* Gov't Br. 17 n.8 (citing MPEP § 2133.03(b)(III)(A)).

Platt, Inc., 516 F.3d 1361, 1363 (Fed. Cir. 2008). Even so, the sale triggered the on-sale bar. *Id.* at 1368.

Importing a confidentiality exception, moreover, would risk conflating the on-sale bar with the public use bar. By the time a public sale occurs, an invention would naturally be in public use—effectively eliminating any separate function of the on-sale bar, except perhaps in cases of unaccepted offers for sale.

The text of Section 102(b) also refutes the notion that the sale must be public. Had Congress intended to limit the bar to public sales, it could have crafted Section 102(b) to bar the issuance of a patent where the invention was "in public use or on sale *to the public*" before the critical date. That Congress omitted the italicized words signifies that it did not intend to limit the bar as proposed by MedCo and its amici.[11]

2. Both The Text Of Section 102(b) And This Court's Precedent Foreclose MedCo's Alternative Rule.

The Court also should reject MedCo's contention that, so long as "the inventor" does not put the invention on sale, the bar does not apply. MedCo Br. 49-50.

[11] Although the United States recognizes that the AIA version of the on-sale bar does not apply here, it argues that (a) that version's language implies that "on sale" inherently means "on sale to the public"; and (b) the pre-AIA on-sale bar therefore should be construed to apply only to public sales. Gov't Br. 15-17. Particularly in light of decades of case law interpreting "on sale" to encompass secret or confidential sales, the government's argument is simply too slender a reed on which to rest a decision narrowing the bar's previously settled scope. If anything, the government's argument highlights that any significant revision of the on-sale bar should take place not in this case, but instead in a case subject to the AIA.

As *Special Devices* observed, Section 102(b) includes no limitation regarding who must put the invention on sale, or who must purchase it, to trigger the on-sale bar. *See* 270 F.3d at 1355; Hospira Br. 44-45. And, consistent with the text, this Court has repeatedly rejected exceptions based on the seller's identity. Hospira Br. 45-46 (collecting cases).[12] MedCo's proposed test would starkly depart from both this Court's prior decisions and the clear language of Section 102(b).

Equally unsustainable is the "under the control of the inventor" aspect of MedCo's proposed rule. Certainly, inventor control may be relevant to determining whether activities were experimental and therefore exempt from the on-sale bar. *See, e.g.*, *Atl. Attachment*, 516 F.3d at 1366. But *Special Devices* already accommodates experimental use, as explained above. And this Court has previously rejected efforts to except manufacturer-inventor sales even where the inventor "may have retained control over the manufacturing of the patented invention." *Brasseler*, 182 F.3d at 890. MedCo's proposed rule would expand the experimental use exception beyond recognition, by allowing even non-experimental sales

[12] MedCo is wrong to characterize *Brasseler* as a case where "*the patentee* offered the invention for sale." MedCo Br. 49 (emphasis in original). Although the manufacturer's employees had helped to develop the invention, Brasseler both owned the patent and was the purchaser. *Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 182 F.3d 888, 890 (Fed. Cir. 1999).

of significant volumes of a product to take place without starting the clock to apply for a patent.[13]

This Court's decision in *Trading Technologies* does not support MedCo's proposed new test, either. MedCo relies on *Trading Technologies* for the principle that "[i]nventors can request another entity's services in developing products embodying the invention without triggering the on-sale bar." *Trading Techs.*, 595 F.3d at 1361-62; *see* MedCo Br. 48. Yet *Special Devices* recognized this principle as well, and it is consistent with the experimental use doctrine. *Special Devices*, 270 F.3d at 1356. That doctrine *already* provides sufficient protection to inventors who wish to enlist manufacturers to assist in development of their inventions. An inventor's possible need to enlist another's assistance in "developing" embodiments of the invention does not justify exempting commercial-scale transactions from the on-sale bar.

3. Policy Interests Counsel Against A Supplier Exception.

MedCo also is incorrect that policy interests support its proposed new exception. *See* MedCo Br. 51-53. It is simply wrong that an inventor "cannot profit from and is not commercializing the invention" when purchasing significant volumes of saleable product from a supplier. MedCo Br. 51. *Special Devices* correct-

[13] In any event, the record does not bring the transactions at issue here within the supplier exception that MedCo proposes. MedCo's brief points to no competent evidence that BVL's activities were under MedCo's control—much less that the two companies were "effectively functioning as one." Gilead Br. 2.

ly observed that transactions resulting in commercial stockpiling can be quite valuable. 270 F.3d at 1356-57. So too here: in replenishing its stockpiles of Angiomax, MedCo reaped significant commercial benefit from its pre-critical date transactions with BVL. *See supra* at 4-5; Hospira Br. 7-9, 47-48.

MedCo is likewise wrong to argue that—despite delaying the requirement to file a patent application—its rule could promote *earlier* disclosure to the public by allowing inventors to use suppliers "to produce a product that they could not efficiently otherwise create themselves." MedCo Br. 52. Under current law, including *Special Devices*, nothing prohibits inventors from using suppliers in this manner. They simply must file a patent application within one year. A supplier exception, by contrast, would only delay an inventor's filing for a patent—contrary to the on-sale bar's primary purpose. *See, e.g.*, *Woodland Trust v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1370 (Fed. Cir. 1998) (explaining that the on-sale bar "is primarily concerned with the policy that encourages the inventor to enter the patent system promptly").

Limiting the on-sale bar to *public* sales—and thus overruling decades of precedent that the MPEP itself incorporates—would be even worse. Under such a rule, an inventor could extend the term of its patent indefinitely, while reaping great commercial success, simply by ensuring that it sells the invention only in secret. This sort of gamesmanship to prevent or delay public disclosure is the oppo-

site of what Congress intended. *See Pfaff*, 525 U.S. at 63 ("[T]he patent system . . . encourages both the creation and public disclosure of new and useful advances in technology . . . .").

Finally, contrary to MedCo's claims (MedCo Br. 44-45), the supplier exception is not unfair to small inventors. Small and large inventors alike use third-party manufacturers—as multiple amici acknowledge. *E.g.*, Gilead Br. 17 ("Almost all pharmaceutical companies have determined that using outside manufactures is the most efficient option."); PhRMA Br. 4.[14] As discussed above, moreover, the use of third-party manufacturing for experimental purposes will not trigger the bar. And in all events, the on-sale bar *does not prohibit any transaction*; it merely places the burden on the inventor to apply for a patent.

C. *Stare Decisis* Requires This Court To Uphold *Special Devices*.

Finally, MedCo fails to offer adequate justification to upend settled precedent and overrule *Special Devices*. MedCo claims *stare decisis* "is not applicable here" because its proposed new rule is "consistent with the precedent of this Court and the Supreme Court." MedCo Br. 54. This is absurd. MedCo's proposed test runs counter to decades of settled case law from this Circuit. *See* Hospira Br. 45-46. The only "special justification" MedCo can muster is its claim (MedCo Br. 65)

[14] Small inventors also have other options to profit from their inventions without triggering the bar, such as through licenses or assignments. *See In re Kollar*, 286 F.3d 1326, 1334 (Fed. Cir. 2002).

that cases after *Special Devices* have misapplied *Pfaff*—but, even if true, this would not warrant a new rule. Any revision of the on-sale bar must come from Congress, not from this Court—and even if the AIA embodies such a revision, it applies only to patents whose effective filing dates are long after the filing dates here.

CONCLUSION

For the foregoing reasons, the district court's decision that MedCo's transactions with BVL did not trigger the on-sale bar should be reversed. In the event that the en banc court holds otherwise, it should remand to the panel for consideration of the remaining issues raised by MedCo's appeal and Hospira's cross-appeal.

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Respectfully submitted,

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March 14, 2016

CERTIFICATE OF SERVICE

I hereby certify that on March 14, 2016, I caused the foregoing Reply Brief of Defendant-Cross-Appellant Hospira, Inc. in Response to the Court's November 13, 2015 Order to be electronically filed with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the CM/ECF system, which also caused a copy of the foregoing to be delivered by electronic means to the counsel of record listed below.

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CERTIFICATE OF COMPLIANCE

I hereby certify that:

1. This Brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because this Brief contains 6,982 words, excluding the parts of the Brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii) and Federal Circuit Rule 32(b).

2. This Brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this Brief has been prepared in a proportionately spaced typeface using Microsoft Office Word 2007 in Times New Roman, Font Size 14.

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