2014-1469, -1504

United States Court of Appeals for the Federal Circuit

THE MEDICINES COMPANY,

Plaintiff-Appellant,

v.

HOSPIRA, INC.,

Defendant-Cross-Appellant.

Appeals from the United States District Court for the District of Delaware in No. 1:09-cv-00750-RGA, Judge Richard G. Andrews.

EN BANC BRIEF FOR AMICUS CURIAE HOUSTON INTELLECTUAL PROPERTY LAW ASSOCIATION IN SUPPORT OF THE MEDICINES COMPANY

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March 1, 2016

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

The Medicines Company v. Hospira, Inc.

Nos. 2014-1469, -1504

CERTIFICATE OF INTEREST

Counsel for the Houston Intellectual Property Law Association certifies the following:

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

   Houston Intellectual Property Law Association.

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 us is:

   Houston Intellectual Property Law Association.

3. All parent corporations and any publicly held companies that own ten percent or more of the stock of the party or amicus curiae represented by us are:

   None.

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

   Tamsen Valoir
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Dated: March 1, 2016

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INTERESTS OF AMICUS CURIAE

The Houston Intellectual Property Law Association (HIPLA) is an association of hundreds of lawyers and other professionals who predominantly work in the vicinity of Houston, Texas. The practice of most of the HIPLA membership relates in substantial part to the field of intellectual property law. Founded in 1961, HIPLA is one of the largest associations of intellectual property practitioners in the United States. HIPLA's mission is to promote the development and understanding of intellectual property law through regular meetings, sponsored CLE opportunities, and *amicus* briefs. As an organization, HIPLA has no stake in the outcome of this case.[1] HIPLA does, however, have an interest in seeking the correct and consistent development of the law affecting patents and other forms of intellectual property.[2]

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[1] In accordance with Fed. R. App. P. 29(c)(5), HIPLA states that no party to the appeal or its counsel authored this brief in whole or in part. Further, no party to the appeal, its counsel, or other person besides HIPLA has contributed money that was intended to fund preparation or submission of this brief. HIPLA's amicus committee and Board of Directors voted on the preparation and submission of this brief, and no HIPLA member voting to prepare and submit this brief has served as record counsel to any party in the subject of this appeal.

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

QUESTIONS PRESENTED AND BRIEF ANSWERS

The Court identified the following issues in its November 13, 2015, Order setting this matter for consideration:

> **(a) Do the circumstances presented here constitute a commercial sale under the on-sale bar of 35 U.S.C. § 102(b)?**
>
> > **(i) Was there a sale for the purposes of § 102(b) despite the absence of a transfer of title?**
> >
> > **(ii) Was the sale commercial in nature for the purposes of § 102(b) or an experimental use?**
>
> **(b) Should this court overrule or revise the principle in *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353 (Fed. Cir. 2001), that there is no "supplier exception" to the on-sale bar of 35 U.S.C. § 102(b)?**

Amicus Curiae HIPLA briefly answers questions (a)(ii)[3] and (b) as follows:

> (a)(ii) The facts in the instant case fully support an experimental use negation because FDA regulations mandated most of The Medicine Company (MedCo)'s actions, not commercial intentions. Further, it is likely that

[3] Question (a)(i) is not addressed herein because that question was well briefed by the *Amicus Curiae* AIPLA, and *Amicus Curiae* HIPLA supports that analysis.

the drug product could *not* be legally sold prior to FDA approval of the changed manufacturing protocol.

(b) *Special Devices* should be revised to the extent needed to expressly recognize an "outsourcing" exception to the on-sale bar, and thereby provide a safe harbor for outsourced services or products. This would level the playing field for large and small companies, and is consistent with the *Pfaff* test since outsourcing and any subsequent private internal activities are not "commercial" sales under the on-sale bar. Even if this Court does not create an express outsourcing exception, the Court should consider creating an express safe harbor for FDA-mandated experimentation.

SUMMARY OF THE ARGUMENT

In the instant case, the panel decision concluded that the first three validation batches were not for experimental purposes, perhaps because the panel failed to appreciate the full scope of FDA regulations, which dictated most of The Medicine Company's (MedCo's) actions.

The fact that a bivalirudin drug product had been approved under a prior manufacturing protocol did not mean that the three validation batches (or the eight subsequent batches) could be sold to the public—they probably could not. MedCo had produced the three validation batches using a process that included major changes, and all major changes to a drug manufacturing process must be approved by the FDA *before* any drugs made by an amended process are permitted to be sold.

Drug stability testing is done at appropriate intervals, and it is one type of testing typically required to be performed in changing the manufacturing process. FDA regulations mandate that stability testing be performed on the product in its *packaged and marketed form* and on *an adequate number of batches*. FDA regulations also mandate *labeling all drugs with batch or lot numbers*, and they mandate *quarantining* such drugs before release for sale. Therefore, MedCo's activities were largely FDA mandated, and these

activities should *not* be interpreted incorrectly as evidence of patent-invalidating commercial intentions.

The fact that MedCo bought large batches of drug, packaged each in accordance with commercial labels, and then stockpiled the packaged product did not make these batches commercial, nor are they indicative of commercial intent where these actions are mandated by law. The batches might eventually become commercial products, but *not* until the FDA approved the changes in manufacturing processes and MedCo lifted the quarantine. If the FDA had not approved the changes, the batches would have been destroyed.

Furthermore, the batches that were subsequently made and stockpiled in anticipation of FDA final approval for sale illustrate the need for an "outsourcing" exception, which would allow a small company—one that *must* outsource (*e.g.*, particularly to comply with regulatory law)—to accomplish the otherwise private activities that a larger company could safely accomplish in-house, thus leveling the playing field.

The outsourcing exception is also consistent with the *Pfaff v. Wells* test, because such sales are not commercial in nature where the patentee intends only private activities with the outsourced goods or services. Therefore, so long as the patented goods or services are neither sold nor used by the

patentee to manufacture another product that is sold, the sale is *not* a commercial sale.

Further, an outsourcing exception would comply with the policies underlying the 102(b) bar in preventing a patentee from extending patent term beyond 20 years, but yet allow a smaller company patentee to outsource supplies and services—just as a larger, vertically integrated company patentee could accomplish entirely in-house.

Finally, in a case like this, an outsourcing exception would also serve the public interest in ensuring a continuous supply of drug, because stockpiling would help to eliminate any gap in supply of the drug.

ARGUMENT

I. *Pfaff v. Wells* retained the experimental use negation of the on-sale bar.

Pfaff v. Wells Electronics, Inc., 525 U.S. 55 (1998), eliminated the prior "totality of the circumstances test" used to determine if there was an on-sale bar in favor of a new two-part test. The new test provides:

> First, the product must be the subject of a commercial offer for sale.
>
> Second, the invention must be ready for patenting. That condition may be satisfied in at least two ways: by proof of reduction to practice before the critical date; or by proof that prior to the critical date the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention.

Id. at 67.

The first prong of the test was not at issue in the *Pfaff* case because Pfaff admitted that he had made a commercial sale. *See Pfaff v. Wells Electronics, Inc.* 124 F.3d 1429, 1433 (Fed. Cir. 1997) ("Pfaff acknowledged in his testimony that, as a result of his meetings with TI, he had a 'go' situation and that they had a 'deal' prior to the critical date. Pfaff further admitted that the arrangement with TI was purely commercial, with no experimentation or additional development involved."). Therefore, the first

prong of the test was not extensively discussed in the Supreme Court's opinion.

Nonetheless, the Supreme Court expressly *retained* the experimental use negation of the on-sale bar. *Pfaff*, 525 U.S. at 67 ("there is no question that the sale was commercial rather than experimental in character."); *Id.* at 64 ("The law has long recognized the distinction between inventions put to experimental use and products sold commercially."). *See also EZ Dock, Inc. v. Schafer Systems, Inc.*, 276 F.3d 1347, 1352 (Fed. Cir. 2002) (discussing *Pfaff* and noting that "the Supreme Court explicitly preserved proof of experimentation as a negation of statutory bars.").

The Supreme Court also made it reasonably clear that a "commercial" sale is for the purpose of *profit*, and that a sale primarily for experimentation was not a commercial sale, by quoting the *City of Elizabeth* case with approval. *Id.* at 35 ("'it is the interest of the public, as well as himself, that the invention should be perfect and properly tested, before a patent is granted for it. Any attempt to use it for a profit, and not by way of experiment, for a longer period than two years before the application, would deprive the inventor of his right to a patent.'"), citing *City of Elizabeth v. Am. Nicholson Pavement Co.*, 97 U.S. 126, 137 (1877). *See also Atlanta Attachment Co. v.*

Leggett & Platt, Inc., 516 F.3d 1361, 1365 ("Our patent laws deny a patent to an inventor who applies for a patent more than one year after making an attempt to profit from his invention by putting it on sale."); *Electromotive Div. of GMC v. Transp. Sys. Div. of GE*, 417 F.3d 1203, 1210 (Fed. Cir. 2005) ("If the sale was primarily for experimentation rather than commercial gain, then the sale is not invalidating under § 102(b)."") (citation omitted); *Trading Techs. Int'l, Inc. v. eSpeed, Inc.*, 595 F.3d 1340, 1362 (Fed. Cir. 2010) ("Brumfield's request to TT to make software for his own secret, personal use could not constitute a sale under 35 U.S.C. § 102(b).").

II. While *Pfaff v. Wells* retained the experimental use negation, some confusion remains about its application.

Although *Pfaff* affirmed the continuing existence of the experimental use negation to the "commercial offer for sale" prong of the on-sale bar, there is some confusion surrounding the scope and application of the negation.

For example, the vacated panel opinion (as well as other panel decisions) stated that experimental use cannot occur after reduction to practice. *See, e.g.*, *The Medicines Company v. Hospira Inc.*, 791 F.3d 1368, 1372 (Fed. Cir. 2015) ("[E]xperimental use cannot occur after a reduction to practice.") (citation omitted).

However, neither durability nor stability testing[4] can be performed *before* reduction to practice because there is no final product to test. Therefore, "experimental use cannot occur after reduction to practice" cannot be a correct statement of the law because the Supreme Court in *City of Elizabeth* expressly recognized that durability testing was an acceptable form of experimental use. *City of Elizabeth*, 97 U.S. at 135:

> If durability is one of the qualities to be attained, a long period, perhaps years, may be necessary to enable the inventor to discover whether his purpose is accomplished. And though during all that period he may not find that any changes are necessary, yet he may be justly said to be using his machine only by way of experiment, and no one would say that such a use, pursued with a bona fide intent of testing the qualities of the machine, would be a public use within the meaning of the statute.

See also Atlanta Attachment Co. v. Leggett & Platt, Inc., 516 F.3d 1361, 1368-69 (Fed. Cir. 2008), *concurrence* by J. Prost, ("If we were to accept that reduction to practice eliminates availability of the experimental use doctrine as a whole, the continuing viability of that doctrine would exist only between the time an invention is ready for patenting and the time it is reduced to practice. Such a result would severely restrict the rights of inventors to

[4] Stability testing of drugs is the chemical equivalent to durability testing of mechanical products.

conduct ongoing work on an invention . . . a proposition flatly contradicted by *Pfaff*.").

Other panels have suggested that experimentation cannot exist outside the scope of the claims. *EZ Dock*, 276 F.3d at 1353 ("This court and its predecessor have noted that experimentation negates a bar when the inventor tests claimed features of the invention.") (citing *In re Theis*, 610 F.2d 786, 793 (CCPA 1979) ("It is settled law that . . . experimental use . . . does not apply to experiments performed with respect to non-claimed features of an invention.")).

City of Elizabeth again shows that this statement of the law cannot be true. The patents at issue in this wooden pavement case included US102991 and USRE3274, *neither* of which claimed durability,[5] yet durability was expressly accepted by the Supreme Court as an acceptable purpose for experimentation. *See City of Elizabeth*, 97 U.S. at 135, quoted above.

These issues are squarely implicated in this case. For example, do experiments required by the FDA fall within the scope of the experimental use

[5] Neither patent mentions durability, but US102991 concludes with claim language "…for the purpose described [above]" and among the purposes described above in US102991 is "to prevent any gravel from working under the paving-blocks."

negation, even if outside the scope of the claims or not required for reduction to practice? It is hoped that the *en banc* court will provide some clarity in this regard, but *City of Elizabeth* strongly suggests that the experimental use negation *does include* experimentation for such purposes.

III. The panel decision erred in concluding that validation batches were not produced for experimental purposes; FDA regulations, not commercial intentions, primarily dictated MedCo's actions.

In the instant case, the panel concluded that the first three validation batches were not for experimental purposes, perhaps because the plethora of relevant FDA regulations were not adequately provided to the court.

In order to truly appreciate experimental use in the medical context, one needs an appreciation of FDA regulation of drugs and devices. While MedCo provided a few of the relevant regulations, *e.g.*, in its *Combined Petition for Panel Rehearing and Rehearing En Banc*, we believe that it would be beneficial to provide more detail on these FDA regulations. We therefore begin with some of the most relevant FDA statutes and regulations.

A. FDA regulations addressing drug production and control are particularly relevant.

All new pharmaceuticals (and certain classes of medical devices) are heavily regulated and require premarket approval under the Federal Food,

Drug, and Cosmetic Act ("FDCA"). *See* 21 U.S.C. §§ 301-399d [FDCA], particularly § 351 ("Adulterated drugs . . ."), § 352 ("Misbranded drugs . . ."), and § 355 ("New drugs"). Generally speaking, the FDCA prevents adulterated or misbranded drugs, and also requires that drugs be safe and effective. Before approval, new drugs cannot legally be sold.[6]

However, regulation continues even *after* drug approval. For example, post-approval studies are often required. *See, e.g.*, 21 CFR[7] Sec. 314.81 ("Other postmarketing reports"). In addition, the entire manufacturing process and labeling are heavily regulated, even *after* approval. *See, e.g.*, 21 CFR Sec. 201.1 to 201.327 ("Part 201 – Labeling"); 21 CFR Sec. 211.1- 211.208 ("Part 211 – Current Good Manufacturing Practice for Finished Pharmaceuticals"), and particularly 21 CFR Sec. 211.122; 211.125; 211.130; 211.132; 211.134; and 211.137 (all sections of "Subpart G – Packaging and Labeling Control").

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[6] There are unapproved drugs for sale in the US, most of which are pre-FDCA drugs or variations on these historical drugs. *See, e.g.*, <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm070290.pdf > (viewed Feb. 22, 2016).

[7] A full text, searchable copy of all nine volumes of 21 CFR is available at: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm> (viewed Feb. 22, 2016).

Drugs are typically made in "batches" and batch manufacture is regulated. *See, e.g.*, 21 CFR 211.188 ("Batch Production and Control Records")("Batch production and control records shall be prepared for each batch of drug product produced and shall include complete information relating to the production and control of each batch."); 21 CFR 211.192 ("Production record review")("All drug product production and control records, including those for packaging and labeling, shall be reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed.").

In addition, FDA regulations mandate that drug labels include batch and lot numbers, and failure to include these may result in a drug being declared misbranded. 21 CFR 211.130 ("Packaging and labeling operations") (requiring "Identification of the drug product with a lot or control number that permits determination of the history of the manufacture and control of the batch."); and 21 CFR 201.18 ("Drugs; significance of control numbers") ("An incorrect lot number may be regarded as causing the article to be misbranded.").

Quarantining of drugs until quality control is complete is also mandated. 21 CFR 211.192 ("Production record review") [cited and quoted above]; 21 CFR 211.142 ("Warehousing procedures") ("Written procedures describing the warehousing of drug products shall be established and followed. They shall include: (a) ***Quarantine*** of drug products before release by the quality control unit.") (emphasis added).

All major changes to a manufacturing protocol must be preapproved. 21 CFR 314.70 ("Supplements and other changes to an approved application") ("(b) Changes requiring supplement submission and approval prior to distribution of the product made using the change (major changes). (1) A supplement must be submitted for any change in the drug substance, drug product, production process, quality controls, equipment, or facilities that has a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product . . . (3) The applicant ***must obtain approval of a supplement from FDA prior to distribution of a drug*** product made using a change under paragraph (b) of this section.") (emphasis added).

The FDA filing to implement a major change to a Master Batch Record is called a "Prior Approval Supplement" or "PAS." In the instant case, a change to the Master Batch Record affecting the level of Asp-9 impurity in the bivalirudin final product is probably a major change, and thus likely required a PAS. 21 CFR 314.70 ("Supplements and other changes to an approved application") ("(2) These [major] changes include, but are not limited to . . . (iv) Changes in the synthesis or ***manufacture of the drug substance that may affect the impurity profile*** and/or the physical, chemical, or biological properties of the drug substance") (emphasis added).

Stability testing is one type of testing required at appropriate intervals, and such testing would typically be required to support a PAS. 21 CFR 211.166 ("Stability testing") ("The written program [for stability testing] shall be followed and shall include: (1) Sample size and test intervals based on statistical criteria for each attribute examined to assure valid estimates of stability").

Stability tests are performed on an adequate number of batches—not a single batch. *Id.* ("An adequate number of batches of each drug product shall be tested . . ."). In addition, the batches are to be tested in the same packaging in which they are marketed. *Id.* ("Testing of the drug product in the same

container-closure system as that in which the drug product is marketed"). Thus, stability testing is not performed on small bench-top samples of drugs, but requires full batch synthesis and complete packaging of multiple batches.

Stability tests will only consume a tiny amount of any batch, and the remaining amount typically would be stored under appropriate conditions and under quarantine until release once all required testing confirms that the batch was made and packaged in accordance with regulations (*e.g.*, those governing production and control records). *See, e.g.*, 21 CFR 211.192 ("Production record review") [cited and quoted above]. Further, if a PAS is required because a major change in manufacturing is proposed, then the quarantine will continue until the proposed change is approved. *See, e.g.*, 21 CFR 211.142 ("Warehousing procedures") [cited and quoted above].

A batch that is not removed from quarantine status because of quality issues or rejection of a PAS cannot be legally sold. 21 CFR 211.165 ("Testing and release for distribution") ("Drug products failing to meet established standards or specifications and any other relevant quality control criteria shall be rejected. Reprocessing may be performed. Prior to acceptance and use, reprocessed material must meet appropriate standards, specifications, and any other relevant criteria.")

B. FDA regulations primarily dictated MedCo's actions.

MedCo followed the above-noted regulations. Indeed, the District Court opinion details MedCo's general operating procedures, as follows:

> Generally, after Ben Venue would manufacture a batch, it would create a batch record, which was sent to The Medicines Company. The Medicines Company would review the batch records and issue a Certificate of Manufacture if the records met the specifications. Once The Medicines Company issues the Certificate of Manufacture, it clears the product for delivery to the packager. After the packager applies the required labeling and boxing, the batch is released and sent to the distributor, ICS, under "quarantine" conditions." Once The Medicines Company conducts a final review [confirming the quality and compliance with written controls of each batch], the batch is removed from quarantine status and is available for sale [to the public].

The Medicine Company v. Hospira, Inc. [trial opinion], 2014 WL 1292802, *9 (D. Delaware).

The fact that a bivalirudin drug product was already approved under a prior manufacturing protocol did not mean that the three validation batches (or eight subsequent batches) could be sold to the public—they probably could not. MedCo had produced the three validation batches using a process that included major changes, and all major changes to the manufacturing process must be approved by the FDA before any drugs made by an amended process could be sold. 21 CFR 314.70(b) ("Supplements and other changes to

an approved application") ("The applicant ***must obtain approval of a supplement from FDA prior to distribution of a drug*** product made using a [major] change . . .") (emphasis added).

The regulations mandate that stability testing be performed on the product in its packaged and marketed form and on an adequate number of batches. 21 CFR 211.166 ("Stability testing") ("Testing of the drug product in the ***same container-closure system as that in which the drug product is marketed***; . . . ***An adequate number of batches*** of each drug product shall be tested . . . .") (emphasis added). The regulations further mandate labeling all drugs with batch or lot numbers and mandate quarantining of such drugs before release for sale. 21 CFR 201.18 ("Drugs; significance of control numbers"); 21 CFR 211.130 ("Packaging and labeling operations"); and 21 CFR 211.142 ("Warehousing procedures") [each cited and quoted above].

Thus, the fact that MedCo bought multiple large batches of drug, packaged each in accordance with commercial labels, and then stockpiled the unused packaged product did not make these batches commercial, nor are these actions evidence of patent-invalidating commercial intent, because MedCo was *required* by law to follow all regulations. The batches might eventually become commercial products, but not until the FDA approved the

changes and the quarantine was lifted. If the FDA had not approved the changes, the batches would have been destroyed.

Furthermore, the potential market value of 10 million dollars that is noted in the panel opinion, 791 F.3d 1368, 1371, is misleading. In fact, this market value probably represents only about a six-day supply of drug in the United States.[8] While the panel made much of such numbers, stockpiling a few days of drug supply hardly seems culpable enough to warrant the severe punishment of patent invalidity, especially where the statute prohibits *sales* more than a year before filing, not *stockpiling*. 35 U.S.C. § 102(b). Furthermore, the alternative is to destroy the excess drug or otherwise dispose of it, which would be wasteful.

[8] U.S. sales of Angiomax totaled to about 600 million dollars in 2014, which translates to about 1.6 million dollars per day. Thus, 10 million dollars worth of product would last a little more than 6 days. *See* Matthew Bultman, "Full Fed. Circ. To Review On-Sale Bar In Angiomax Patent Suit," *Law360* (Nov. 13, 2015) http://www.law360.com/articles/726914/ ("Angiomax, which had U.S. sales of $599.5 million in 2014, is the brand name of bivalirudin, which is used to treat blood clots in people with severe chest pain or who are undergoing angioplasty to open blocked arteries.") (viewed Feb. 22, 2016).

IV. An outsourcing exception of some kind is needed to level the playing field.

In addition to the three validation batches used to provide data to the FDA, eight additional batches were made and transferred to MedCo before the critical date, and Hospira alleges these were also commercial sales. *Defendant-Cross-Appellant Hospira, Inc.'s Opposition To Petition For Rehearing En Banc*, p. 3 ("Subsequent to validation—but still before the critical date—MedCo paid Ben Venue to manufacture eight more commercial batches of Angiomax with the revised process.").

However, the patents at issue provide that 24 batches were assayed in order to provide *statistically significant proof* that the maximum impurity level of Asp9-bivalirudin was less than 0.6%. *See, e.g.*, Table 7 of both US7582727 and US7598343; *see also* Table 8 of both patents, which shows statistical significance ($p < 0.05$); *Response And Reply Brief Of Plaintiff-Appellant The Medicines Company*, p. 39 ("it was not until after 25 batches[9] were made and analyzed before the claimed 'maximum impurity level of Asp9-bivalirudin' was appreciated and verified."). Therefore, the facts appear to fully support a finding of experimental use for these eight batches as well.

[9] [Sic]. "25 batches" should probably be "24 batches" since "[t]he results of one batch was not included in the data presented in Table 7, as the method used to generate the batch was not compliant with the protocol established for this study." US7582727, col. 23, ll. 14-16; and US7598343, col. 23, ll. 53-55.

But even if the eight batches were not for experimental use, there is no evidence provided that the drugs were ever sold to the public before the critical date, and the FDA regulations make it clear that they could *not* be sold until the PAS was approved. 21 CFR 314.70(b) ("applicant must obtain ***approval*** of a supplement from FDA ***prior to distribution*** . . .") (emphasis added).

Nevertheless, Hospira alleges that the "stockpiling" in the instant case was a commercial benefit, relying on the holding in *Special Devices*. *Principal Brief Of Defendant-Cross-Appellant Hospira, Inc. In Response To The Court's November 13, 2015 Order*, pp. 21-22 ("[*Special Devices*] recognizes that commercially stockpiling an invention—as MedCo did here—can provide an inventor with enormous commercial benefit regardless of whether the inventor makes any sales itself.").

The existence of these batches clearly indicates a need for an "outsourcing"[10] safe harbor and a potential revision to the *Special Devices*

[10] The term "outsourcing" is intended to imply outsourcing for private uses only, and it is believed to have narrower implications than a potentially broader "supplier" exception, which may imply obtaining supplies for later sale, as seemed to be the case in *Special Devices*. We recognize of course that the Federal Circuit can define the parameters of either term as it sees fit.

holding to the extent needed. *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353, 1357 (Fed. Cir. 2001) ("we . . . hold that no 'supplier' exception exists for the on-sale bar.").

An "outsourcing" exception is needed to "level the playing field" for large and small companies. For example, a vertically integrated company "VertiCo" may begin manufacturing and stockpiling drug under these facts without risking an on-sale bar. Furthermore, such stockpiling would be in the public interest because the alternative could result in a gap in the supply of the drug if the interruption in manufacturing resulted in prior supplies running out. Thus, stockpiling would ensure that patients could receive the drug as soon as the FDA approved the change in manufacturing protocol. There would be no risk to VertiCo in stockpiling in anticipation of FDA approval, because the statute doesn't prohibit stockpiling more than a year before patent filing—only commercial sales. 35 U.S.C. § 102(b).

However, a smaller company that *must* outsource manufacturing cannot stockpile under the panel's holding in the instant case—penalizing the smaller company and providing an additional advantage to a larger VertiCo.

For this reason, an "outsourcing" exception should be provided. The outsourcing exception would allow smaller companies to obtain products that

can be used for testing, as was done with the validation batches, and also allows them to stockpile in anticipation of future approval for sale. Such an exception is consistent with the statutory language, which prohibits public uses and sales more than a year before patent filing—not stockpiling.

Further, an outsourcing safe harbor would also serve the public interest in ensuring a continuous supply of drug because patentee could now safely stockpile outsourced drugs.

A. A focus on "profit" prevents the "commercial benefit" inquiry from expanding to cover all actions.

In determining whether an offer or a sale is primarily for experimental or commercial purposes, a focus on "profit" (or potential profits) would prevent a "commercial benefit" inquiry from expanding unreasonably to cover every action a patentee might undertake. In this case, the panel held that the manufacturing services provided a commercial benefit to patentee because Medco used the batches to prove to the FDA that the batches met the already approved specifications for the product. *The Medicines Company*, 791 F.3d at 1368. Under such an expansive reading of commercial benefit, the experimental use negation is stripped of all vitality, and the dangers of focusing on "commercial benefit" rather than sales, and the potential profits generated by sales, become apparent. How can generating data needed for

FDA approval be closer to a commercial sale than an experimental use when, absent that approval, no commercial sale is even possible? Recognition of an express outsourcing exception for otherwise private activities properly places the focus on potential profits and would help to prevent this kind of error in the future. *Atlanta Attachment Co.*, 516 F.3d at 1365 ("Our patent laws deny a patent to an inventor who applies for a patent more than one year after making an attempt to profit from his invention by putting it on sale."); *Trading Techs. Int'l, Inc. v. eSpeed, Inc.*, 595 F.3d 1340, 1362 (Fed. Cir. 2010) ("Brumfield's request to TT to make software for his own secret, personal use could not constitute a sale under 35 U.S.C. § 102(b).").

B. An outsourcing exception would comply with the policies underlying the 102(b).

The policies behind the 102(b) bars have been enumerated as follows:

> (1) discouraging the removal from the public domain of inventions that the public reasonably has come to believe are freely available; (2) favoring the prompt and widespread disclosure of inventions; (3) allowing the inventor a reasonable amount of time following sales activity to determine the potential economic value of a patent; and (4) prohibiting the inventor from commercially exploiting the invention for a period greater than the statutorily prescribed time of one year.

Continental Plastic Containers v. Owens Brockway Plastic Prods., Inc., 141 F.3d 1073, 1077 (Fed. Cir. 1998) (citation omitted).

An outsourcing exception would comply with the policies underlying the 102(b) in preventing a patentee from extending his term beyond 20 years, because subsequent sales for potential profit *to the public* of either the goods or products made using the goods would still initiate the bar clock. The public would not be deprived of anything because such an exception covers only a patentee's outsourcing and private activities, not any public activity. *Trading Techs. Int'l*, 595 F.3d at 1362 ("Brumfield's request to TT to make software for his own secret, personal use could not constitute a sale under 35 U.S.C. § 102(b).").

Such an outsourcing exception is also consistent with the concurrence by Judge Prost in *Atlanta Attachment Co.*, 516 F.3d at 1370 ("When the inventor conducts a commercial transaction in order to facilitate development, but the development activity meets the requirements of the experimental use doctrine, the inventor avoids the on-sale bar. This exception to the on-sale bar does not evaporate upon reduction to practice. In essence, just as inventors could develop any aspect of the invention privately, they may employ the concepts of agency and confidentiality to also accomplish

the same result."); *see also Trading Techs. Int'l, Inc. v. eSpeed, Inc.*, 595 F.3d 1340, 1361-62 (Fed. Cir. 2010) ("Inventors can request another entity's services in developing products embodying the invention without triggering the on-sale bar."); *Continental Plastic Containers*, 141 F.3d 1073, 1077 (§ 102 serves to "prohibit[] the inventor from commercially exploiting the invention for a period greater than the statutorily prescribed time of one year").

V. A safe harbor consistent with the policies of *Merck v. Integra* (2005) would allow small companies to comply with FDA regulations.

Even if an express outsourcing exception is not created, the Court should consider creating an express safe harbor for FDA-mandated experimentation, even if post-approval. In *Merck v. Integra* (2005), a unanimous Supreme Court held that the safe harbor of 35 U.S.C. § 271(e)(1) is not limited only to research conducted in clinical trials, but also extends to preclinical studies. 545 U.S. 193, 208. Similarly, the Federal Circuit extended the safe harbor to post-approval studies in *Classen Immunotherapies, Inc. v. Elan Pharmaceuticals, Inc.*, 786 F.3d 892 (Fed. Cir. 2015).

Although the Supreme Court in *Merck* was concerned with interpreting FDA-mandated experimental uses under § 271(e)(1) and not § 102(b), the *Merck* opinion represents both a sound understanding of the interaction

between patent law and FDA law, as well as a preference for interpreting patent law exceptions so as to favor the submission to the FDA of data on drug safety.

Just as the Supreme Court in *Merck* interpreted the § 271(e)(1) safe harbor exception so as to favor submission to the FDA of data on drug safety, so *Amicus Curiae* HIPLA respectfully requests the *en banc* Federal Circuit recognize a safe harbor for FDA-mandated experimentation under 35 U.S.C. § 102(b). Under such a safe harbor, an innovative small company like MedCo could comply with FDA regulations for gathering and submitting even post-approval data on drugs as packaged for delivery to patients without risk of triggering the on-sale bar.

As Professor Andrew Baluch (and former Clerk to the Honorable Richard Linn of this Court) has concluded in a related context, "[t]he infringer's experimental use defense to § 271(a) should be drawn roughly equal to the inventor's experimental use negation of § 102(b) because both exceptions share common historical origins . . . , further similar policy goals, and are evidenced by similar objective factors of experimentation." Baluch, Andrew S., "Relating the Two Experimental Uses in Patent Law: Inventor's Negation and Infringer's Defense," *Boston University Law Review*, Vol. 87, pp. 213-253, 253 (2007).

CONCLUSION

Amicus Curiae HIPLA respectfully urges the *en banc* court to overrule the panel holding as to experimental uses and to provide clarity surrounding application of the experimental use negation. *Amicus Curiae* HIPLA also urges the court to level the playing field by providing an express outsourcing exception because outsourcing and subsequent private activities do not constitute "commercial" sales within the meaning of the statute or the *Pfaff v. Wells* test.

If questions should arise about this conclusion or our analysis, please do not hesitate to contact us.

Respectfully submitted,

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APPENDIX

APPENDIX

35 U.S.C. § 102(b) (2010)

A person shall be entitled to a patent unless

(a) . . .

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or

(c) . . .

35 U.S.C. § 271(e)(1)

(e)(1) It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

CERTIFICATE OF SERVICE

I, Robyn Cocho, being duly sworn according to law and being over the age of 18, upon my oath depose and say that:

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