2014-1469, -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 IN 1:09-CV-00750-RGA, JUDGE RICHARD G. ANDREWS

BRIEF OF AMICUS CURIAE
ROBERTA J. MORRIS, ESQ., PH.D.
IN SUPPORT OF CROSS-APPELLEE
THE MEDICINES COMPANY

March 2, 2016

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CERTIFICATE OF INTEREST

Counsel for the amicus, Roberta J. Morris, Esq., Ph.D., certifies the following:

1. The full name of every party or amicus represented by me is
   Roberta J. Morris, Esq., Ph.D.

2. The name of the real party in interest represented by me is:
   Roberta J. Morris, Esq., Ph.D.

3. All parent corporations and any publicly held companies that own 10 percent of the party or amicus curiae represented by me are listed below:
   None

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trail court or agency or are expected to appear in this court (and who have not or will not enter an appearance in this case) are:
   None

March 2, 2016

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Abbreviations

Docketed Documents

"Appeal Dkt. #XXX" refers to docket item number XXX in the docket for this litigation in this Court, 14-1469

"Trial Dkt. #XXX" refers to docket item number XXX in the docket for this litigation in the District of Delaware, 09-750(RGA)

Other Terms

"Inventor" is used here to mean the inventor or patent owner

"Critical Date" means the date one year before an application was filed; events that precede that date are considered "prior" to a claimed invention that issues on that application. 35 USC § 102(b)

RULE 29 STATEMENT OF AMICUS CURIAE
ROBERTA J. MORRIS, ESQ., PH.D.

Identity: I, Roberta J. Morris, Esq., Ph.D., amicus curiae and principal counsel for myself, am a member of the patent bar and of the bars of New York and Michigan. I was a lecturer on patent law from 1991 to 2013, first at the University of Michigan Law School and then at Stanford Law School. From 1986 to 1990 I was an associate at the patent litigation firm of Fish & Neave, now Ropes & Gray. I have a JD from Harvard (1975) and a Ph.D. in Physics from Columbia (1986). At present I do not engage in private practice and I have no clients.

Interest in the Case: I have no stake in this case. My interest is in the fundamental principles of patent law.

Authority to File: This Court's November 12, 2015 Order granting Medicines' petition for a rehearing en banc authorized the filing of amicus briefs without consent of the parties and leave of court.

Responses to Rule 29(c)(5) Questions:
(A) No party's counsel has authored the brief in whole or in part.
(B) No party and no party's counsel has contributed money that was intended to fund preparing or submitting the brief.
(C) No person - other than I, the amicus curiae - has contributed money that was intended to fund preparing or submitting the brief.

Date: March 2, 2016

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I. INTRODUCTION

Cross-appellant Hospira, Inc. ("Hospira") argues that, before the critical date of the patent in suit, patent owner The Medicines Company ("Medicines") engaged in conduct which ran afoul of the on-sale bar of 35 USC § 102(b). The on-sale bar comes from the language in the statutory provision that states that "A person shall be entitled to a patent unless the invention was ... on sale or in public use more than a year prior to the date of the application for patent." Placing the invention "on sale" has long been held to include offers for sale as well as outright sales; experimental use has long been held to negate "public" use.

But even in Hospira's view of the facts, what Medicines did was buy, not sell, the claimed invention. The distinction matters because the statute is directed to specific actions of inventors. (When other people engage in 102(b) activities it is more logical to refer to them as prior art rather than "bars." See part III A, below.)

In the transaction relied on by Hospira, the only party selling anything was the contract manufacturer. Whatever the manufacturer sold,* Medicines was the buyer. To establish that the inventor made a

* The trial court found that the manufacturer was paid for manufacturing services not for the claimed pharmaceutical batches, based on evidence including the invoice and a contract clause by which title remained with Medicines. Trial Dkt. #827 at 21 (pdf 22); see also Appeal Dkt. #58 at 4.

sale, Medicines must be charged with its manufacturer's conduct. But then it would be on both sides of the transaction. That is a wash. The only bar Medicines could have violated is an on-buy bar, but there isn't one.

II. THERE IS NO ON-BUY BAR, NOR SHOULD THERE BE

The statute contains no prohibition against inventors buying their own invention. To understand why not, consider the reasons behind the statutory scheme.

A. Why There Is An On-sale Bar And A Grace Period

The reasons for American patent law's on-sale bar and grace period have been stated in many decisions in a variety of ways. E.g., *Pfaff v. Wells Electronics, Incbb.*, 525 US 55, 63-65 (1998). Those discussions can be summarized as follows: The grace period and the on-sale bar act as a carrot and stick to ensure use of the patent system, considered under our Constitution to be a public good. Art. I, § 8, cl. 8. The grace period and the on-sale bar together also carry moral weight, discouraging both sin and crime.

1. The carrot is the grace period: a year in which to perfect the invention before embarking on the costly and time-consuming process of obtaining a patent. The grace period gives good ideas a better chance to be developed and made public -- patented -- rather than being abandoned or kept secret. When inventors use the patent system, the public domain

is enriched by the teachings of the published application or issued patent, and by the right to practice the invention freely when it rises to the public domain at the end of the patent term.

2. The stick is the threat of invalidity for inventors who wait too long to file. On-sale activity (sales, offers to sell, and public uses) starts the clock ticking. Once the year is up, the inventor must forgo claims that read on that activity. This reflects Congress' balancing the patent system's public benefit -- promoting Progress -- with the private one -- the promise to Inventors of an exclusive Right for limited Times to their Discoveries. Art. I, § 8, cl. 8.

3. Discouraging sin is accomplished by using that stick against inventors who commit the sin of commercial exploitation. Inventors ought not unilaterally to confer on themselves a longer period of exclusivity than the law allows. The penalty is not just invalidity of specific claims but also unenforceability of the patent and possibly other related patents. Filing an application without disclosing the inventor's own 102(b) activity can lead to a finding of inequitable conduct. E.g., *Brasseler, U.S.A.I., L.P. v. Stryker Sales Corp.*, 267 F.3d 1370 (Fed. Cir. 2001).

4. Discouraging crime is another aspect of the carrot and stick scheme. The crime is that of robbing the public domain of what the

inventor had given it via commercial exploitation more than one year before filing for a patent.

Explaining the crime of robbing the public domain is a little tricky. True, the public is free to practice the invention once it has been placed on sale or in public use. The public may, however, have to put on the brakes if, within a year, the inventor timely files an application and succeeds at obtaining a patent. Then the invention will be subject to exclusive rights for the life of the patent.

But even during the period of exclusivity, the public has possession of the invention in the sense that it is free to learn from the teachings of the patent. The patent's written and illustrated disclosure may teach more, or better, than does inspection or purchase and use of the claimed invention. And after expiration of the patent, the document will live forever in patent databases, while te physical objects that were on sale or in public use may be lost to history.

B. A Buy Is Not Like A Sale, Offer Or Public Use

1. Inventors' Buys And The Sin of Commercial Exploitation

A sale or public use is commercial exploitation all by itself. An offer of sale is, too, whether or not accepted, because it opens a dialogue with a potential customer.

Compare a buy. When an inventor purchases embodiments of its own intellectual property -- which is how Hospira would characterize Medicines' contract for manufacturing services -- commercial exploitation of the invention does not occur until there is a separate, subsequent transaction. The buy may be necessary but it is not sufficient. It is only the preliminary. It places the non-manufacturing inventor in the same position as a manufacturing one. Until either kind of inventor takes those embodiments and does something else -- for example, offers or sells them to customers or uses them to obtain regulatory approval -- the commercial exploitation has not happened.

A buy by an inventor of its own invention has another feature that is absent from a commercial sale. The inventor is effectively on both sides of the transaction. It tells the manufacturer what to do. The manufacturer does not have the option of selling the invention to the public or using the invention publicly. The manufacturer's ability to engage in invalidating activity, absent fraud or breach of contract, is zero. The manufacturer-seller's business commercially exploits its manufacturing capabilities by manufacturing other people's inventions but its business is the same whether those inventions are patented, to-be-patented, or neither. It has no intellectual property rights in those inventions that permit it to exploit them. It is limited to dealings authorized by the inventor. There is no sin of commercial exploitation any more than there is sin when a manufacturing inventor does its own manufacturing before the critical date.

2. Inventors' Buys And The Crime Of Robbing The Public Domain

Unlike an inventor's sale, offer or public use, a buy from the inventor's contract manufacturer does not put knowledge of the claimed invention in the public domain. The subsequent issuance of a patent on an application filed more than one year after that buy does not rob the public of anything it had: the public was never placed "in possession of the invention" by the buy.

3. Why The On-Stockpile Bar Has Been Asserted

Hospira's arguments here implicitly call for an on-stockpile bar as well as an on-buy bar. Without the stockpiling, or rather without the subsequent <u>depleting</u> of that stockpile, the commercial exploitation is absent. A manufacturing inventor can stockpile its invention forever and apply for a patent whenever it wants to, regardless of the size of the stockpile.

An on-stockpile bar that only applies to non-manufacturing patent owners is wrong. First, it is unfair. Second, it is ineffective at protecting public: stockpiles can still be amassed before the critical date by manufacturing inventors. Third, it is unnecessary. Both in-house and contract manufacturing create stockpiles out of the purview of the public domain. Neither robs the public domain.

The <u>depletion</u> of the stockpile is the real exploitation. Such activities are already covered by the on-sale bar. Resort to an on-buy/on-stockpile bar is unnecessary.

III. SALES WITH THE INVENTOR ON BOTH SIDES OR NEITHER SIDE

A. <u>The On-Sale Bar v. (Plain) Prior Art</u>

When the inventor is essentially on both sides of an alleged sale, as is the case here, or on neither side, the policy justifications for applying the statutory bar may be absent.

The easiest case of "neither side" is when what is sold is the invention of someone else. If the inventor of the patent-in-suit has a claim that reads on such activity, the other inventor's sale more than a year before the patent owner's application is invalidating prior art. An inventor is in no sense barred from filing a patent application because (unknown to that inventor) some other inventors put their invention on sale or in public use. The former's claims may read on the sale and therefore be invalid, but the sale, like any other kind of prior art, is not rightly denominated a bar. The "more than a year" of the statute defines what is "prior."

The more difficult cases are those where the inventor is on both sides of the transaction (as here) and those in which the inventor apparently is on neither side of the transaction but is in backround by reason of derivation or theft. The facts of the difficult cases lead to holdings that may seem troublesome. The cause may be the failure to consider the policies behind the on-sale bar.

B. Examples

1. Inventors on Both Sides: *Brasseler*

Brasseler, U.S.I.A., L.P. v. Stryker Sales Corp., 182 F.3d 888 (Fed. Cir. 1999) is an example of inventors on both sides of an on-sale transaction. Each of the four inventors had an employment or ownership relationship with one or the other of the two companies involved in the transaction. A contract between the companies required the manufacturing company to manufacture the items solely for the buying company. There were no sales to the public. There was no "public disclosure" by this transaction. There was no sin of commercial exploitation. The inventors had perpetrated no crime of robbing the public domain by waiting too long to set the patent term clock ticking. Invalidating this patent seemed to forfeit some of the moral high ground that on-sale bar cases should occupy.

2. Inventor on Neither Side

Evans Cooling Systems, Inc. v. General Motors Corp., 125 F.3d 1448 (Fed. Cir. 1997) is another case where the inventor was on neither side of the asserted on-sale transaction. The invention had been stolen and thereafter the thief placed the invention on sale. The inventor committed neither the sin of commercial exploitation nor the crime of taking back what it had earlier placed in the public domain. Permitting a thief's action to start the clock ticking on the victim's grace period does nothing to effectuate the policies of the on-sale bar. Invalidating this patent seemed to forfeit some of the moral high ground that on-sale bar cases should occupy.

IV, ACKNOLWEDGLING A LEGAL FICTION

As with all questions of invalidity, the key question in an on-sale case is "does the claim read on this prior art?" In on-sale bar cases, the prior art is the thing sold, offered or publicly used. The legal fiction arises because the on-sale activity occurs more than a year before there is a filed application and quite a bit longer before there is an issued claim.

The on-sale bar against issued patents applies when: (a) the seller, offeror or user is the inventor or patent owner (if it is anyone else, the activity is better described as being just prior art, see Part III A, above); (b) the patent application was filed more than a year after the date of that sale, offer or use; (c) a patent ultimately issues on that application or a child application; and (d) a claim of that patent *reads on* what was sold, offered or publicly used.

That description sounds complicated and it is, because of the chronology. The doctrine employs a legal fiction that something we can identify as "the claimed invention" existed more than a year before any patent application was filed. Without a time machine, that does not seem provable. Sometimes, of course, the ultimately issued claim may be exactly what was in draft before the sale, and there may be no dispute that that claim reads on the thing sold. In such a case, the legal fiction reflects reality.

Whether or not that is true in the instant case, the legal fiction cannot be ignored. In deciding this case, the court may rely on precedent where the legal fiction was absolutely in play but never acknowledged.

The metes and bounds of a patent claim, the description of in a patent's specification of how to make and use the claimed invention, may not be known or even knowable more than a year before the filing date. Sometimes analysis under 102(b) must employ a time machine because the claimed invention, a creature born in year X, is asserted to have been offered for sale several years before. For example, the experimental use doctrine represents the desire to do justice in what may be called time machine cases. Offer cases (such as *Pfaff*) also often show signs of struggle with this legal fiction. It is respectfully submitted that acknowledgment of the time machine problem will make for better analysis of precedent in this area of the law.

V. *SPECIAL DEVICES*

In the Order for Rehearing (Appeal Dkt. #68) this Court asked whether *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353 (Fed. Cir. 2001) should be overruled. It can be distinguished on its facts. Overruling it, however, will have the advantage of removing the on-buy/on-stockpile bar from further expansion.

A. Facts

Like Medicines, Patent owner Special Devices, did not have the facilities to manufacture its invention. Like Hospira, accused infringer OEA characterized what Special Devices did with the manufactured items as "stockpiling." The real difference lies in the patent owner's concessions.

Before the critical date, Special Devices made a proposal to a manufacturer to have the manufacturer make its invention, placed an order, and appears to have taken partial delivery. (The court also mentions that Special Devices accepted the manufacturer's offer to enter into a requirements contract and asked the manufacturer to prepare that contract.)

A classic case for the assertion of the on-buy bar, right? Special Devices' approach to avoid a 102(b) bar was to ask for a "supplier exception" and to make key admissions and concessions that would make dealings with contract manufacturers easier, and less of a trap for unwary patent owners. It lost.

The concessions are noteworthy. Special Devices conceded that (a) the transaction was a "commercial [offer for] sale" by the manufacturer to the patent owner; (b) the transaction was a sale as defined by *In re Caveney*, 761 F.2d 671 (Fed. Cir. 1985) (contract to pass property rights for consideration); and (c) at that time the invention was "ready for patenting" as defined by *Pfaff*, and not under experiment.

B. Medicines' Contract With Its Manufacturer

Medicines' Conract with its manufacturer was a contract for manufacturing services. Title to what was manufactured remained in Medicines throughout. These facts make *Special Devices* distinguishable. Because the manufacturer never had title, it had no legal right to sell, offer to sell or publicly use what it manufactured absent the owner's permission.

A confidential relationship may be spelled out in such contracts as a matter of course. Oddly, however, no such clause appears to have been addressed by the *Special Devices* court nor the trial court or panel decisions in the instant case, *Medicines* (Del. 2014) and *Medicines* (Fed.Cir. 2015, *vacated*). Medicines' Combined Petition for Panel Rehearing and Rehearing En Banc (Appeal Dkt #59 at 1-3 (pdf 7-9) uses the word "confidential" several times, stating for example that the contract manufacturer was "hired to perform confidential services," and Medicines' post-trial brief (Trial Dkt. #819 at 3 (pdf 10)) is similar. That the arrangements called for confidentiality may well be undisputed. Hospira's responsive briefs do not mention it.

The fact of confidentiality should not be ignored. It means that the transaction does not place the sold items in the public domain and cannot be the basis for finding that the public domain was robbed of what it was led to think it had.

VI. CONCLUSION

It is respectfully submitted that this Court en banc refrain from reading into 102(b) an on-buy bar and an on-stockpile bar, and approve a method of analysis that views the circumstances of this case and 102(b) precedents through the lens of the justifications for that provision and with due acknowledgement of any time machine problems. This will best guarantee the progress of Useful Arts.

Respectfully Submitted,

Date: March 2, 2016

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2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6). The brief has been prepared in a proportionally spaced typeface using WordPerfect 5.1 in 14-point font Times New Roman type style.

Dated: March 2, 2016

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