No. 04-10688-AA

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

SCHERING-PLOUGH CORPORATION

and

UPSHER-SMITH LABORATORIES, INC.,

Petitioners,

v.

UNITED STATES FEDERAL TRADE COMMISSION,

Respondent.

On Petition for Review From the United States Federal Trade Commission

BRIEF OF *AMICUS CURIAE* PUBLIC PATENT FOUNDATION IN SUPPORT OF RESPONDENT

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July 31, 2004

Case No. 04-10688-AA, ***Schering-Plough Corp. v. FTC***

CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure and Rule 26.1-1 of the Rules of the Court of Appeals for the Eleventh Circuit, *Amicus Curiae* Public Patent Foundation hereby advises the Court that:

1. Public Patent Foundation is not a subsidiary or affiliate of a publicly owned corporation;

2. No publicly held company owns 10% or more of the stock of Public Patent Foundation; and

3. The following persons have an interest in the outcome of the above-captioned matter in addition to those persons already listed by the parties:

Public Patent Foundation

Daniel B. Ravicher, counsel for Public Patent Foundation

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STATEMENT OF INTEREST

Amicus curiae Public Patent Foundation ("PUBPAT") is a New York based not-for-profit public-interest legal services organization that represents the public's otherwise unrepresented interests in the patent system. More specifically, PUBPAT represents the public's interests against the harms caused by wrongly issued patents and unsound patent policy. PUBPAT also provides those persons otherwise deprived of access to the system governing patents with representation, advocacy and education. PUBPAT is funded by the Echoing Green Foundation, a not-for-profit grant making organization that has made over $22 million in seed and start up grants to over 380 social entrepreneurs.

In less than a year since its founding, PUBPAT has argued for sound patent policy before the United States Court of Appeals for the Federal Circuit, the United States Patent & Trademark Office, the National Institutes of Health, and the United States House of Representatives Subcommittee on Courts, the Internet, and Intellectual Property. PUBPAT has also requested that the Patent Office reexamine specifically identified patents causing significant harm to the public. The Patent Office has granted each such request. These accomplishments have established PUBPAT as the leading provider of public service patent legal services and one of the loudest voices advocating for comprehensive patent reform.

None of the counsel for the parties nor any other *amici* are registered patent attorneys. As such, PUBPAT believes its brief, authored by a registered patent attorney, addressing the issue of the exclusionary power of the patent involved in this matter, will be helpful to the Court in deciding this matter.[†] This is especially true since PUBPAT has significant experience in determining the exclusionary power of patents, as such an exercise is a fundamental part of each of its core activities.

PUBPAT has an interest in this matter because the Court's decision will have a significant effect on the public's interests represented by PUBPAT and because PUBPAT's mission is to represent those interests against harm that could be or is caused by unsound policy with respect to patents. More specifically, resolution of this matter will determine whether

[†] PUBPAT requested consent of the parties to the filing of a brief *amicus curiae* in this matter. Respondent gave its consent to PUBPAT, but Petitioners refused to give theirs. Instead, Petitioners demanded that PUBPAT allow them to review the proposed brief or fully disclose what its contents would be. Only after a substantive review of PUBPAT's positions and arguments would Petitioners consider whether or not to give their consent. PUBPAT believes such demands were improper, but nonetheless attempted good faith discussions with Petitioners to address any questions or issues they had regarding PUBPAT and its interests in this matter. Unfortunately, such attempts proved futile. Therefore, PUBPAT has filed a Motion for Leave to File Brief as *Amicus Curiae* with this Court.

patent holders and their privy may use patents as a way to undermine otherwise sound competition law. PUBPAT has an interest in ensuring the power of patents is not unjustifiably extended in such manner.

STATEMENT OF THE ISSUES

Is the exclusionary power of a patent always measured by its full term, or, in cases such as this where a patentee agrees to allow a certain product to be sold prior to the patent's expiration, can the exclusionary power of the patent with respect to that product be more properly determined by an analysis of the agreement between the parties?

Should the proper application of antitrust law be avoided for fear that such would devastate pharmaceutical competition or conflict with the Hatch-Waxman Act?

SUMMARY OF ARGUMENT

It is erroneous to assume that the exclusionary power of a patent is always measured by its full statutory term. Not only is such assumption unsupported by empirical analysis of patents generally, which shows that only about ½ of all asserted patents have any exclusionary power whatsoever, but such assumption is categorically contradicted when a patentee and accused infringer agree on a date prior to the patent's expiration at which time the alleged infringer can, without compensation or consequence, freely sell its product.

In those circumstances, the exclusionary power of the patent, with respect to *that* product, is measured by the agreed to pre-expiration free-entry date, because such date is, in effect, a specifically tailored patent expiration date vis-à-vis that product. Since the Commission performed such an analysis in this matter, it complied with this Court's requirement to consider the exclusionary effect of the patent in determining whether an agreement violates the antitrust laws.

Arguments against application of sound antitrust principles for fear that such may deter pro-competitive conduct, be it patent settlements in general or Hatch-Waxman patent challenges specifically, are completely circular, as, by definition, application of sound antitrust principles under the rule of reason can only deter conduct with a net anti-competitive effect. Further, deterring anti-competitive patent settlements, above and beyond protecting competition, also has the significant pro-competitive effect of encouraging more patent challenges to result in judgments.

ARGUMENT

People unfamiliar with the patent system tend to give patents entirely too much credit. Rather than being rock-solid undeniable fortresses of legal dominance over a segment of technology, patents today give their owner nothing more than, at best, a fifty-fifty chance of having any exclusionary power at all. As such, the assumption that patents have an exclusionary power equal to their full term is without merit.

Beyond generalities, when a patent holder agrees to allow the sale of a certain product prior to a patent's expiration, it is possible to determine the exclusionary power of the patent with respect to that product without resort to full-blown patent litigation. One need only look at the details of the agreement and identify what the parties negotiated the exclusionary power of the patent to be.

In compliance with this Court's requirement that the exclusionary power of a patent be considered before passing judgment regarding whether a patent settlement violates the antitrust laws, the Commission performed such an analysis of the patent in this case. *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003).

I. SCHERING'S PATENT DID NOT HAVE THE POWER TO EXCLUDE UPSHER'S GENERIC PRODUCT BEYOND SOME DATE PRIOR TO SEPTEMBER 2001.

There is no one measure of the exclusionary power of a patent, as such is merely a relative term describing the capability of the patent to prevent the manufacture, use or sale of a specific product. The same patent can have many different exclusionary powers depending upon the characteristics of the product against which it is asserted. The exclusionary power of a patent is also affected by the capabilities of the party against whom it is asserted to mount an invalidity or non-infringement defense.

While it is correct that ***one*** way to determine the exclusionary power of a patent with respect to a certain product is through resolution of the patent dispute by court judgment, that is not the ***only*** way to do so. Another effective way to determine the exclusionary power of a patent is through resolution of the dispute by agreement between the parties. It is the resolution of the dispute, not the means through which the dispute is resolved, that provides a measurement of the exclusionary power of the patent with respect to the specific product against which it has been asserted.

As an aside, attempting to identify the "potential" exclusionary effect of a patent is an impossible task, because such term has several meanings at the same time. Every patent has an array of "potential" exclusionary power ranging from no potential to exclude anything to absolute potential to exclude something. However, no patent has the "potential" to exclude everything. Therefore, it is improper to assume that all issued patents have a potential exclusionary power equivalent to their full term with respect to any product against which they are asserted. This not only fails to recognize that such a patent has the potential to have ***no*** exclusionary power with respect to any product, it also is contrary to the significant empirical evidence regarding the exclusionary power of patents available from the literature.

A. The Exclusionary Power of Patents, Generally, is Much Less Than Their Full Term.

Patents are not as powerful as many presume. First, roughly half of all issued patents later challenged in litigation are proven to be invalid. John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 205-206 (1998) (demonstrating that 46% of patents litigated to judgment on validity issues are held invalid); Patstats, U.S. Patent Litigation Statistics, University of Houston Law Center, available at http://www.patstats.org/2003.html (detailing that, in 2003, of 201 validity decisions, the patent was found to be invalid 117 times, 58%).

Second, even if no challenge to the validity is made, accused infringers still frequently nullify any exclusionary power of the asserted patent with respect to their product by proving that their product does not infringe the patent. Patstats, U.S. Patent Litigation Statistics, University of Houston Law Center, available at http://www.patstats.org/ 2003.html (detailing that, in 2003, of 339 infringement decisions, the patent was found to not be infringed 255 times, 75%).

Although one comprehensive analysis performed in the late 90's determined that patent holders were successful in asserting their patents against accused infringers 58% of the time, more recent data suggests that the exclusionary power of patents in general is declining. Kimberly A. Moore, *Judges, Juries, and Patent Cases-An Empirical Peek inside the Black Box*, 99 Mich. L. Rev. 365, 385 (2000); Patstats, U.S. Patent Litigation Statistics, University of Houston Law Center, available at http://www.patstats.org/2003.html.

Since roughly half of all asserted patents end up having no exclusionary power whatsoever, it is improper to assume that any particular asserted patent will have complete exclusionary power with respect to any product throughout its full term. Such an assumption is no more justified than assuming the patent will have no exclusionary power with respect to any product.

Rather than leave the analysis at an all-or-nothing hypothesis, the data supports a determination that the average exclusionary power of litigated patents with respect to any given product is about half of their full term. This estimation, of course, is not as precise as other mechanisms for measuring the exclusionary power of a patent, but it will be more correct than assuming all litigated patents have the power to exclude all products for their full term.

One can analogize asserted patents to lottery tickets having a 50% chance of being worth their face value and a 50% chance of being worth nothing. Although the precise value of any specific lottery ticket cannot be determined until it is scratched, the value of each lottery ticket is better approximated to be half its face value than its full face value. Similarly, since roughly only half of all asserted patents litigated to judgment have exclusionary power for their full term, the exclusionary power of an asserted patent that has not yet been litigated to full judgment is better approximated to be half its term than its full term.

B. When a Patent Holder Allows a Product to Be Freely Sold Prior to Expiration of a Patent, the Exclusionary Power of that Patent With Respect to that Product Ends on the Date the Product was Allowed to be Freely Sold.

Beyond empirical analysis, there are several ways to determine what the exclusionary power of a patent is with respect to a specific product. First, and most obviously, a court can make a final determination regarding whether the patent has the power to exclude the product during the term of the patent. However, completed patent litigation is not the only way for the exclusionary power of a patent to be determined.

If a patent holder and a manufacturer of a product come to an agreement regarding the effect of a patent on that product, another way to determine the exclusionary power of the patent with respect to that product is to identify what the parties negotiated it to be. For example, if a patent holder and alleged infringer settle a dispute between them regarding whether a specific patent has the power to exclude a specific product for the full term of the patent and the terms of that settlement allow the product to be freely sold without payment of any license fees or other consideration to the patent holder, then the exclusionary power of the patent with respect to that product ends as of the date the product is allowed to be freely sold.

Some may argue that the exclusionary power of a patent can only be absolute; either zero or full term. However, such an argument fails to recognize that patent rights are fraught with inherent uncertainty and that it is economically efficient to allow patent owners to recognize through private arrangements that their patent has the power to exclude a certain product for an amount of time less than the full term of the patent. When such a deal is struck, the exclusionary power of the patent is determined by analyzing the amount of exclusion achieved by the patent holder through the negotiation.

Therefore, it is entirely possible, and actually quite frequently the case, that the exclusionary power of a patent with respect to a specific product is less than its full term.

In this case, the agreement between Schering-Plough ("Schering") and Upsher-Smith ("Upsher") had three distinct and separate economic aspects. The first economic aspect of the agreement was that Schering permitted Upsher to sell its generic K-Dur product prior to the asserted patent's expiration date without any requirement that Upsher make any payment or give any consideration to Schering other than a promise to abstain from selling the generic K-Dur product prior to that date. That agreed-to date of entry, referred to herein as T, is the most precise measure of the asserted patent's exclusionary power with respect to Upsher's product, as that was a date negotiated by parties who were, at the time of negotiation, adversaries regarding the patent's power to exclude the generic K-Dur product. In effect, T was a specifically tailored expiration date for the patent with respect to Upsher's product.

According to the Commission's finding, the second economic aspect of the agreement was that Schering paid Upsher some amount less than $60M for an additional promise to not sell generic K-Dur between the specifically tailored patent expiration date, T, and September 2001.[1] This additional delay was not within the exclusionary power of the patent. Rather, it began on the day the exclusionary power of the patent ended and extended the total amount of time Upsher delayed its sale of the generic K-Dur product.

Had Schering not paid Upsher for any additional delay, then T would be properly identified as being September 2001, or, had Upsher instead paid Schering consideration for Schering's allowance of the generic K-Dur product to be sold prior to the patent's expiration, then T would have been some date after September 2001. But, since Schering compensated Upsher for its delay with a combination of cash and a waiver of the exclusionary power of the patent, only a portion of the delay can be attributed to the patent's exclusionary power. This is why T must have been, under the terms of this agreement, some date prior to September 2001.

The final aspect of the agreement was that Schering paid Upsher some amount less than $60M for a license to Niacor-SR. The combination of the amount paid to Upsher for the additional delay and the amount paid for the license to Niacor-SR equaled the total $60M under the agreement. Set forth

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[1] This brief adopts the Commission's factual findings and does not address what level of deference they deserve.

below in Figure 1 is a chart identifying these three aspects of the agreement and the consideration exchanged by the parties to achieve those aspects.

Aspect	**Consideration Given by Schering**	**Consideration Given by Upsher**
1. Exclusionary Power of Schering's Patent	Promise to Not Assert Patent Against Generic K-Dur after Date T (T is before Sept. 2001)	Promise to Not Produce Generic K-Dur before Date T
2. Additional Exclusion	$ X (where $0 < X < $60M)	Promise to Not Produce Generic K-Dur Between Date T and September 2001
3. Niacor-SR License	$ Y (where Y = $60M – X)	License to Niacor-SR

FIGURE 1: Economic Aspects of Schering – Upsher Settlement Agreement

Admittedly, the negotiations and text of the agreement obfuscated these economic aspects. Instead of delineating each economic aspect and dealing with them separately, Petitioners combined the considerations that were of like form. The consideration given by Schering for the second and third aspect of the agreement was cash, and therefore they were merged. The consideration given by Upsher for the first and second aspect of the agreement was combined into a single promise to not sell generic K-Dur prior to September 2001. Set forth below in Figure 2 is the same chart as set forth above in Figure 1, except that the considerations merged through the text of the agreement are shown as being merged in the chart.

<table>
<tr><th>Aspect</th><th>Consideration Given by Schering</th><th>Consideration Given by Upsher</th></tr>
<tr><td>1. Exclusionary Power of Schering's Patent</td><td>Promise to Not Assert Patent Against Generic K-Dur after Date T
(T is before Sept. 2001)</td><td rowspan="2">Promise to Not Produce Generic K-Dur before September 2001</td></tr>
<tr><td>2. Additional Exclusion</td><td rowspan="2">$ 60M</td></tr>
<tr><td>3. Niacor-SR License</td><td>License to Niacor-SR</td></tr>
</table>

FIGURE 2: Economic Aspects of Schering – Upsher Settlement Agreement as Obfiscated by the Agreement Provisions

This merging of like-consideration is understandable, as it is easier to negotiate and draft two forms of consideration flowing from each party to the other, rather than three. However, that does not change the economic realities of the deal. Since a portion of Upsher's delay was compensated for by part of Schering's $60M, only the remaining portion of Upsher's delay was due to the power of the patent to exclude generic K-Dur. Therefore, the exclusionary power of the patent in this case with respect to Upsher's generic product was determined by the parties, whether they realized it or not at the time, to be some date prior to September 2001.

Admittedly, this is not a precise determination of the exclusionary effect of the patent. But, effective resolution of antitrust issues relating to the exclusionary power of a patent does not necessarily require a precise determination, because, as in this case, antitrust analysis can be appropriately applied merely by identifying the bounds of the exclusionary effect of a patent. Therefore, it is sufficient for resolution of this matter to recognize that the parties determined, through their negotiations, that Schering's patent did not have the power to exclude the generic K-Dur product after some date prior to September 2001.

In determining whether the agreement violated the antitrust laws, the Commission considered the exclusionary power of the patent through an analysis not substantially different from that set forth above. As such, it complied with this Court's requirement to do so set forth in *Valley Drug*. *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003).

II. PROPER APPLICATION OF ANTITRUST LAW WILL NOT HARM COMPETITION OR CONFLICT WITH THE POLICY OF THE HATCH-WAXMAN ACT

Application of sound antitrust law and policy comports with the policies implemented in the Hatch-Waxman Act. The entire point of Hatch-Waxman was to encourage and protect competition in the pharmaceutical industry, which it did in two principal ways: (i) making it easier for competition to already available products to be introduced; and (ii) encouraging new innovative products to be brought to market by strengthening patent rights. *See* H. Rep. No. 98-857(I). Unfortunately, pharmaceutical companies, both brand and generic, have been able to circumvent the pro-competitive intent of Hatch-Waxman because it is "littered with loopholes." Lara J. Glasgow, *Stretching the Limits of Intellectual Property Rights: Has the Pharmaceutical Industry Gone Too Far?*, 41 IDEA 227 (2001). By condemning net-anticompetitive gaming of the Hatch-Waxman regime, this Court will promote, not frustrate, its goals.

Further, discouraging anticompetitive settlements of patent infringement cases has, in itself, a recognized pro-competitive effect. Accused infringers who prove a patent invalid perform an important public service by correcting the PTO's errors on their own nickel. *See Lear v. Adkins*, 395 U.S. 653, 670 (1969) (explaining that if those "with economic incentive to challenge the patentability of an inventor's discovery" do not do so, "the public may continually be required to pay tribute to would be monopolists without need or justification"); *Pope Mfng. Co. v. Gormully*, 144 U.S. 224, 234 (1892) ("[i]t is as important to the public that competition should not be repressed by worthless patents as that the patentee of a really valuable invention should be protected in his monopoly"). Even those who try but fail to prove a patent invalid perform a public service by narrowing uncertainty as to the patent's validity, thus encouraging others to respect it. *Kloster Speedsteel AB v. Crucible, Inc.*, 793 F.2d 1565, 1581 (Fed. Cir. 1986).

Similarly, accused infringers who do not raise invalidity challenges to an asserted patent, but instead raise substantial noninfringement defenses also aid competition because their efforts lead to a judicial opinion declaring the patent's metes and bounds, on which the public may rely. Determining the true scope of a patent is accomplished by the courts through a process called claim construction, which is often difficult, as evidenced by the fact that the U.S. Court of Appeals for the Federal Circuit reverses over 30% of district court claim constructions. *See* Christian Chu, *Empirical Analysis of the Federal Circuit's Claim Construction Trends*, 16 Berkeley Tech L.J. 1075 (2001); *see also* Kimberly A. Moore, *Are District Court Judges Equipped to Resolve Patent Cases*?, 15 Harv. J. L & Tech 1 (2001). As such, a party that litigates the scope of a patent through the stage of claim construction aids the public in determining what the patent covers and, more importantly, what it does not. These are significant pro-competitive effects that result from the discouragement of anti-competitive settlements.

CONCLUSION

For the foregoing reasons, this Court should find that the Commission considered the exclusionary power of the patent.

Respectfully submitted

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July 31, 2004

CERTIFICATE OF COMPLIANCE WITH RULE 32

Pursuant to Federal Rule of Appellate Procedure 32(a)(7)(C), the undersigned counsel for *Amicus Curiae* Public Patent Foundation hereby certifies that this brief complies with the type-volume limitation of Rule 32(a)(7)(B) because it contains 3,671 words.

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July 31, 2004

CERTIFICATE OF SERVICE

I, Daniel B. Ravicher, hereby certify that I caused a copy of the foregoing Brief of Amicus Curiae Public Patent Foundation to be served this 31st day of July, 2004, by first class mail, postage prepaid, upon each of the following:

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