

No. 05-273

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In The  
**Supreme Court of the United States**

—◆—  
FEDERAL TRADE COMMISSION,

*Petitioner,*

v.

SCHERING-PLOUGH CORPORATION, *ET AL.*,

*Respondents.*

—◆—  
**On Petition For A Writ Of Certiorari  
To The United States Court Of Appeals  
For The Eleventh Circuit**

—◆—  
**MOTION OF THE PUBLIC PATENT  
FOUNDATION FOR LEAVE TO FILE BRIEF AS  
AMICUS CURIAE AND BRIEF OF AMICUS  
CURIAE IN SUPPORT OF PETITIONER**

—◆—  
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September 30, 2005

**MOTION OF THE PUBLIC PATENT  
FOUNDATION FOR LEAVE TO FILE BRIEF AS  
AMICUS CURIAE IN SUPPORT OF PETITIONER**

Pursuant to Rule 37.2 of the Rules of this Court, the Public Patent Foundation, Inc. (“PUBPAT”) respectfully moves this Court to grant it leave to file the accompanying brief as *amicus curiae* in support of the petition for a writ of certiorari. Counsel for Petitioner has consented to the filing of this brief, counsel for one of the Respondents, Upsher-Smith Laboratories, Inc., has withheld consent, and counsel for the other Respondent, Schering-Plough Corporation, did not respond to a request for consent.

PUBPAT is a not-for-profit legal services organization founded in 2003 to represent the public’s otherwise unrepresented interests in the patent system, and most particularly the public’s interests against the harms caused by wrongly issued patents and unsound patent policy. PUBPAT provides the general public and specific persons or entities otherwise deprived of access to the patent system with representation, advocacy, and education and it is funded by grants from the Rockefeller Foundation, the Echoing Green Foundation, the Rudolph Steiner Foundation and the Open Society Institute and by private donations from the public.

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 European Parliament, 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 wrongly

issued patents causing significant harm to the public. The Patent Office has granted each such request. These accomplishments have established PUBPAT as a leading provider of public service patent legal services and one of the loudest voices advocating for comprehensive patent reform.

PUBPAT has an interest in this matter because the decision of the Eleventh Circuit below will have a significant negative effect on the public's interests represented by PUBPAT and because PUBPAT's mission is to represent those interests against the harm caused by unsound policy with respect to patents. More specifically, PUBPAT has an interest in ensuring that patent holders and their privy are not allowed to undermine otherwise sound competition law simply because they own a patent.

Although technically an antitrust case, this matter involves an evaluation of the exclusionary power of patents. As such, PUBPAT believes its brief, authored by a registered patent attorney and addressing that issue, provides the Court with relevant legal and factual information that may not otherwise be brought to its attention. 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.

Accordingly, PUBPAT respectfully requests that the Court grant leave to file the attached brief as *amicus curiae*.

Respectfully submitted,

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## INTEREST OF THE *AMICUS CURIAE*

PUBPAT is a not-for-profit legal services organization founded in 2003 to represent the public's otherwise unrepresented interests in the patent system, and most particularly the public's interests against the harms caused by wrongly issued patents and unsound patent policy.<sup>1</sup> PUBPAT provides the general public and specific persons or entities otherwise deprived of access to the patent system with representation, advocacy, and education and it is funded by grants from the Rockefeller Foundation, the Echoing Green Foundation, the Rudolph Steiner Foundation and the Open Society Institute and by private donations from the public.

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 European Parliament, 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 wrongly issued patents causing significant harm to the public. The Patent Office has granted each such request. These accomplishments have established PUBPAT as a leading provider of public service patent legal services and one of the loudest voices advocating for comprehensive patent reform.

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<sup>1</sup> Pursuant to Supreme Court Rule 37.6, *amicus* states that no counsel for a party authored this brief in whole or in part, and that no person or entity, other than *amicus curiae* and its counsel made a monetary contribution to the preparation or submission of this brief.

PUBPAT has an interest in this matter because the decision of the Eleventh Circuit below will have a significant negative effect on the public's interests represented by PUBPAT and because PUBPAT's mission is to represent those interests against the harm caused by unsound policy with respect to patents. More specifically, PUBPAT has an interest in ensuring that patent holders and their privy are not allowed to undermine otherwise sound competition law simply because they own a patent.

Although technically an antitrust case, this matter involves an evaluation of the exclusionary power of patents. As such, PUBPAT believes its brief, authored by a registered patent attorney and addressing that issue, provides the Court with relevant legal and factual information that may not otherwise be brought to its attention. 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.



### **SUMMARY OF ARGUMENT**

The Court of Appeals in this case made the erroneous assumption that the exclusionary power of a patent is always measured by its full statutory term. Not only is that assumption unsupported by empirical analysis of patents generally, which shows that only about one half of all asserted patents have any exclusionary power whatsoever, 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.

If an accused infringer is given consideration in addition to a pre-expiration free-entry date, then the exclusionary power of the patent with respect to the accused infringer's product is equivalent to some date prior to the agreed-to pre-expiration free-entry date, because the extra consideration, in the absence of any other explanation, is in exchange for additional delay in entry. The Court of Appeals ignored this simple truth in this case and, in effect, promulgated a virtual exemption from antitrust law for any agreement that involves a patent. Such an exemption conflicts with this Court's precedents and with sound legal and economic theory.

Further, the Court of Appeals' unwillingness to apply sound antitrust principles for fear that such may deter pro-competitive patent settlements is based on unsound circular reasoning. By definition, application of sound antitrust principles can only deter conduct that has an anti-competitive effect. More specifically with respect to this case, 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.

Therefore, to protect the public from anti-competitive settlements of patent infringement litigation whereby a potential competitor is offered a share of the monopoly profits that can be maintained if it stays off the market,

this Court should grant the petition for a writ of *certiorari* and correct the mistake made by the Eleventh Circuit in this case.



### REASONS FOR GRANTING THE PETITION

People unfamiliar with the patent system, including specifically the Court of Appeals in this case, 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 Court of Appeals' assumption that any patent has an exclusionary power equal to its full term over any product is without merit. *Schering-Plough Corp. v. F.T.C.*, 402 F.3d 1056 (11th Cir. 2005), *petition for cert. filed* (Aug. 29, 2005) (No. 05-273).

If 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. Instead of recognizing this fundamental truth of the patent system, the Court of Appeals instead chose to blindly adopt the position that all patents are to be presumed to have total exclusionary power over any product against which they are asserted for their entire term and, thus, any settlement of a patent infringement allegation that allows an accused product to enter the market prior to the patent's expiration is exempt

from the competition laws. This conclusion is wrong and, if left undisturbed, will lead to substantial harm being caused to the American public through lessened competition and its attendant higher prices and lower choices. To be sure, this effect will be felt not only in the pharmaceutical industry, but in many other industries as well. As such, the petition for a writ of *certiorari* should be granted.

**I. THE COURT OF APPEALS ERRED BY FAILING TO RECOGNIZE THAT SCHERING'S PATENT DID NOT HAVE THE POWER TO EXCLUDE ALL GENERIC PRODUCTS FOR ITS ENTIRE TERM.**

There is no one measure of the exclusionary power of a patent. Such is merely a relative term describing the capability of a 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 several other factors, including the capabilities of the party against whom it is asserted to mount an invalidity or non-infringement defense. In no case, however, can a patent be said to have the "potential" to exclude everything. At most, any given patent can only have the "potential" to exclude some defined thing or class of things.

The Court of Appeals made a critical error in this case by assuming that Schering-Plough's ("Schering") patent had an exclusionary power equivalent to its full term with respect to any generic product. This not only failed to recognize that the patent had the potential to have *no* exclusionary power with respect to those products, it was

also contrary to the significant empirical evidence regarding the exclusionary power of patents generally that is available from the literature.

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.

**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 of a patent 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.<sup>2</sup> 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 (Nov. 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 was improper for the Court of Appeals to assume that Schering's patent would have complete exclusionary power with respect to all generic products throughout its full term. Such an assumption was no more justified than assuming the patent will have no exclusionary power with respect to any product.

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<sup>2</sup> The Court of Appeals manifested an incorrect understanding of patent law when it stated that “[b]y virtue of its ‘743 patent, Schering obtained the legal right to exclude Upsher and ESI from the market until they proved either that the ‘743 patent was invalid or that their products . . . did not infringe Schering’s patent.” *Id.* at 1066. In fact, although the burden of proving a patent invalid does lie with an accused infringer, the patent holder has the burden of proving infringement. An accused infringer need not prove it does not infringe a patent in order to be outside the patent’s right to exclude.

**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 general 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 in the absence of a payment from the patentee. 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.

The Court of Appeals seems to think 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 patents have 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.

For example, in this case the agreement between Schering and Upsher-Smith (“Upsher”) implicitly 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.

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. 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 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.

<b>Aspect</b>	<b>Consideration Given by Schering</b>	<b>Consideration Given by Upsher</b>
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, Respondents 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.

<b>Aspect</b>	<b>Consideration Given by Schering</b>	<b>Consideration Given by Upsher</b>
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 September 2001
2. Additional Exclusion	\$60M	
3. Niacor-SR License		

FIGURE 2: Economic Aspects of Schering – Upsher Settlement Agreement as Obfuscated 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.

Although this is not a precise determination of the exclusionary effect of the patent, resolution of antitrust issues relating to the exclusionary power of a patent does not necessarily require a precise determination. 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 to recognize that the parties determined, through their negotiations, that Schering's patent did not have the power to exclude Upsher's generic K-Dur product after some date prior to September 2001.

Similarly, the exclusionary effect of Schering's patent with respect to ESI Lederle's ("ESI") generic product can be determined by reviewing the Schering – ESI agreement, which is easier to analyze because it did not include the third aspect present in the Schering – Upsher agreement. In the Schering – ESI agreement, Schering allowed the ESI generic product to enter the market prior to expiration of its patent and also paid ESI \$10M above and beyond its litigation costs. Since there was no other justification for that additional payment, it could only have been in exchange for additional delay of entry of ESI's generic product into the market. Therefore, the parties determined, through their agreement, that Schering's patent did not have the power to exclude ESI's generic product after some date prior to January 1, 2004, referred to herein as S. Set forth below in Figure 3 is a chart identifying these aspects of the Schering – ESI agreement and the consideration exchanged by the parties to achieve those aspects.

Aspect	Consideration Given by Schering	Consideration Given by ESI
1. Exclusionary Power of Schering's Patent	Promise to Not Assert Patent Against Generic K-Dur after Date S (S is before January 1, 2004)	Promise to Not Produce Generic K-Dur before Date S
2. Additional Exclusion	\$10M	Promise to Not Produce Generic K-Dur Between Date S and January 2004

FIGURE 3: Economic Aspects of Schering – ESI Settlement Agreement

The Court of Appeals failure to adopt this reasoning led it to make the erroneous decision that any settlement of patent litigation is pro-competitive so long as the accused infringing product is allowed to enter the market any time before expiration of the asserted patent. This decision, if left uncorrected, will cause significant harm to the American people by permitting anti-competitive settlements of patent infringement litigation whereby potential competitors, instead of competing, take a share of the monopoly profits that can be maintained if they stay off the market. Unquestionably, such agreements are very good for the parties, and perhaps even the court system, which will have the burden placed on it lessened by the termination of patent infringement cases, but it is also just as clear to see how such agreements spell nothing but disaster for our competition-based economy and the American consumer.

## II. THE COURT OF APPEALS IGNORED THIS COURT'S PRECEDENT BY EXEMPTING A SIGNIFICANT PORTION OF PATENT SETTLEMENTS FROM ANTITRUST LAW.

This Court has recognized that discouraging anti-competitive settlements of patent infringement cases has, in itself, a 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 Mfg. 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 significant pro-competitive effects that result from the discouragement of anti-competitive settlements went unrecognized by the Court of Appeals in this case.

Further, the Court of Appeals failed to recognize that 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). The use of patent settlement agreements to fashion a sharing of monopoly profits made by one of them instead of competing with one another in the marketplace, such as occurred in this case, is but one example of how pharmaceutical companies are attempting to circumvent Hatch-Waxman. By condoning net-anticompetitive gaming of the Hatch-Waxman regime

through patent infringement litigation settlement agreements, the Court of Appeals' decision will frustrate, not promote, Hatch-Waxman's goals.



### CONCLUSION

For the foregoing reasons, this Court should grant the petition for a writ of *certiorari*.

Respectfully submitted,

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