American Bar Association
www.supremecourtpreview.org

No. 12-416

In the
Supreme Court of the United States

FEDERAL TRADE COMMISSION,

Petitioner,

v.

WATSON PHARMACEUTICALS, INC., *et al.*,

Respondents.

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

BRIEF OF THE PUBLIC PATENT FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

Daniel B. Ravicher
Counsel of Record
PUBLIC PATENT FOUNDATION, INC.
BENJAMIN N. CARDOZO SCHOOL OF LAW
55 Fifth Avenue
New York, NY 10003
(212) 790-0442
ravicher@pubpat.org

Counsel for Amicus Curiae

*Gibson*Moore Appellate Services, LLC ♦ 421 East Franklin Street, Suite 230
Richmond, VA 23219 ♦ 804-249-7770 ♦ www.gibsonmoore.net

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases:

Statutes

Rule

Legislative History

Other Authorities

INTEREST OF THE *AMICUS CURIAE*[1]

The Public Patent Foundation ("PUBPAT") is a not-for-profit legal services organization affiliated with the Benjamin N. Cardozo School of Law. PUBPAT achieves its mission of protecting freedom in patent system by representing the public interest against undeserved patents and unsound patent policy. PUBPAT has argued for sound patent policy before this Court, various Courts of Appeals and District Courts, Congress, the U.S. Patent & Trademark Office (PTO), and many other national and international bodies. PUBPAT has also successfully challenged specific undeserved patents causing significant harm to the public through both litigation and administrative proceedings. *See*, *e.g.*, *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 132 S. Ct. 1794 (2012). PUBPAT is a leading provider of public service patent legal services and advocate for comprehensive patent reform.

PUBPAT has an interest in this matter because the decision of this Court will have a significant effect on the public interest represented by PUBPAT. More specifically, PUBPAT represents the public interest in ensuring that only valid patents remain in force so that full and fair competition can take place without the impediment of improperly granted patents. Unfortunately, our patent system today is severely flawed in ways that cause mass

---

[1] In accordance with Supreme Court Rule 37.6, *Amicus Curiae* states that: (1) no counsel to a party authored this brief, in whole or in part; and (2) no person or entity, other than amicus, their members and counsel have made a monetary contribution to the preparation or submission of this brief. Copies of consents from the parties to file this brief have been provided to the Clerk.

production of low-quality patents. Anticompetitive reverse-payment agreements between patent-holding brand name pharmaceutical companies and potential generic challengers eliminate Congressionally intended and socially beneficial incentives for those potential generic challengers to compel judicial review of invalid patents. Allowing the holders of bogus patents to bribe would-be challengers to those patents to drop their challenge causes substantial public harm.

PUBPAT believes this brief, authored by a registered patent attorney and professor of patent law, provides the Court with relevant legal and factual information that may not otherwise be brought to its attention. This is especially true because PUBPAT has particular experience with issues relating to patent quality and the critical role the judicial process plays in the Constitutionally intended checking of illegitimate governmental encroachment on freedom and free markets through an ever-increasing issuance of unjustified patents.

SUMMARY OF ARGUMENT

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 the claimed subject matter, patents today are nothing more than some overly worked patent examiner's decision to allow claims requested by an applicant. They result from a Patent Office with perverse incentives to grant, rather than deny, applications and, in reality, give their owner nothing more than, at best, a fifty-fifty chance of

having any exclusionary power at all. In fact, in the vast majority of pharmaceutical patent cases, 70% or more, the generic challenger wins.

As such, the Court of Appeals' assumption that a given patent has a potential exclusionary power equal to its full term is factually meritless and legally unsustainable. The Court of Appeals also erred by failing to recognize the substantial pro-competitive benefits of legal challenges to patents, and in particular the judiciary's critical role in checking patent quality and patent scope, which this Court has repeatedly recognized. In short, earnest patent litigation is pro-competitive, as are legitimate settlements thereof that recognize the relative strengths and weaknesses of the parties' respective positions. However, settlements with transparent bribes for challengers to take a dive cannot be reconciled with any sound public policy or legal precedent.

ARGUMENT

I. COURT CHALLENGES TO PATENTS ARE A NEEDED CHECK ON THE PTO'S RUBBER STAMPING OF INVALID CLAIMS TO PUBLIC PROPERTY

Quality is the single most important issue in our patent system, because without quality, the system risks losing credibility and the support of the American people. We must, above all other goals, ensure that only deserving patents are issued and maintained, otherwise the public will become rightfully skeptical of the merits of any patent and the patent system as a whole. Permitting anticompetitive reverse payments that incentivize

legitimate challengers to undeserved patents to drop their challenges harms the public by shielding undeserved patents from critical judicial review. The Court of Appeals' decision to offer safe harbor for such clear bribes to drop challenges to patents so that their owners can continue to charge monopolistic prices for the covered product betrays common sense, sound public policy, and, most importantly, the clear law of this Court.

A. Patent Quality In The United States Today Is Extremely Poor

The current level of quality for U.S. patents is extremely poor. There are several independent sources, including the Patent Office's own data, that prove this to be true.

For one, an ongoing project of the University of Houston Law School, known for having one of the most reputable patent departments in the country, tracks the results of patent litigation and empirically categorizes those results according to the specific issues involved with each case. *See* Patstats, available at http://www.patstats.org/. Its data shows that approximately 30% of all issued patents reviewed by courts in recent years were found to lack novelty, meaning they claimed subject matter that was identical to what was already in the prior art. Further, another 40% of the remaining patents reviewed by courts were found invalid for being obvious in light of the prior art. 35 U.S.C. § 103; *See* Univ. of Houston Law Ctr. Inst. for Intellectual Prop. & Info. Law, Full Calendar Year 2010 Report, http://www.patstats.org/2010_full_year.rev5.htm; Univ. of Houston Law Ctr. Inst. for Intellectual Prop.

& Info. Law, Full Calendar Year 2011 Report, http://www.patstats.org/2011_Full_Year_Report.html.

Although the cited Patstats data is limited to only the very small portion of issued patents that are litigated to a judgment, litigated patents tend to have a much greater significance to the public, on average, than non-litigated patents. John R. Allison, Mark A. Lemley, Kimberly A. Moore & R. Derek Trunkey, *Valuable Patents*, 92 Georgetown Law Journal 435 (2004). The technology related to litigated patents is by definition valuable to a certain extent, as it at least merits the related cost of patent litigation, which prevents the litigation of worthless patents. Thus, any mistakes regarding the validity of litigated patents causes meaningful public harm by denying the public access to the covered technology during the period between the patent's wrongful issuance by the Patent Office and its invalidation by the courts.

The PTO's own statistics show that more than 90% of all the patents that it granted that it is later asked to review (through a procedure called reexamination) have at least one "substantial question of patentability." *Inter Partes Reexamination Filing Data - June 30, 2012*, USPTO, http://www.uspto.gov/patents/stats//IP_quarterly_report_June_30_2012.pdf ("*Inter Partes* Report") (94% of all requests for *inter partes* reexamination granted); *Ex Parte Reexamination Filing Data - June 30, 2012*, USPTO, http://www.uspto.gov/patents/stats/EP_quarterly_report_June_30_2012.pdf ("*Ex Parte* Report") (92% of all requests for *ex parte* reexamination granted); 35 U.S.C. § 312. Looking

deeper, the PTO's data shows that 89% of patents challenged through the *inter partes* reexamination process, which allows for ongoing participation by the challenger, are canceled or changed, while more than 78% of patents challenged through the *ex parte* reexamination process, which does not allow the challenger to participate after submitting the initial request, have their claims canceled or changed. *Inter Partes Report* (all claims canceled 42% of the time, claims changed 47% of the time); *Ex Parte Report* (all claims canceled 11% of the time, claims changed 67% of the time).

One way to confirm how grim the state of affairs is for U.S. patent quality is to compare our system's patent application outcomes to those of other well-respected patent offices. Firstly, the PTO ultimately grants patents from 78% of all original applications, while that rate is only 61% in Japan and 55% in the European Union. Cecil D. Quillen, Ogden D. Webster, and Richard Eichman, *Continuing Patent Applications and Performance at the U. S. Patent and Trademark Office-One More Time*, 18 Fed. Cir. B.J. 379 (2009) (http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1429809).

An even better comparative picture is drawn by a study of roughly 70,000 issued U.S. patents and their corresponding foreign applications, which found that counterparts to patent applications *issued in the U.S.* were issued by (i) the European Patent Office only 72.5% of the time, (ii) the Japanese Patent Office only 44.5% of the time, and (iii) both the EPO and JPO only 37.7% of the time. Paul H. Jensen, Alfons Palangkaraya & Elizabeth Webster, *Disharmony in International Patent Office Decisions*,

16 Fed. Cir. B.J. 679 (2006). This evidence shows that the U.S. Patent Office is indeed granting a very disproportionally high number of patents relative to the rest of the world.

In short, it is not unfair to accuse the U.S. Patent and Trademark Office of being a rubber stamp, approving virtually any private claim made to it, regardless of whether the claimed subject matter is in the public domain or not. The overarching cause of poor patent quality is not, however, incompetence at the PTO, but rather perverse incentives on it and other actors within the patent system that reward the issuance of patents without regard any concern for quality.

For example, the Patent Office receives roughly ten times as much money from issuing a patent than it does from denying a patent. This is because the Patent Office charges an "Issuance Fee" to issue a patent after the application has been approved and then also "Maintenance Fees" every four years of a patent's life in order to keep it enforceable. *See*, *e.g.*, United States Patent and Trademark Office Fee Schedule, http://www.uspto.gov/about/offices/cfo/finance/fees.jsp (effective September 26, 2011) (charging $380 for basic filing fee, $620 for search fee, and $250 for examination fee, each of which is required to apply for a patent, but then $1,740 for issue fee and $1,130 for 3.5-years maintenance fee, $2,850 for 7.5-years maintenance fee, and $4,730 for 11.5-years maintenance fee). Thus, the USPTO is financially incentivized to grant rather than deny patents, as it is a fee-funded agency. Michael Frakes and Melissa F. Wasserman, *Does Agency Funding Affect Decisionmaking?: An*

Empirical Assessment of the PTO's Granting Patterns, 66 Vand. L.R. 2013 (2012) (http://ssrn.com/abstract=1986542).

An arms race amongst patent holders encourages the acquisition of as many patents as possible, regardless of validity, to be used as threats against or bargaining chips with others. Even examiners themselves are encouraged to issue bad patents under the "count" quota system that measures their performance, because issuing a patent takes no more work than a simple signature, while denying a patent requires countless hours of letter and brief writing to continue making and supporting a rejection. *Recently Announced Changes to USPTO's Examiner Count System Go Into Effect*, USPTO (2010) (http://www.uspto.gov/news/pr/2010/10_08.jsp) ("The revised count system that is now in effect is designed to: ... Encourage examiners to identify allowable subject matter earlier in the examination process."). In short, very few actors have any incentive to purge the patent system of the hundreds, if not thousands, of invalid patents issued by the Patent Office every week.[2]

B. Undeserved Pharmaceutical Patents Cause Substantial Public Harm

Brand name pharmaceutical companies implement a purposeful plan to seek and obtain as much patent protection for their drugs as possible. When developing a new drug, they first go to the Patent Office to secure patents on the broad genus of chemical entities they are pursuing, not yet

---

[2] The Patent Office issues approximately 4,500 patents every Tuesday, which is the day of the week patents are granted.

knowing which species within that genus will lead to an actual marketable drug. *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012).

Later, when they isolate particular species of the genus that seem promising, they apply for patents on those species, arguing that the species' particular characteristics were not obvious in light of the previous disclosure of the genus, although it was of course the pharmaceutical company's intention all along to identify the most promising species from within the genus, and methods for doing so are well known within the pharmaceutical arts.

After identifying promising species compounds, the next series of patents sought by the pharmaceutical company are drawn to particular formulations of those species, including salts, prodrugs, enantiomers, crystallized forms, and other common chemical derivatives. Amy Kapczynski *et al.*, *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of "Secondary" Pharmaceutical Patents*, PLOS ONE, e49470, at 6 (Dec. 2012). The formulations are not safer or more efficacious than the species themselves. They are merely more stable compositions for production and distribution purposes.

While methods for developing stable formulations of chemical entities have been well known for decades, the pharmaceutical company will nonetheless argue to the Patent Office, should it even makes any objections to the claims, that it was not obvious that those same tried-and-true formulation techniques would work on their new chemical species. While such a lame argument is

sufficient to satisfy the Patent Office's rubber-stamp standards, the courts have routinely struck such patents as obvious. *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348 (Fed. Cir. 2007) ("[W]e hold that the optimization of the acid addition salt formulation for an active pharmaceutical ingredient would have been obvious where as here the acid addition salt formulation has no effect on the therapeutic effectiveness of the active ingredient and the prior art heavily suggests the particular anion used to form the salt.").

Later still come the "method of use" patents that allow pharmaceutical companies to pretend they did not intend or expect to use their previously patented drug in the particular way over which they now wish to claim exclusivity. *Caraco Pharm*, 132 S. Ct. at 1676. It's a three-card-Monte shell came of the Canal street variety. If you think you know where the Queen is, and you have your finger on it, the pharmaceutical company will lift up a different card and show you they have one there, too. In truth, pharmaceutical companies are not to be maligned for doing what is in their self interest: getting as many patents as possible for their drug, because any patent can have substantial value in delaying competition.

In this case, Solvay and Besins have filed no less than twenty-one additional applications for patents on the same drug. A simple review of the PTO's Patent Application Information Retrieval (PAIR) database (available at http://portal.uspto.gov /external/portal/pair) shows that each of the following applications claim priority to the '894 patent disclosure:

- 09/703,753 filed on 11-01-2000
- 10/033,101 filed on 10-19-2001
- 10/046,454 filed on 10-19-2001
- 10/098,232 filed on 03-15-2002
- 10/153,468 filed on 05-21-2002
- 10/248,267 filed on 01-03-2003
- 10/273,484 filed on 10-18-2002
- 10/787,071 filed on 02-25-2004
- 10/825,540 filed on 04-15-2004
- 10/828,678 filed on 04-20-2004
- 10/829,618 filed on 04-20-2004
- 10/867,435 filed on 06-14-2004
- 10/867,445 filed on 06-14-2004
- 10/925,421 filed on 08-24-2004
- 13/071,264 filed on 03-24-2011
- 13/071,276 filed on 03-24-2011
- 13/275,232 filed on 10-17-2011
- 13/275,254 filed on 10-17-2011
- 13/343,170 filed on 01-04-2012
- 13/430,862 filed on 03-27-2012
- 13/648,694 filed on 10-10-2012

Notice that the most recent application was just filed in October, nearly ten years after the '894 patent was issued. While many of these applications have been abandoned, five are still pending and could indeed mature into patents. More applications could also be filed. While some may find this carpet-bombing of patent applications to be outrageous, it is commonplace, as applicants know that the rubber-stamp PTO will likely grant at least some patents from the deluge of applications. If patent application bombardment did not result in issued patents, actors like Solvay and Besins would not try it. Whether any of those issued patents would

actually stand up in court is unimportant. All they need for delay is an issued patent, not a legitimate one.

As may be transparent to even the most casual interested observer, the later generations of pharmaceutical patents have increasingly weaker validity, in large part because all the previous patents become prior art to the later patents. Thus, a patent on a new chemical entity is often valid, while a later patent on a particular formulation or a particular method of use is more likely to be invalid. What's important about this process, referenced as "secondary" or "evergreening" patenting in the literature, is that all of these patents can be, and typically are, listed in the Orange Book for a particular drug. Thus, frequently generic ANDA filers do not challenge the earliest of patents, but instead the second, third, fourth, and later generation derivative patent, whose arguably novel aspect likely has nothing to do with the underlying active pharmaceutical ingredient at all. C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?*, 8 J. Empirical Legal Stud. 613, 621 (2011). As a perfect example, in this case it is not the underlying pharmaceutical ingredient that is claimed by the challenged patent, but instead a formulation of that public-domain pharmaceutical agent with a certain recipe of excipients, i.e. well known inactive ingredients, like sugar, that perform the function of carriers for the active ingredient in order to make a producible, deliverable, and storable drug product.

Generally speaking, undeserved patents cause substantial harm to the American public, because an issued patent – regardless of its true legitimacy – can be used to threaten and impede otherwise permissible, socially desirable, conduct. The threat of having to incur the costs and potential liability of a patent lawsuit is one that few individuals or small businesses can withstand,even if the patent is of doubtful validity. This chilling effect, when caused by a patent that would be ruled invalid if challenged, provides no social benefit to the American people, because the patent contains nothing new; its invalidity means that whatever it claims or describes was either already known or was obvious in light of what was already known. Particularly in the area of needed medicines, poor patent quality can be devastating to the American people by improperly taxing legitimate businesses, deterring competition and raising consumer prices.

Undeserved pharmaceutical patents can be listed in the Orange Book and then asserted in ANDA litigation to block generic competition to what should in reality be a public domain drug. For example, there have been several patents that were used to preclude competition in pharmaceutical markets worth billions of dollars that were later proven to be undeserved. *See*, *e.g.*, *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348 (Fed. Cir. 2007) (patent preventing competition to $1.2 billion per year hypertension and coronary artery disease drug, Norvasc, proven invalid); *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368 (Fed. Cir. 2001) (patent preventing competition to $1.6 billion per year cancer treatment, Taxol, proven invalid); *Eli Lilly & Co. v. Barr Labs.*, 251 F.3d 955 (Fed.

Cir. 2001) (patent barring alternatives to $2.9 billion per year antidepressant medication, Prozac, proven invalid).

Indeed, studies of pharmaceutical patents subjected to litigation highlight the need for such scrutiny, as they show that generics prevail in proving asserted pharmaceutical patents either invalid or not infringed seventy to seventy-three percent of the time. Janicke & Ren, *Who Wins Patent Infringement Cases?,* 34 AIPLA Q.J. 1, at 21 (2006) (Chart 1, labeled "Percentage of Dispositive Cases Won by Plaintiffs in Various Technologies" indicates 30% for "Chemical (pharm.)" cases). Further, as the Third Circuit just this past summer noted:

> Many patents issued by the PTO are later found to be invalid or not infringed, and a 2002 study conducted by the FTC concluded that, in Hatch-Waxman challenges made under paragraph IV, the generic challenger prevailed seventy-three percent of the time. See FTC, *Generic Drug Entry Prior to Patent Expiration* 16 (2002), available at http://www.ftc.gov/os/2002/07/genericdrug study.pdf; Kimberly A. Moore, *Judges, Juries, and Patent Cases — An Empirical Peek Inside the Black Box*, 99 Mich. L.Rev. 365, 385 (2000) (noting that between 1983 and 1999 the alleged infringer prevailed in forty-two percent of patent cases that reached trial).

In re K-Dur Antitrust Litigation, 686 F.3d 197, at 215 (3rd Cir. 2012).

> The Pharmaceutical Research and Manufacturers of America points to a more recent study concluding that, in the years from 2000 to 2009, generics prevailed in slightly less than half of their challenges. RBC Capital Mkts., Pharmaceuticals: Analyzing Litigation Success Rates 4 (2010), available at http://www.amlawdaily.typepad.com/pharmareport.pdf. Even if the industry's own figures are accepted, they show that a substantial fraction of Hatch-Waxman patent challenges succeed on the merits. Moreover, the study cited by the industry further states that "when you take into account patent settlements and cases that were dropped, the success rate for generics jumps to 76%, substantially in favor of challenging patents."
>
> *Id*. at fn 11.

C. Court Challenges Can Alleviate The Public Harm Caused By Invalid Pharmaceutical Patents

Given the low standard for obtaining patents in our country, it is no wonder that pharmaceutical patent owners seek to avoid challenges made to the legitimacy of their claimed rights. It's rational for them to list such patents in the Orange Book as this delays the introduction of generic competition through the automatic 30 month stay in FDA approval of the generic. It is also entirely rational to then pay off any generic competitor that challenges the patent to preserve the patent's apparent legitimacy for use when another generic drug company files an ANDA. Courts can, and should, quash this opportunistic behavior by disallowing

anticompetitive reverse-payment settlements that do an end-run around full and fair adjudication of the validity challenge mounted to the patent by the first generic challenger. Such challenges would help purge meritless patents from society, which is an entirely pro-competitive result.

This Court has recognized that discouraging anticompetitive 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 38% of district court claim constructions. *See* David L. Schwartz, *Practice Makes Perfect? An Empirical Study of Claim Construction Reversal Rates in Patent Cases*, 107 Mich. L. Rev. 223 (2008). 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 circumvented the pro-competitive intent of Hatch-Waxman by sharing monopoly profits made by one of them instead of competing with one another in the marketplace. Lara J. Glasgow, *Stretching the Limits of Intellectual Property Rights: Has the Pharmaceutical Industry Gone Too Far?*, 41 IDEA 227 (2001) (explaining that the Act is "littered with loopholes"). 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 reverse the Court of Appeals decision below and hold that reverse-payment agreements are presumptively anticompetitive and unlawful.

Respectfully submitted,

/s/ Daniel B. Ravicher
Daniel B. Ravicher
Counsel of Record
PUBLIC PATENT FOUNDATION, INC.
BENJAMIN N. CARDOZO SCHOOL OF LAW
55 Fifth Avenue
New York, New York 10003
(212) 790-0442

Counsel for *Amicus Curiae*