No. 10-762

In The Supreme Court of the United States

LOUISIANA WHOLESALE DRUG CO., INC., CVS PHARMACY, INC., RITE AID CORPORATION, ARTHUR'S DRUG STORE, INC.,

Petitioners,

v.

BAYER AG, BAYER CORP., formerly doing business as Miles Inc., HOECHST MARION ROUSSEL, INC., THE RUGBY GROUP, INC., WATSON PHARMACEUTICALS, INC., BARR LABORATORIES, INC.,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Second Circuit

BRIEF OF *AMICUS CURIAE* NATIONAL ASSOCIATION OF CHAIN DRUG STORES, INC. IN SUPPORT OF PETITIONERS

DON L. BELL, II
NATIONAL ASSOCIATION OF CHAIN DRUG STORES, INC.
413 North Lee Street
P.O. Box 1417-D49
Alexandria, VA 22313
(703) 549-3001
dbell@nacds.org

Counsel for Amicus Curiae National Association of Chain Drug Stores, Inc.

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OR CALL COLLECT (402) 342-2831

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STATEMENT OF INTEREST[1]

The National Association of Chain Drug Stores, Inc. ("NACDS") is a non-profit association of nearly 140 retail pharmacy chains. NACDS members operate more than 39,000 retail community pharmacies and dispense approximately 72% of Americans' prescription drugs. Anticompetitive practices by drug manufacturers, such as the practice at issue in this case, harm NACDS members and their customers by maintaining artificially high prices for prescription drugs. NACDS believes that its industry-wide perspective on this important issue will be of assistance to the Court and therefore respectfully submits this *amicus curiae* brief in support of the Petition.

SUMMARY OF ARGUMENT

The rule of decision adopted by the Second Circuit in *Tamoxifen* and applied in this case disregards this Court's patent precedents by allowing private

[1] All parties were notified ten days prior to the due date of this brief of the intention to file. All parties have consented to the filing of this brief, and their letters of consent have been filed with the Clerk of the Court. Pursuant to this Court's Rule 37.6, *amicus* states that no counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amicus* made a monetary contribution to the preparation or submission of this brief.

parties to create what is in effect a "private patent" that provides its owner with greater protection from competition than that afforded by the federal patent laws. Federal patent law, however, incorporates a policy favoring competition in the American economy except to the extent that competition is displaced by the narrow and carefully drawn legal rules that define the scope and duration of a federal patent. By allowing private patents that fall outside those legal rules, the *Tamoxifen* standard seriously undermines federal patent policy. This Court should grant certiorari to maintain the proper balance between competition and intellectual property protection.

ARGUMENT

THE SECOND CIRCUIT'S RULING IS INCOMPATIBLE WITH FEDERAL PATENT LAW

Generic entry is a critical event in the life of a branded pharmaceutical. As Judge Posner has noted, prior to entry of an AB-rated generic most "manufacturers of brand name prescription drugs . . . have market power." *In re Brand Name Prescription Drugs Antitrust Litigation*, 186 F.3d 781, 786 (7th Cir. 1999). Generic entry effectively dissipates that market power and brings the benefits of lower-priced pharmaceuticals to wholesalers, retail pharmacies and American consumers. Of course, since the savings achieved by pharmaceutical purchasers along the distribution chain come directly out of the pockets of

the branded pharmaceutical manufacturers, those manufacturers have a strong financial incentive to delay the entry of an AB-rated generic as long as possible.

In evaluating the lawfulness of the practices at issue in this case, the Second Circuit applied the legal standard adopted in a prior 2-1 panel decision of the same court. *See In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187 (2005). While the *Tamoxifen* standard attempts to balance the societal interests in promoting economic competition and enforcing legitimate intellectual property rights, it gives too little weight to the former and too much weight to the latter. In particular, the standard applied by the Second Circuit is inconsistent with federal patent law because it disregards several critical limitations inherent in the substantive and procedural rules that make up that body of law.

The federal patent laws define not only what *is* protected by patent law, but also – and just as importantly – what is *not* protected. *See Bonito Boats, Inc. v. Thundercraft Boats, Inc.*, 489 U.S. 141, 151 (1989). Patent law itself, unaided by federal antitrust law, incorporates a federal policy favoring competition before, after and during the existence of a U.S. patent, so long as that competition falls outside the narrow and carefully limited scope of the monopoly conferred by the patent laws. This policy is strong enough to preempt state laws that purport to offer inventors protection from competition for inventions that do not qualify for protection under federal patent

law. *Id.* at 151-57. As Justice O'Connor wrote in *Bonito Boats*, the provisions of federal patent law "embody a congressional understanding, implicit in the Patent Clause itself, that *free exploitation of ideas will be the rule*, to which the protection of a federal patent is the exception." *Id.* at 151 (emphasis supplied).

The *Tamoxifen* standard threatens to make "free exploitation of ideas" the exception rather than the rule in a number of independent ways.

First, the *Tamoxifen* standard rests on the proposition that the holder of a federal patent has an absolute "right to exclude" that may be enforced by paying competitors not to compete. *See In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 363 F. Supp. 2d 514, 524 (E.D.N.Y. 2005); *see also Schering-Plough Corp. v. Federal Trade Comm'n*, 402 F.3d 1056, 1066 (11th Cir. 2005). But patent law provides no such absolute right to exclude. As this Court has noted, "[a] patent, in the last analysis, simply represents a legal conclusion reached by the Patent Office," and one "as to which reasonable men can differ widely." *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969). Contrary to the decision below, patent law provides for *judicial* determination of both patent validity and infringement, with the burden of proof imposed on the patentee to prove infringement and the burden on the alleged infringer to prove invalidity. 35 U.S.C. §§ 281, 282; *see Medimmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007) (federal courts have jurisdiction to decide patent validity even when the parties have

entered into a license and are complying with that license agreement). Thus, any appropriate analysis of exclusion payments must take into account the possibility that the patent being enforced will be declared invalid. *See In re Terazosin Hydrochloride Antitrust Litigation*, 352 F. Supp. 2d 1279, 1298 (S.D. Fla. 2005) ("any construction of the patent's exclusionary scope . . . that fails to take into account the chances of the patent being held invalid would essentially afford pioneer drug manufacturers an unbridled power to exclude others without regard to the strength of their patent rights").

Second, in relying on the *rebuttable* presumption of patent validity to justify exclusion payments, the *Tamoxifen* standard not only disregards the distinction between rebuttable and conclusive but also transforms a procedural device into a substantive legal right. The presumption of validity "is a procedural device, not substantive law." *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1534 (Fed. Cir. 1983). Moreover, the presumption of validity applies only in a full adjudication on the merits. In proceedings short of full adjudication – for example, at the preliminary injunction stage – "the *patentee* carries the burden of showing likelihood of success with respect to the patent's validity." *Nutrition 21 v. United States*, 930 F.2d 867, 869 (Fed. Cir. 1991) (emphasis in original). In pharmaceutical as well as other patent cases, courts applying patent law frequently deny preliminary injunctions on the ground that, at least until a court has ruled on validity and infringement, the

alleged infringer has a "right to compete." *See, e.g., Illinois Tool Works, Inc. v. Grip-Pak, Inc.*, 906 F.2d 679, 684 (Fed. Cir. 1990).

Third, the *Tamoxifen* standard assumes that a finding of validity and infringement automatically results in a judicially enforceable order excluding the infringer from competing. In fact, even after a court has entered a final judgment finding infringement, the patentee is not automatically entitled to exclude the infringer, but instead must satisfy the traditional requirements for injunctive relief. *See eBay Inc. v. MercExchange, LLC*, 547 U.S. 388 (2006).

Fourth, the *Tamoxifen* standard disregards the fact that, because patent enforcement imposes costs on society in the form of monopoly rents, there is a public interest in judicial determination of patent validity that is absent or greatly muted in other areas of the law. As the Supreme Court has emphasized, "[a] patent by its very nature is affected with a public interest" because of its potentially "far-reaching social and economic consequences." *Precision Mfg. Co. v. Auto Maintenance Machine Co.*, 324 U.S. 806, 816 (1945). As a result, the Court has adopted rules that reduce the likelihood that invalid patents will be enforced.

For example, in *Cardinal Chemical Co. v. Morton Int'l, Inc.*, 508 U.S. 83 (1993), the Court disapproved the Federal Circuit's practice of vacating a district court declaration of patent invalidity once the Court of Appeals affirmed a finding of non-infringement.

The Court noted that "'of the two questions [validity and infringement], validity has the greater public importance,'" and that a court follows the "'better practice by inquiring fully into the validity of [the] patent.'" *Id.* at 100 (quoting *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 330 (1945)). Likewise, in *Blonder-Tongue Laboratories, Inc. v. Univ. of Ill. Foundation*, 402 U.S. 313 (1971), the Court ruled that a finding of patent invalidity in one case collaterally estops the patent holder from relitigating the issue in a subsequent case against a different defendant, despite the fact that a finding of patent *validity* has no such preclusive effect, because "the opportunity to relitigate might, as a practical matter, grant monopoly privileges to the holders of invalid patents." *Cardinal Chemical*, 508 U.S. at 101. And in *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969), the Court held that federal patent law preempted a rule of state contract law providing that a patent licensee cannot raise the invalidity of the patent as a defense in an action for unpaid royalties. The Court relied on the principle that "federal law requires, that all ideas in general circulation be dedicated to the common good unless they are protected by a valid patent." *Id.* at 668.

Even before *Lear* was decided, this Court created an exception to the doctrine of patent licensee estoppel in cases where the licensee alleged that the license violated the Sherman Act. *See Sola Elec. Co. v. Jefferson Elec. Co.*, 317 U.S. 173 (1942). In *Sola*, the Court ruled that, as a matter of federal law, the licensee *must* be permitted to raise patent invalidity

as a defense in an action to enforce a license agreement alleged to be unlawful under the antitrust laws because "[a]greements fixing the competitive sales price of articles moving interstate, not within the protection of a [valid] patent, are . . . prohibited by the Sherman Act." *Id.* at 176.

In each of these four respects, the *Tamoxifen* standard magnifies the branded manufacturer's rights beyond those it actually enjoys under federal patent law. It thereby contravenes the federal policy in favor of competition embodied in that law.

CONCLUSION

In *Bonito Boats*, this Court ruled that the State of Florida could not constitutionally create patent-like intellectual property rights broader than the limited and carefully delineated rights embodied in federal patent law. The Court ruled that "state regulation of intellectual property must yield to the extent that it clashes with the balance struck by Congress in our patent laws." 489 U.S. at 152. Yet the *Tamoxifen* standard allows *private parties* to do precisely what the State of Florida is constitutionally prohibited from doing.

The Petition should be granted.

Respectfully submitted,

DON L. BELL, II
NATIONAL ASSOCIATION OF
CHAIN DRUG STORES, INC.
413 North Lee Street
P.O. Box 1417-D49
Alexandria, VA 22313
(703) 549-3001
dbell@nacds.org

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Chain Drug Stores, Inc.

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