No. 12-416

In The
Supreme Court of the United States

FEDERAL TRADE COMMISSION,

Petitioner,

v.

ACTAVIS, INC., ET AL.,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Eleventh Circuit

BRIEF OF *AMICI CURIAE* DAVID W. OPDERBECK AND ERIK LILLQUIST IN SUPPORT OF RESPONDENTS

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STATEMENT OF INTEREST OF *AMICI CURIAE*[1]

Amici curiae David W. Opderbeck and Erik Lillquist are Professors of Law at Seton Hall University Law School and are Directors of The Gibbons Institute of Law, Science & Technology, an academic center located within Seton Hall University Law School in Newark, New Jersey. The Gibbons Institute provides a forum for lawyers, judges, scientists, and government officials to discuss the legal, political and social problems that will continue to arise as scientific and technological changes challenge our existing laws and legal institutions. Professors Opderbeck and Lillquist have published and/or taught and lectured in the area of pharmaceutical patent and antitrust law and are interested in the proper interpretation and enforcement of the antitrust laws with respect to pharmaceutical products.

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[1] No counsel for a party authored this brief in whole or in part and no party of counsel for a party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than amici curiae or its counsel made a monetary contribution to its preparation or submission. Counsel of record for all parties received notice of the amici curia's intention to file this brief. The parties have all either filed blanket waivers with the Court or have explicitly consented to the filing of this brief.

SUMMARY OF ARGUMENT

The FTC's proposed "quick look" approach is inadequate because it passes over a fundamentally important consideration: product market definition. Product market definition is basic to antitrust analysis under the rule of reason. Antitrust analysis of restraints such as license agreements involving patents routinely requires product market definition. The Court held in *Illinois Tool Works Inc. v. Independent Ink, Inc.,* 547 U.S. 28, 126 S.Ct. 1281, 164 L.Ed.2d 26 (2006), that a finding that a tying arrangement involving a patent is unlawful "must be supported by proof of power in the relevant market rather than by a mere presumption thereof." *Id.* at 43. The same should be true for reverse payment settlements. Pharmaceutical product markets are complex and often are not delimited by an individual molecule, making a "quick look" inadequate.

ARGUMENT

I. PRODUCT MARKET DEFINITION IS AN INDISPENSABLE STEP IN THE ANTITRUST EVALUATION OF REVERSE PAYMENT SETTLEMENTS

The FTC's proposed "quick look" approach passes over a fundamentally important consideration: product market definition. This is surprising, because a patent's impact on market concentration is a key determinant of the patent's power. *See* David W. Opderbeck, *Rational Competition Policy and Reverse Payment Settlements in Hatch-Waxman Patent Litigation*, 98 GEO. L.J. 1303 (2010).

Product market definition is fundamental to antitrust analysis under the rule of reason. As one leading treatise notes, "[t]he determination of the relevant market is inextricably related to the question of whether the defendant's competitors have been or will be foreclosed from the market by virtue of the challenged acts." CALLMAN ON UNFAIR COMPETITION § 4:31. Only in the context of *per se* liability, or in the case of a "quick look," where the conduct is deemed inherently anticompetitive, is the question of market definition set aside. The FTC and *amici* that seek some kind of *per se* or "quick look" rule concerning reverse payment settlements do not explain why such agreements are inherently anticompetitive, except in a circular fashion that inevitably points back to the need for product market definition.

All of the authorities agree that valid patents provide a legitimate zone of exclusion. The *scope* of a patent's legitimate exclusionary zone is defined by the scope of the claims. The *power* of a patent's legitimate exclusionary zone, however, cannot be defined without reference to product market definition. *See, e.g., Illinois Tool Works Inc. v. Independent Ink, Inc.,* 547 U.S. 28, 126 S.Ct. 1281, 164 L.Ed.2d 26 (2006). The definition of a patent's exclusionary zone must encompass both scope and power.

Scope and power are complementary, but not identical, concepts. It is true that scope and power usually involve a proportional relationship: as the scope of a patent's claims expands, its potential market power expands. A patent claim for "pharmaceutical compounds to treat depression" obviously would confer greater market power than a patent claim for the chemical formulation of *fluoxetine hydrochloride*.[2] The doctrines that limit claim scope – novelty, non-obviousness, and the rules regarding claim construction and the range of equivalents – therefore also serve to constrain patent power. But these doctrines do not fully circumscribe the range of a patent's power. If fluoxetine hydrochloride is the only compound capable of treating depression, a patent claiming that

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[2] Fluoxetine hydrochloride is the generic name for a selective serotonin reuptake inhibitor originally sold under the brand name PROZAC. See Eli Lilly and Company Prozac.com website, available at http://www.nlm.nih.gov/medlineplus/druginfo/meds/a689006.html (last visited February 24, 2013).

compound obviously confers greater market power than is the case when there are multiple non-infringing compounds that can be used to treat depression with similar clinical results.

A response to this view might be that *any* agreement that arguably expands a patent's power should be considered an unlawful restraint of trade. This closely resembles the argument over tying arrangements involving patents, which recently was resolved by the Supreme Court in *Illinois Tool Works*, 547 U.S. 28, 126 S.Ct. 1281, 164 L.Ed.2d 26 (2006).

In *Illinois Tool Works*, the Court reversed a line of precedent holding that tying arrangements involving the tie of patented and unpatented products are *per se* unlawful. According to the Court, the conclusion that a particular tying arrangement involving a patent is unlawful "must be supported by proof of power in the relevant market rather than by a mere presumption thereof." *Id.* at 43. The Court based this conclusion, in part, on Congress' distinction between patent rights and market power in the Patent Act.

The *Illinois Tool Works* Court essentially adopted Justice O'Connor's reasoning in her concurrence in *Jefferson Parish Hospital v. Hyde*, 466 U.S. 2, 37 n. 7, 104 S.Ct. 1551, 80 L.Ed.2d 2 (1984) (Justice O'Connor concurring), a patent tying case abrogated by *Illinois Toolworks*. Justice O'Connor there stated that

> A common misconception has been that a patent or copyright, a high market share, or a unique product that competitors are not able to offer suffice to demonstrate market power. While each of these three factors might help to give market power to the seller, it is also possible that a seller in these situations will have no market power: for example, a patent holder has no market power in any relevant sense if there are close substitutes for the patented product. Similarly, a high market share indicates market power only if the market is properly defined to include all reasonable substitutes for the product.

Id. at 37-38; *see also Walker Process Equipment, Inc. v. Food Machinery and Chemical Corp.*, 382 U.S. 172, 177, 86 S.Ct. 347, 350 15 L.Ed.2d 247 (1965)(stating that "[w]ithout a definition of [the relevant market] there is no way to measure [the patent holder's] ability to lessen or destroy competition."). Neither the nominal nor adjudicated scope of a patent can in themselves define the relevant product market.

Justice O'Connor's reasoning is consistent with antitrust policy concerning intellectual property generally, including the Federal Trade Commission and Department of Justice guidelines for intellectual property licenses. *See* DOJ / FTC ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY, April 6, 1995. A reverse payment

settlement is not, of course, merely a license agreement. However, the antitrust concern over reverse payment settlements is the same as the concern over exclusive licenses: will the agreement result in an unacceptable degree of market concentration? A license agreement can allow the parties to aggregate the legitimate exclusionary power of multiple intellectual property rights in a way that illegitimately concentrates market power. But intellectual property license agreements usually represent an efficient means of allocating rights, without producing excessive product market concentration. Intellectual property licenses therefore are not ordinarily subject to greater or lesser scrutiny under antitrust law than other sorts of transactions allocating property rights. *See id.* § 2.1 (stating that "[a]s with other forms of private property, certain types of conduct with respect to intellectual property may have anticompetitive effects against which the antitrust laws can and do protect. Intellectual property is thus neither particularly free from scrutiny under the antitrust laws, nor particularly suspect under them."). The same should be true of reverse payment settlements.

II. A QUICK LOOK IS INSUFFICIENT BECAUSE MANY, IF NOT MOST, PHARMACEUTICAL PRODUCT MARKETS ARE NEITHER MONOPOLIES NOR DUOPOLIES

Some scholars who have attempted to model the effects of reverse payment settlements have recognized the need for objective measurement of product market concentration. *See, e.g.,* Carl Shapiro, *Antitrust Limits,* 34 RAND J. OF ECON. at

402-04 (2003); Opderbeck, *Rational Antitrust Policy*, 98 GEO. L.J. 1303 (2010). As noted, this is consistent with the way in which enforcement agencies currently evaluate exclusive intellectual property licenses.

Most existing economic models of reverse payment settlements, however, assume only duopoly competition if the settlement is not consummated and the patent is held valid but not infringed. *See* Jeremy Bulow, *The Gaming of Pharmaceutical Patents*, in Adam B. Jaffe, Josh Lerner, and Scott Stern, eds., INNOVATION POLICY AND THE ECONOMY (MIT Press 2004), at 160 (modeling "monopoly days, triopoly days, and duopoly days" resulting from paragraph IV ligation settlements); Robert D. Willig and John P. Bigelow, *Antitrust Policy Toward Agreements that Settle Patent Litigation*, 2004 THE ANTITRUST BULLETIN 655, 656 (2004) (recognizing that the patent holder might not have monopoly power in real markets but adopting assumption of market power to simplify modeling). This assumption is unrealistic in many pharmaceutical product markets.

In antitrust cases, the relevant market "is composed of products that have reasonable interchangeability for the purpose for which they are produced – price, use and qualities considered." *U.S. v. E.I. Dupont Nemours Co.*, 351 U.S. 377, 404, 76 S.Ct. 994, 100 L. Ed. 1264 (1956). The joint DOJ FTC Merger Guidelines indicate that a product market can be defined by examining whether buyers likely would shift to a substitute product in response to a "small but significant nontransitory increase in

price" – in other words, by the cross-price elasticity of demand. DOJ / FTC MERGER GUIDELINES (April 2, 1992), § 1.1. For pharmaceutical products, "the only logical place from which to determine the relevant product market is from the array of therapeutically substitutable choices available to the doctor." *In the Matter of Schering-Plough Corp.,* FTC Docket No. 9297, Initial Decision, June 27, 2002, at 88.

Expert testimony from physicians, pharmacists, third party payors, and other sources can help establish which products are therapeutic substitutes. It also is possible to quantify the cross-price elasticity of demand for branded and generic products in the same therapeutic class. *See* Sara Fisher Ellison, Iain Cockburn, Zvi Grilliches and Jerry Hausman, *Characteristics of Demand for Pharmaceutical Products: an Examination of Four Cephalosporins*, 28 RAND JOURNAL OF ECONOMICS 426 (1997) (examining cross-price elasticities of cehpalosporins, in a product market that included four different branded compounds); s*ee also* Patricia Danzon and Li-Wei Chao, *Does Regulation Drive Out Competition in Pharmaceutical Markets*, 63 JOURNAL OF LAW & ECONOMICS 311, 312 (2000) (noting that "patent-protected drugs may face competition from 'therapeutic substitutes' – drugs with different active ingredients but similar therapeutic effects.").

It is simply not the case that a single molecule necessarily defines a pharmaceutical product market. Often, a significant variety of competing patented and generic products exist in the same class to treat the same condition. For example, at least

five variations of selective serotonin reuptake inhibitors have been approved by the FDA to treat depression.[3] These are sold under at least seven brand names by four different branded manufacturers. *See* Haiden A. Huskamp, et al., *Generic Entry, Reformulations and Promotion of SSRIs in the US*, 26 PHARMACOECONOMICS 603, 604 (2008) (noting that branded SSRIs include PROZAC, PAXIL, ZOLOFT, CELEXA, PAXIL CR, PROZAC WEEKLY, and LEXAPRO). Four of the patents relating to these compounds have expired, and generic versions of these drugs are sold by generic manufacturers. *See id.* In such a product market, the loss of generic competition with respect to one compound would not result in a monopoly, nor would the presence of generic competition with respect to one patent result in a duopoly. In other words, the scope of the patent claims for any one compound does not define the boundaries of the relevant product market.

The definition of a product market for pharmaceuticals, to be sure, is complicated by the need for therapeutic fit between a given compound within a drug class and the patient. It is quite possible, for example, that a patient suffering from depression might respond only to one particular compound within the class of SSRI's. Moreover, some patients being treated with certain types of

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[3] These include citralopram, escitralopram, fluoxetine, paroxetine, and sertraline. See Mayoclinic.com entry for SSRI's, available at http://www.mayoclinic.com/health/ssris/MH00066 (last visited February 22, 2013).

drugs – including psychiatric drugs – report better results from the branded version of a particular compound than from a generic, even though the FDA has found the products to be bioequivalent. Whether this is due to a placebo effect or to some subtleties of the formulation process is unclear. *See, e.g.,* Giuseppe Borgherini, *The Bioequivalence and Therapeutic Efficacy of Generic Versus Brand-Name Psychoactive Drugs*, 25 CLINICAL THERAPEUTICS 1578 (2003). Thus, for any given patient, the product market might not be as broad as the total range of potential treatments.

Even with this caveat, however, it seems reasonable to reject the assumption that all pharmaceutical product markets in which a paragraph IV validity challenge has been mounted to a patent are either only potential monopolies or duopolies. Therefore, at least as a first rough measure of competitive effect, it is reasonable to define the relevant product market to include all potentially competing drugs in the same class. An objective measure of product market concentration, such as the commonly used Herfindahl-Hirschman Index ("HHI"), could readily be employed "[a]s an aid to the interpretation of [this] market data." DOJ / FTC HORIZONTAL MERGER GUIDELINES, § 1.5. This measure of product concentration could be employed together with an approximate assessment of patent strength to establish an index for gauging the likely competitive effects of a reverse payment settlement in a particular market. *See* Opderbeck, *Rational Competition Policy*, 98 GEO. L.J. 1303. In any event, reverse payment settlements should not be declared *per se* or presumptively illegal. Product market

analysis is essential to antitrust review of most restraints of trade, including most restraints involving patents. *See Illinois Tool Works*, 547 U.S. 28, 126 S.Ct. 1281, 164 L.Ed.2d 26.

III. CONCLUSION

The FTC's proposed presumptive illegality approach to evaluating reverse payment settlements should be rejected because it fails to consider the importance of product market definition.

Respectfully submitted,

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