No. 04-1329

IN THE
SUPREME COURT OF THE UNITED STATES

ILLINOIS TOOL WORKS INC., ET AL.,
Petitioners,

v.

INDEPENDENT INK, INC.,
Respondent.

On Writ of Certiorari To The
United States Court of Appeals
For the Federal Circuit

BRIEF OF AARP, THE PUBLIC PATENT FOUNDATION AND CONSUMERS UNION AS *AMICI CURIAE* IN SUPPORT OF RESPONDENT

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QUESTION PRESENTED

Whether, in an action arising under Section 1 of the Sherman Act, 15 U.S.C. § 1, alleging unlawful tying of a patent license to the purchase of a nonpatented good, market power in the tying product market should be presumed from the tying party's patent over the tying product.

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INTEREST OF *AMICI CURIAE*[1/]

AARP is a nonpartisan, nonprofit membership organization of over 35 million persons, age 50 or older, dedicated to addressing the needs and interests of older Americans. AARP seeks through education, advocacy, and service to enhance the quality of life for all by promoting independence, dignity, and purpose. In its efforts to promote independence, AARP works to foster the health and economic security of individuals as they age by attempting to ensure the availability of quality and economical health coverage. As the country's largest membership organization, AARP has a long history of advocating for access to affordable health care and

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[1] In accordance with Supreme Court Rule 37.6, AARP, Consumers Union and the Public Patent Foundation (*amici curiae*) state that: (1) no counsel to a party authored this brief, in whole or in part; and (2) no person or entity, other than *amici curiae,* their members and counsel have made a monetary contribution to the preparation or submission of this brief. The written consents of the parties to the filing of this brief have been filed with the Clerk of the Court pursuant to Supreme Court Rule 37.3.

for controlling costs without compromising quality.

A decision in this case will determine how litigation regarding patents used in tying arrangements will be conducted in virtually every consumer industry in America. Tying can affect the price of many consumer products and services, and is an emerging issue in the prescription drug marketplace. AARP is interested in this case to the extent it will affect tying arrangements in the pharmaceutical industry.

Access to prescription drug treatments is particularly important to the older population which, because of its higher rates of chronic and serious health conditions, has the highest rate of prescription drug use. AARP conducts research and engages in educational activities and advocacy to increase access to affordable prescription drugs. Since May of 2004, AARP's Public Policy Institute has issued a series of reports that closely monitor the pricing actions of the pharmaceutical industry. *See, e.g.,* David Gross et al., *Trends in Manufacturer Prices of Brand Name Prescription Drugs Used by Older Americans – First Quarter 2005 Update*, AARP Public Policy Institute (July 2005), *available at* http://assets.aarp.org/rgcenter/health/dd122drugprices.pdf. AARP has filed *amicus curiae* briefs in prescription drug litigation aimed at lowering the costs of prescription drugs including *In re Cardizem CD Antitrust Litig*., 332 F.3d 896 (6th Cir. 2003), *cert denied sub nom Andrx Pharma., Inc. v. Kroger Co.*, No. 03-779 (Oct. 12, 2004); *Valley Drug Co., v. Geneva Pharms., Inc.* 344 F.3d 1294 (11th Cir. 2003) *cert. sub nom Walgreen Co. v. Abbot Labs.*, No. 03-1178 (Oct. 12, 2004). AARP also filed an amicus curiae brief in the recent case of *Merck KgaA v. Integra Lifesciences I, Ltd.,* _U.S._, 125 S. Ct. 2372 (2005)(involving patent infringement exception).

The Public Patent Foundation ("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 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 how patents on one product that are used through tying arrangements to eliminate competition on another un-patented product are evaluated under antitrust law. PUBPAT has an interest in ensuring that the power of patents is adequately appreciated in such circumstances so that patents are not allowed to be unjustifiably extended in ways that harm competition.

Consumers Union ("CU") is a nonprofit membership organization chartered in 1936 to provide consumers with information, education and counsel about goods and services and to advocate for state and federal policies that advance and protect consumers' interests. CU has a long history of advocating for health care including safe, effective, and affordable prescription drugs.

CU is the nonprofit publisher of *Consumer Reports* magazine, with approximately 4.5 million print subscribers and more than two million subscribers to its online site *ConsumerReports.org*, which regularly carries articles on health-related topics, including federal and state consumer protection laws, policies and programs. Consumer Reports

ranks 7th nationally among print periodicals in terms of number of subscriptions.

CU has an interest in this case because it will affect patent litigation in cases of illegal tying. Tying can affect the price of many consumer products and services, and is an emerging issue in the prescription drug marketplace. The outcome of this case may affect the ability of consumers to afford necessary medicines, and the case therefore raises significant concerns for consumer health and costs.

SUMMARY OF ARGUMENT

Patents are designed to confer market power upon inventors. The commercial reality in many markets, including the pharmaceutical industry, is that patents do in fact give their owners market power. The issue here is not whether patents can confer market power on their owner, but rather whether the presumption that they do makes sound policy. This Court has long recognized – and correctly so – that the presumption is indeed reasonable because it is precisely those technologies over which patents are most likely to confer market power that a patent holder will implement a tying arrangement that harms competition. The class of patents to be looked at when deciding whether to have a presumption or not is not all issued patents, but instead only those patents that an owner could successfully attempt to leverage through a tying arrangement, because it is those tying arrangements that will end up being challenged in court.

Patents often confer market power on their owner because they define the relevant market (the drug covered by the patent) and the exclusive rights they provide their owner give power within that market. This fact is widely recognized throughout the pharmaceutical industry by the drug companies themselves. Tying in the form of combination pills, which are part patent protected drug and part non-exclusive drug, is an emerging business model in the pharmaceutical industry. Competition in the market for the non-exclusive component of a combination pill is injured as a result of such tying, which is

only successful because of the market power provided by the patent on the other component. This results in higher prices and fewer choices in the market for the tied non-exclusive component. Thus, as just one example, the presumption that a patent confers market power on its owner makes sound policy in cases involving the tying of separate pharmaceutical products and it should not be abandoned.

Further, pragmatically speaking, economic rationality ensures that the only people who will bring tying claims are those being competitively injured as a result of the tying arrangement. Under those circumstances, as discussed above, it is extremely likely that market power in the tying product market is provided by the patent, because it is that market power that is being leveraged to cause the competitive harm in the tied product market. Truth be told, tying arrangements involving patents occur all the time, but contrary to what Petitioner and their *amici* would have this Court believe, only a very few are ever challenged as being anticompetitive. With respect to those cases, the market power resulting from the patent on the tying product is clear and the presumption of market power should be maintained.

ARGUMENT

I. THE PHARMACEUTICAL INDUSTRY ILLUSTRATES HOW PATENTS FREQUENTLY CONFER MARKET POWER

The presumption that a patent confers market power on its owner is just as correct today as it has been throughout the nearly sixty years that this Court has recognized it. *Jefferson Parish Hosp. Dist. No. 2 v. Hyde,* 466 U.S. 2, 16 (1984) ("if the government has granted the seller a patent or similar monopoly over a product, it is fair to presume that the inability to buy the product elsewhere gives the seller market power"). This is because a patent confers on its owner the exclusive right to manufacture, use, and sell the particular invention during its twenty year term. 35 U.S.C. §154(a)(1)-(2). As such, it has been recognized that, "[b]y their nature, patents create an

environment of exclusion, and consequently, cripple competition." *Schering-Plough v. FTC,* 402 F.3d 1056, 1065-1066 (11th Cir. 2005), *petition for cert. filed* (Aug. 29, 2005)(No. 05-273). Petitioner and its *amici* concede as much. (*See, e.g.*, United States Br. 9) ("[i]t is certainly possible that a patent holder could possess market power sufficient to support a per se tying claim").

In fact, the market power conferred by a patent has actually increased over time. For one reason, trends in Congress have been to strengthen, not weaken, intellectual property rights. John H. Barton, *Reforming the Patent System*, 287 Science 1933-1934 (March 17, 2000), *available at* http://www.biotech-info.net/reforming.html. In addition, there has long been a statutory presumption of validity of a patent that strongly favors the holder of even an invalid patent. 35 U.S.C. § 282; *see also Doddridge v. Thompson*, 22 U.S. (9 Wheat.) 469, 483 (1824) (holding that a patent is presumed valid until the contrary is shown). Thus, generally speaking, the presumption that a patent confers on its owner market power in the market for the patent protected invention is correct.

The pharmaceutical industry illustrates the direct causal relationship between the issuance of a patent and the receipt of market power. Thus, when a pharmaceutical company receives a patent on a new drug, that patent gives the company the exclusive right to sell the new drug, which is frequently so innovative that it creates its own market. That exclusive right in the new market gives the company considerable market power, which it would not have without the patent. The pharmaceutical industry is one example of the correctness of the presumption that patents confer market power on their owner, but it is also correct in many other industries with respect to many other technologies.

A. Patents Confer Market Power When The Scope

Of The Patent Defines The Scope Of The Relevant Market.

In antitrust law, relevant product markets are determined by examining the reasonable interchangeability of products. *See Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962) ("The outer boundaries of a product market are determined by the reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it.") Market power is the ability for a single seller to raise price and restrict output within a relevant market. *Eastman Kodak Co. v. Image Technical Services*, 504 U.S. 451, 464 (1992); *see also United States v. E. I. Du Pont de Nemours & Co.*, 351 U.S. 377, 391 (1956) ("Monopoly power is the power to control prices or exclude competition.").

In this case, the Federal Circuit held that in tying cases "a patent presumptively defines the relevant market as the nationwide market for the patented product itself, and creates a presumption of power within this market." *Indep. Ink, Inc. v. Ill. Tool Works, Inc.*, 396 F.3d 1342, 1352 (Fed. Cir. 2005). A patent will always give its holder market power in cases where the patent itself defines the relevant market, since a patent allows its holder to completely exclude competition from that market. The patent holder is given an unfettered ability to raise price and restrict output in that market during the term of the patent and that power granted by the patent is significant.

While it may not always be correct to define a market as one patented product, this type of narrow market definition is common in antitrust law.[2/] For example, a product may constitute its own market when it is so highly differentiated that for some consumers nothing else will do. *United States v. Grinnell Corp.*, 384 U.S. 563, 574 (1966). In fact, even one brand of a particular product can constitute a separate market

[2] The Federal Trade Commission often argues for this type of narrow market definition in its antitrust cases involving the pharmaceutical industry, as discussed in the next section.

for antitrust purposes. *Kodak*, 504 U.S. at 482. In addition, a broader product market may contain "well-defined submarkets . . . which, in themselves, constitute product markets for antitrust purposes." *Brown Shoe*, 370 U.S. at 325. In general, this Court has emphasized that market definition must take into account the "'commercial realities' faced by consumers." *Kodak*, 504 U.S. at 482 (citation omitted). The commercial reality in many markets, including specifically the pharmaceutical industry, is that patents do give their owners market power.

B. Patents Routinely Confer Market Power In The Pharmaceutical Industry.

Petitioner and its *amici* concede that patents can confer market power in certain markets; they just argue that this is a rare occurrence. For example, the American Intellectual Property Law Association ("AIPLA") argues that "the mere issuance of a patent neither defines a relevant product market nor conveys market power in a relevant market, *except in very rare cases*." (AIPLA Br. 3) (emphasis added). They believe this is rare because "[i]n AIPLA's experience, virtually all patents cover improvements to existing products that represent modest, incremental advances. Rarely do they claim pioneering inventions that open entirely new economic markets. Thus, the issuance of a patent, standing alone, only rarely affords its owner or licensor any appreciable market power in a relevant product market in the antitrust sense, i.e., the power to raise prices or restrict output in that market." *Id.* at 5.

This implies that in industries where innovators patent inventions that are totally new products, as opposed to improvements to existing products, patents do give their owners market power. The pharmaceutical industry is an example of one industry where patent inventions can be totally new products.

The United States makes the argument that "[a] market participant's possession of a patent right, and the consequent

statutory right to exclude infringing products from the marketplace, cannot give the participant market power if-as is *usually* the case-there are noninfringing alternatives to the patented product that qualify, in the economic sense, as good substitutes." (United States Br. 11) (emphasis added). By this, the Government makes the point that products do not have to be substantially identical in the patent infringement sense in order to function as economic substitutes for antitrust purposes. *Id.* at n.6. As an example, the Government points out that wooden pencils and mechanical pencils could both be included in a "pencil" or "manual writing instrument" market. *Id*.

Unlike pencils, however, many patented prescription drug products do *not* have acceptable noninfringing substitutes because even within a therapeutic class there may be significant differences in effectiveness and toxicity. For example, one Court of Appeals found that although there is a "certain degree of interchangeability among all antibiotics" there are certain features of cephalosporins (including their effectiveness against a wider range of infectious organisms, their ability to treat penicillin-allergic patients, and their production of fewer side effects) that reduce their interchangeability with other drugs and make them a relevant product market. *SmithKline Corp. v. Eli Lilly & Co.*, 575 F.2d 1056, 1064 (3d Cir. 1978) ("Thus, although there is a certain overlap in therapeutic capability, . . . cephalosporins possess sufficiently unique features to warrant their characterization as a discrete product market, one lacking interchangeability with antibiotics in general."). In many recent antitrust cases involving the pharmaceutical industry, the Federal Trade Commission ("FTC") has determined that the relevant market constitutes of only a branded drug and its generic bioequivalents as listed in the Food and Drug Administration ("FDA") Orange Book.[3/] The FTC's market definitions

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[3] *See, e.g.*, *Biovail Corp.*, F.T.C. Docket No. C-4060 (Oct. 2, 2002) (Complaint ¶¶ 18-20, 22), *available at* http://www.ftc.gov/os/2002/10/bioavailcmp.pdf; *Abbott Labs. & Geneva Pharm., Inc.*, F.T.C. Docket Nos. C-3945, 3946 (May 22, 2000) (Complaint ¶¶ 10, 12), *available at* http://www.ftc.gov/os/2000/05/c3945complaint.htm ("The relevant product

highlight the fact that differences in safety, efficacy, and side effects reduce the interchangeability of prescription drugs, even within the same therapeutic class.

The pharmaceutical industry itself has always emphasized the importance of patents to their market power. When the Federal Trade Commission and the Department of Justice held hearings on patents and competition policy, pharmaceutical representatives testified that "patent protection is indispensable in promoting pharmaceutical innovation for drug products containing new chemical entities[NCEs] . . . By preventing rival firms from free riding on the innovating firms' discoveries, patents can enable pharmaceutical firms to cover their fixed costs and regain the capital they invest in R&D efforts." Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* ch. 3, at 4 (Oct. 2003), *available at* http://www.ftc.gov/os/2003/10/innovationrpt.pdf [hereinafter *FTC Report*]. *See also id.* at 9 ("Participants in the Hearings overwhelmingly expressed the view that patent rights for pharmaceuticals are essential for brand-name companies to prevent free riding and recoup their significant investments in research and development of NCEs."). The drug companies also routinely tell their investors about the severe economic consequences of patent expiration. In a quarterly report filed with the Securities

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market for assessing respondents' anticompetitive conduct is terazosin hydrochloride . . . . Other drugs are not effective substitutes for terazosin HCL because they are different in terms of chemical composition, safety, efficacy, and side effects. In addition, there is little price sensitivity between terazosin HCL and non-terazosin HCL products."); *Hoechst Marion Roussel, Inc. & Andrx Corp.*, F.T.C. Docket No. 9293 (Mar. 16, 2000) (Complaint ¶ 12), *available at* http://www.ftc.gov/os/2000/03/hoechstandrxycomplaint.htm ("A relevant product market for assessing respondents' anticompetitive conduct is once-a-day diltiazem. . . . Other calcium channel blockers are not acceptable substitutes for diltiazem for several reasons, including, inter alia, the differences in efficacy and side effects, and the risks associated with switching patients from one calcium channel blocker to another. In addition, narrower relevant product markets may be contained within the market for once-a-day diltiazem products.").

and Exchange Commission, Pfizer cautioned its investors that "[t]he loss of patent protection with respect to any of our major products could have a material adverse effect on revenue and net income." Pfizer Inc., Quarterly Report (Form 10-Q) (July 3, 2005).[4] When discussing various legal proceedings in which it was involved, Pfizer went on to say that "a loss in any of these cases could result in a loss of patent protection for the drug at issue, which could lead to a significant loss of sales of that drug and could materially affect future results of operations." *Id.* In its annual report, Pfizer also emphasized that "[t]he expiration of a basic product patent or loss of patent protection resulting from a legal challenge normally results in significant competition from generic products against the originally patented product and can result in a significant reduction in sales of that product in a very short period." Pfizer Inc., Annual Report (Form 10-K) (Dec. 31, 2004).[5/] Other pharmaceutical companies make similar statements to investors about the direct relationship between patent protection and market power.[6/]

Lastly, the circumstances in which Petitioner's *amici* concede that patents confer market power (circumstances they

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[4] *Available at* http://www.sec.gov/Archives/edgar/data/78003/000007800305000213/q2-05pfe1.htm.

[5] *Available at* http://www.sec.gov/Archives/edgar/data/78003/000095012305002379/y06124e10vk.htm.

[6] *See* Schering-Plough Corp., Annual Report (Form 10-K) (Dec. 31, 2004), *available at* http://www.sec.gov/Archives/edgar/data/310158/000095012305002785/y05567e10vk.htm ("When a product patent expires, the patent holder often loses effective market exclusivity for the product. This can result in a rapid, sharp and material decline in sales of the formerly patented product, particularly in the U.S."); Johnson & Johnson, Quarterly Report (Form 10-Q) (July 3, 2005), *available at* http://www.sec.gov/Archives/edgar/data/200406/000020040605000106/secondqtrtenq.txt ("In the event the Company is not successful in defending a lawsuit resulting from an Abbreviated New Drug Application filing, the generic firms will then introduce generic versions of the product at issue, resulting in very substantial market share and revenue losses.").

allege are "rare" and "not usual") are precisely those situations where the patent holder will be able to execute an effective tying arrangement. If the owner of a pencil patent tried forcing its customers to also buy its pencil boxes, it would not be successful, because consumers would have the ability to acquire pencils from other manufacturers that did not require the purchase of a box. Although these types of arrangements are tried frequently, no one ever litigates them because they do not cause competitive harm. The pencil manufacturer's competitors are not impacted by the tie, except that they may actually benefit from it in that it will force consumers *away* from the tying party's products.

To the contrary, it is precisely those "rare" and "not usual" cases where a patent prevents consumers from accessing substitutes that the tying arrangement works to the benefit of the tying party and the detriment of competition. The market power in the tying product, provided by the patent that excludes alternatives to the tying product, is what enables the forced purchasing of the tied product. That forcing creates the anticompetitive injury sufficient to justify another party to challenge the arrangement under antitrust law, something that is "rare" and "not usual". Therefore, even if the frequency with which patents confer market power on their owner is "rare" or "not usual," in some industries, that does not impact the reasonableness of presuming that the *small* number of patents involved in tying arrangements which are harmful enough to justify being challenged in court do confer market power on their owner. Additionally, in many industries, like the pharmaceutical industry, there is no doubt that a patent does in fact confer market power.

C. The Market Power Conferred By Patents in the Pharmaceutical Industry Has Increased.

Over the past two decades, Congress has enacted a series of laws that have greatly increased the effective patent life enjoyed by brand name prescription drugs. Michie I. Hunt, *Prescription Drugs and Intellectual Property Protection: Finding the Right Balance Between Access and Innovation,*

Nat'l Inst. for Health Care Mgmt. (Aug. 2000), *available at* http://www.nihcm.org/prescription.pdf. The market power that goes hand in hand with owning a patent on a prescription drug has been recognized by commentators and in fact "the operation of the patent system is on the forefront of controversies, both domestic and international, about its effects upon pricing and exclusion in the pharmaceutical industry." Daniel J. Gifford, *How Do the Social Benefits and Costs of the Patent System Stack Up in Pharmaceuticals?,* 12 J. Intell. Prop. L. 75, 78 (Fall 2004). The market power conferred by patents in the prescription drug industry is so great, that government intervention has been suggested by some parties. "The special case for government intervention in pharmaceutical prices derives from the monopoly market power granted by the state to patented drugs." Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets,* 5 Yale J. Health Pol'y, L. & Ethics 193, 239 (2005).

It is not surprising that patents in the pharmaceutical industry confer market power, since that is the intended consequence of the current regulatory environment. The pharmaceutical industry involves a delicate balance between the need for innovators to recoup research and development expenditures and the desire for consumers to pay affordable prices for drugs. Congress has attempted to achieve this balance through the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 15 U.S.C. §§ 68b-68c, 70b; 21 U.S.C. §§ 301 note, 355, 360cc; 28 U.S.C. § 2201; 35 U.S.C. § 156, 271, 282) (known as the Hatch-Waxman Act). Hatch-Waxman made it easier for generic drugs to enter the market by creating an abbreviated approval process for generics. Cong. Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* xii (July 1, 1998) [hereinafter *CBO Report*], *available at* http://www.cbo.gov/ftpdocs/6xx/doc655/pharm.pdf.

One of the additional goals of Hatch-Waxman was to allow pharmaceutical companies to recoup their investments in

research and development. According to the Congressional Budget Office ("CBO") Report, pharmaceutical innovators "quickly lose over 40 percent of their market, on average, to generic drugs." *Id.* at 37. The Act's patent term extensions were enacted to partially offset this loss for branded drug companies because the patents give them exclusive rights for a period of time so they can recoup their investment in research and development. *Id.* According to the CBO, "[t]he patent system provides a period of protection during which manufacturers of innovator drugs can charge relatively high prices, earning profits that enable them to compensate for the costs of a drug's discovery and development." *Id.* at 13. This period of exclusivity provided by patents is expressly and specifically designed to give innovators market power, in the sense that they can charge supracompetitive prices for a period of time in order to recoup their development costs.[7/] If patents did not give market power to their owner, this scheme would fail because the patent holder would not be able to protect its profits from competition.

Therefore, not only has the presumption that patents confer market power on their owner maintained its veracity since first being promulgated decades ago, recent changes in patent law has increased its soundness with respect to pharmaceutical patents.

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[7] Although some patented drugs may eventually face competition from other branded drugs in the same therapeutic class, this process usually takes at least 6 years. *CBO Report* at xi. In addition, other drugs within the same therapeutic class may not be reasonably interchangeable due to differences in effectiveness and toxicity. Furthermore, the CBO points out that "[w]hen a breakthrough drug is introduced, by definition it has no close substitutes on the market. Demand for the drug is therefore fairly insensitive to price, since no alternative treatment of equal quality and effectiveness exists." *Id.* at 19-20.

II. THE PHARMACEUTICAL INDUSTRY IS RELEVANT TO THIS CASE BECAUSE OF THE NEW TREND IN PHARMACEUTICAL TYING ARRANGEMENTS.

As discussed above, the Hatch-Waxman Act attempted to balance the public's need for affordable medicines with the innovator's need to recoup R&D costs. To achieve this balance, the Hatch-Waxman framework extends the innovator's market exclusivity while making it easier for generic drugs to enter the market once that exclusivity period has expired. When companies improperly expand the scope of their market exclusivity, it destroys the delicate Hatch-Waxman balance and harms the public interest. Pharmaceutical companies have a reputation for "gam[ing]" the system in an attempt to "restrict competition beyond what the Hatch-Waxman Amendments intended." *FTC Report* ch. 3, at 13. Indeed, almost twenty-five percent of new competition investigations by the FTC in recent years have involved pharmaceutical products.[8/]

Pharmaceutical tying occurs when a drug manufacturer forces a patient to buy an un-patented drug or medical product in order to have the right to purchase a patented one. For example, Sandoz Pharmaceutical required purchasers of its schizophrenia drug clozapine, the first new drug for the treatment of schizophrenia in twenty years, to also purchase Sandoz's distribution and patient-monitoring services. Sandoz's "'tying' arrangement raised the price of clozapine treatment and prevented others - such as private laboratories, the Veterans Administration, and state and local hospitals - from providing the related blood tests and necessary patient monitoring." *Sandoz Pharmaceuticals Corp.,* 115 F.T.C. 625

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[8] Timothy J. Muris, Chairman, FTC, *Everything Old is New Again: Health Care and Competition in the 21st Century*, *7th Annual* Competition in Health Care Forum 3 n. 13 (Nov. 7, 2002), http://www.ftc.gov/speeches/muris/murishealthcarespeech0211.pdf (prepared remarks of Timothy Muris).

(1992)(No. C-3385)(consent order).[9/]

An expansion of this new trend in the pharmaceutical industry is to "tie" two different medications together into a combination pill; precluding the consumer from buying only one of the medications in the combination pill separately. Tying through combination pills that are part patent-protected drug and part non-exclusive drug is becoming more prevalent as an attempt by pharmaceutical industries to maximize profits and exclude generic manufacturers from entering the market after the patent expires on the otherwise non-exclusive medication in the combination pill. Lara J. Glasgow, *Stretching the Limits of Intellectual Property Rights: Has the Pharmaceutical Industry Gone Too Far*? 41 IDEA 227, 231-232, 250 (2001). These combination pills allow the branded drug company to tie a non-exclusive drug to a patent-protected drug that still enjoys market exclusivity. This harms competition in the market for the non-patented component because consumers are forced to buy the tying party's non-exclusive drug in order to get the patent protected component. This forcing destroys what would otherwise be a fully competitive market for the non-exclusive drug.

The tying scheme is only successful because of the market power provided by the patent on the patent-protected component. The resulting anti-competitive injury is seen as higher prices and fewer medical choices in the market for the non-patent protected drug. These are exactly the type of arrangements that tying law condemns because "[t]hey deny competitors free access to the market for the tied product, not because the party imposing the tying requirements has a better product or a lower price but because of his power or leverage in another market. At the same time buyers are forced to forego their free choice between competing products." *Northern Pacific Railway Co. v. United States*, 356 U.S. 1, 6 (1958).

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[9] Summarized at *FTC Antitrust Actions in Pharmaceutical Services and Products*, Bureau of Competition FTC (Nov. 8, 2002), http://www.ftc.gov/bc/rxupdate021108.htm.

One example of this tying through combination pill strategy used by the pharmaceutical industry involves the tying of a promising new heart medication with another drug that would otherwise be subject to full and fair competition. Pfizer is developing a new drug, torcetrapib, that has been heralded as a novel weapon against heart disease that may be an important clinical tool in preventive cardiology. Jerry Avorn, *Torcetrapib and Atorvastatin - Should Marketing Drive the Research Agenda?* 352 New Eng. J. Med. 2573, 2573-2574 (June 23, 2005).[10/] However, "[e]nthusiasm about this potentially important new therapeutic tool has been tempered by concern about how the company will study and market the drug." *Id*. at 2574. This is because Pfizer plans on marketing the new drug, which it expects to have fully protected by a patent, only with its own statin, which is but one drug in a class of statins. The patent on Pfizer's statin, marketed under the brand name Lipitor, is due to expire in 2010, which would otherwise leave it subject to full competition from generics. The tying arrangement accomplished by the torcetrapib - Lipitor combination pill will prevent this full competition from happening. Not only will the tying of torcetrapib to Lipitor in one combination pill have a harmful effect on competition, it will also cause clinical problems for patients who cannot tolerate[11/] (or afford) Lipitor. Those patients will have no way of obtaining torcetrapib for use with another statin that might be better for them. *Id*. By combining the two pills, patients will not be able to take torcetrapib without Lipitor, even if

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[10] *See also* Young & Ostrow, *Pfizer's strategy criticized - New Cholesterol Drug Bound to Old*, Detroit Free Press (June 23, 2005), http://www.freep.com/money/business/pfizer23e_20050623.htm.

[11] People with different genetic make-ups respond differently to many medicines. Some people metabolize a drug before it can act. Because people have different genetic make-ups some genetic researchers believe that many drugs only work in a third to a half of the patients who take them. *See, e.g.,* Andy Coghlan, *Blockbuster Challenge,* New Scientist Magazine (June 12, 2004), *available at* http://www.sciencejobs.com /insider/article.action?article.id=insider105&focusId=uk.

Lipitor is not the safest and most effective statin for them. "The torcetrapib-Lipitor bundling studies illustrate where this trend can lead. The current trial designs may not optimally meet the scientific needs of prescribers, the clinical needs of patients, the economic needs of payers, or the regulatory needs of policymakers. But they superbly meet the business needs of the sponsor - to create new knowledge in a way that will protect the market share of the largest drug company's most important product." *Id.* at 2575. For patients, the tying of these two drugs in one combination pill limits their medical choices and serves no purpose other than the suppression of competition.[12/]

Another combination drug is Vytorin, a combination of Zetia, a Schering-Plough drug and Zocor, Merk's statin. *See* Aaron Smith, *Vytorin outsells rival cholesterol drugs,* CNN Money (July 26, 2005), http://money.cnn.com/2005 /07/26/news/fortune500/vytorin/ ("...Zocor is the second most profitable statin. However, the drug's patent is set to expire June 2006. Drug sales generally plummet when a name brand goes generic, but Merck hopes to continue making revenue from Zocor by including it in Vytorin."). Again, the market power held by the pharmaceutical company in the tying product facilitates their ability to tie it to the sale of an un-patented drug, injuring competition in the market for the tied product.

Yet another example of tying through combination pills

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[12] Pfizer also has another combination drug involving atorvastatins. Caduet is a combination pill that treats both high blood pressure and high cholesterol. *See Pfizer's Caduet Debuts Nationwide to Treat High Blood Pressure and High Cholesterol*, Pfizer News Release (June 23, 2004), *http://www.pfizer.com/pfizer/are/news_releases/2004pr/mn_2004_0623.jsp*. According to the Orange Book, Caduet is a combination of amlodipine besylate and atorvastatin calcium. Pfizer's exclusivity period on amlodipine besylate alone (marketed as Norvasc) expires in 2006-2007. But by combining it with atorvastatin calcium, their exclusivity period may extend to 2018.

involves Chicago-based Abbott Laboratories. The maker of the extremely unique and powerful AIDS "booster" drug called Norvir. Abbott bundled Norvir with its own protease inhibitor (PI) drug, Lopinavir, which was but one of several PI's available in the marketplace. The Norvir/Lopinavir combination drug is called Kaletra. Although Abbott still manufactures Norvir separately, patients who did not buy Kaletra (Norvir bundled with Lopinavir) were forced to pay a much higher price for Norvir. The result of this pricing strategy was a 400 percent increase in the price of patented Norvir to patients who did not buy Abbott's bundled drug, Kaletra.[13] Abbott is capable of accomplishing this "forcing" because of the market power it has in the AIDS "booster" market, which is a direct result of it having a patent on its "booster," Norvir.

The possibilities of drug manufacturers combining two drugs in one pill are endless and, as a result, the possible economic and health consequences for the public from such arrangements should be recognized and addressed. Medically, the soundness of fixed drug combinations, as opposed to flexible combinations of separate drugs, is debatable. Marcia Angell, *The Pharmaceutical Industry: To Whom is It Accountable?*, 342 New Eng J. Med. 1902, 1903 (2000). Economically, there remains a powerful truth in the common sense observation of Justice Frankfurter that in many cases "[t]ying agreements serve hardly any purpose beyond the suppression of competition." *Standard Oil Co. v. United States,* 337 U.S. 293, 305-306 (1949). Legally, pharmaceutical companies should not be given free reign to limit competition

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[13] *See* The Prescription Access Litigation Project, *PAL Challenges Abbott on 400% AIDS-Drug Price Hike,* 9 PAL News (Summer 2004), http://www.communitycatalyst.org/resource.php?doc_id=66; Vanessa Fuhrmans, *Abbott Lifts Price of Norvir 400%: Cost of Longtime HIV Drug Jumps, Reigniting Debate Over Drug Pricing Policies,* Wall St. J. (Dec. 19, 2003), http://www.aegis.com/news/wsj/2003/WJ031209.html.

to their products that go off-patent through tying arrangements with new patented drugs. Such free reign left unmonitored by antitrust law would cause substantial harm to the public.

Although the case currently before the Court admittedly does not involve pharmaceutical products, Petitioners have nonetheless asked the Court to change antitrust law for the entire spectrum of patentable technology. This is a broad request, which should be met with equally broad consideration. Further, it is not the intent of AARP, PUBPAT and CU to argue that the presumption *only* makes sense with respect to pharmaceutical products, but rather that the presumption makes sense with respect to many technologies. Pharmaceuticals are merely an example of significant concern to our members and constituency.

III. MAINTAINING THE PRESUMPTION WILL NOT LEAD TO AN OUTBREAK OF LITIGATION

Various *amici* in this case note the high cost of antitrust litigation and the burden of those costs on mid and small size businesses and start-up companies. (*See, e.g.*, AIPLA Br. 11-12.) They continue to argue that maintenance of the presumption that a patent confers market power on its owner in the market for the patented product would result in an outbreak of expensive and burdensome litigation. That result, however, has not been observed in the many decades during which the presumption has existed. Therefore, it is difficult to see how keeping the law the same would cause a dramatic rise in litigation. Further, there will always be a presumption one way or the other: either patents are presumed to confer market power on their owner or they are presumed not to confer market power on their owner. What Petitioner and its *amici* seem to really desire is a dramatic shift in the law of tying cases that they hope will make it harder for plaintiffs to prevail and, as such, discourage potential plaintiffs from bringing tying claims at all. To be sure, we could reduce the amount of litigation by stating that nothing a company does can violate any antitrust law, but such would obviously be disastrous policy.

CONCLUSION

The presumption that a patent confers market power on its owner is just as correct today as it has been throughout the sixty years that this Court has recognized it. The Federal Circuit's decision should be affirmed.

Respectfully submitted,

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