15-2236

IN THE

United States Court of Appeals

FOR THE THIRD CIRCUIT

MYLAN PHARMACEUTICALS, INC.,

Appellant,

v.

WARNER CHILCOTT PUBLIC LIMITED COMPANY; WARNER CHILCOTT COMPANY, LLC; WARNER CHILCOTT US, LLC; MAYNE PHARMA GROUP LIMITED; MAYNE PHARMA INTERNATIONAL PTY. LTD.,

Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

BRIEF OF LAW PROFESSORS GREGORY DOLIN, MD, JD, ADAM MOSSOFF, JD, AND KRISTIN OSENGA, JD, AS AMICI CURIAE IN SUPPORT OF APPELLEES' OPPOSITION TO APPEAL

James B. Reed
BAIRD, WILLIAMS & GREER, LLP
6225 North 24th Street, Suite 125
Phoenix, AZ 85016
Telephone No.: (602) 256-9400
Attorneys for Amici Curiae

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Gregory Dolin, M.D., J.D. (University of Baltimore School of Law), Adam Mossoff, J.D. (George Mason University School of Law), and Kristen Osenga, J.D. (University of Richmond School of Law), together submit this brief as *amici curiae* in support of appellees Warner Chilcott Public Limited Company, LLC, Warner Chilcott US, LLC, Mayne Pharma Group Limited, and Mayne Pharma International Pty, Ltd (referred to collectively herein as "Warner"). For reasons set forth below, *amici* urge this Court to uphold the ruling of the U.S. District Court for the Eastern District of Pennsylvania ("the district court") that allows Warner to manufacture and offer for sale the tablet version of Warner's drug "Doryx" and to cease the manufacture and sale of the capsule version.

INTERESTS OF THE *AMICI CURIAE*

The *amici curiae* are law professors who teach and write on patent and antitrust law and policy, and are thus concerned with the integrity of the legal systems that secures innovation to its creators and to the companies that commercialize it in the marketplace. Although *amici* may differ amongst themselves on other aspects of modern patent and antitrust law and policy, they are united in their professional opinion that the Third Circuit should affirm the district court's order entering summary judgment in favor of Warner[1] and reject a core

[1] Pursuant to FRAP 29(c)(5), *amici curiae* avow that no counsel for any party has authored this brief either in whole or in part, and no party or its counsel has made a monetary contribution intended to fund the preparation or submission of this brief.

legal argument of appellant Mylan Pharmaceuticals, Inc.'s ("Mylan"). Mylan's argument is that Warner, in order to avoid violating the Sherman Act, should not have stopped selling unpatented "Doryx capsules" in 2005 in the United States and instead should have continued to sell the earlier capsule version of Doryx, an oral tetracycline. The *amici* believe that Mylan's position violates basic tenets of antitrust and patent law.

The named *amici* are professors possessing a strong interest and professional background in intellectual property law generally and especially as it relates to heath care and patented drugs or medical products. These professors have a strong interest in ensuring that antitrust law and the legal precedent applying it do not serve to undermine patent rights or to reduce innovation with regard to patented products, most especially with regard to drugs or other patented medical products.

Authority Under Which this Brief is Filed

Appellant Mylan Pharmaceuticals, Inc., and appellees Warner Chilcott Public Limited Company, LLC, Warner Chilcott US, LLC, Mayne Pharma Group Limited, and Mayne Pharma International Pty, Ltd, have consented to these *amici's* filing of this brief. *Amici* thus file their brief under Fed. R. App. P. 29(a).

SUMMARY OF ARGUMENT

Mylan's legal argument, if it were to prevail, upsets the careful balance which Congress achieved regarding the economic concepts of dynamic efficiency

sought by the Patent Act (35 U.S.C. § 154, *et seq*.) with the static efficiency protected by antitrust law, most notably Section 2 of the Sherman Antitrust Act (15 U.S.C. § 2). The Third Circuit's reversal of the district court's ruling, as requested by Mylan, would open a pathway for courts to tamper with the Patent Act and the Sherman Act and to upset previously predictable standards for antitrust law governing patent application and enforcement.

Mylan's appeal seeks overreaching intervention by the Third Circuit into a traditionally legislative function of setting the boundaries of the Patent Act's safe harbor from antitrust proscriptions (35 U.S.C. § 271(d)), both civil and criminal, which would deter the investment needed for critical pharmaceutical innovation. If the district court order of summary judgment is vacated and ultimately the court grants the relief sought by Mylan's complaint, the Third Circuit's ruling would render the application of civil, and even potentially criminal, antitrust penalties to pharmaceutical research and development too unpredictable and therefore too risky for investors to support. The pharmaceutical innovation upon which America's consumer welfare is so dependent will suffer as a result, particularly with respect to consumers of oral tetracycline drugs and of other patented products as well. Accordingly, *amici* urge this Court to reject Mylan's arguments and affirm the district court's ruling.

ARGUMENT

I. The Third Circuit's Affirmance of the District Court's Ruling Will Advance the Interests of Consumers

A. The Legal Arguments of Mylan, as Applied to Manufacturers such as Mayne and Warner, Would Cause Short-Term Consumer Injury In the Form of Reduced Consumption of Next Generation Pharmaceuticals

The district court's entry of summary judgment in favor of Warner means that Warner was within its rights in 2005 to stop selling its oral tetracycline Doryx capsules in favor of its superior, next generation Doryx tablets. By shifting its focus to the new, improved Doryx tablets, and later scoring the tablets, Warner was able to introduce 37.5, 50, 75, 100 and 150mg strengths for the treatment of acne, along with a 200mg tablet that could be used to treat both acne and, by a new indication, also treat Chlamydia. Mylan appeals to this Court to reverse the district court's order of summary judgment, so that Mylan, at minimum, may proceed to trial in the district court. Mylan seeks a ruling that at least implicitly requires manufacturers such as Warner, in order to avoid Sherman Act penalties, to continue to make and sell earlier versions of products such as Doryx capsules. Mylan suggests that Warner should have continued to manufacture Doryx capsules in order to assist competitors of the more advanced version of the same drug. In the instant case, assisting consumers to continue to purchase Doryx capsules would have been to the detriment of both Warner and consumers of oral tetracyclines.

Mylan's desired outcome does not advance the consumer-oriented goals of antitrust or patent law. As the *amici* explain herein, antitrust law and patent law, when properly applied, serve the same ultimate goal: the promotion of overall consumer welfare. *See* Greg Dolin, *Resolving the Patent-Antitrust Paradox: Promoting Consumer Welfare Through Innovation*, May 2013, p. 1 (http://cpip.gmu.edu/wp-content/up loads/2013/08/Dolin-Patent-Antitrust-Paradox.pdf.) Consumer benefit depends not simply upon impacts upon price levels that additional market participants *might* promote (but are not guaranteed to result in),[2] but also from the introduction of improved products or new categories of products that competitive innovation creates:

> Although a patent *may* provide the patent owner with an opportunity to charge super-competitive prices to consumers, on balance consumers benefit from having access to new, innovative technology that is invented and commercialized as a result of the incentives created by patents. Patents spur innovation and bring consumer-desired improvements to the market.

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[2] The *amici* herein do not suggest that prices in the oral tetracyclines market were not reasonable as of 2005 when Warner suspended its production of Doryx capsules or since then. One critical reason: rarely do markets, such as the present market for oral tetracyclines consist of the patented product alone. The market must include drugs with the same or similar mechanisms of action. *See* Gregory Dolin, *Nonprice Competition in 'Substitute' Drugs: The FTC's Blind Spot*, 59:3 ANTITRUST BULLETIN 579, 583 (2014), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2639824. This is perhaps the main reason why patent exclusivity or refusal to practice a patent does not impair competition: because competition that does not infringe upon the patent continues to exist.

See id. at 2. The protections to innovators offered by patents and the flexibility to pursue those patents in the most competitive context possible both cohabitate with antitrust policy.[3] If this Court reverses the district court's order, *amici* submit that the result will harm the interests of innovation in general and will injure consumers who are dependent on cutting edge versions of drugs.

B. Warner's Exercise of its Rights in 2005 to Terminate Sale of Its Unpatented Doryx Capsules in Favor of Full Pursuit of its Patented Doryx Tablets is Supported by Patent Law

1. The extensive federal common law that supports Warner's right to terminate Doryx capsules in 2005 if the capsules had been patented is equally supportive of Warner's right to terminate production of an unpatented product that was always vulnerable to competition from generic market entrants

At the core of Mylan's legal arguments is the radical proposition that antitrust laws require patent holders[4] - such as Doryx with respect to its patented

[3] As this brief explains, predictability in patent law application is not merely critical to pharmaceutical innovation, but the concept of patents as property rights is embedded in the intellectual firmament of American property law. *See* Adam Mossoff, *Patents as Constitutional Private Property: The Historical Protection of Patents under the Takings Clause*, 87 BOSTON UNIVERSITY LAW REVIEW 689 (2007); and *see* Adam Mossoff, *Who Cares What Thomas Jefferson Thought About Patents? Reevaluating the Patent "Privilege" in Historical Context*, 92 Cornell L. Rev. 953 (2007); *see* generally, Gregory Dolin and Irina D. Manta, *Taking Patents*, 73 WASH. AND LEE L. REV., (forthcoming 2016) http://papers. ssrn.com/sol3/ papers. cfm?abstract_id=2652526.

[4] In patent litigation against Mylan, Warner's patent for Doryx tablets was adjudicated in favor of Warner on the merits on the issue of validity (i.e., that the patented pellets in a tablet were a valid innovation over the prior art), entitling Warner's tablets patent to its full effect under *SCM* and its progeny.

Doryx tablets - to take affirmative steps to assist potential future competitors and maximize the market for the patent holder's earlier product version to assist transition over to its competitor's generic products. This proposition is obviously at odds with the Second Circuit's ruling in *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1206 (2d Cir. 1981), which held that a patent holder's exercise and fulsome pursuit of its core rights under a lawfully-acquired patent does not and cannot create antitrust liability. This includes abandoning production of an earlier, non-patented version of a patented version of the updated product.[5]

While the Second Circuit opinion in *New York ex rel. Schneiderman v. Actavis plc*, 787 F.3d 638 (2d Cir. 2015) ("Namenda") considered the discontinuation of a patented, earlier version of a product (Namenda IR), the logical underpinnings of the Patent Act's grant to a patent owner of a "right to exclude others from making, using, offering for sale, or selling the invention" (35

[5] Warner's Doryx capsules were protected, at best, by trade secrets, and were not protected from reverse engineering by Mylan or other manufacturers of oral tetracyclines. An "upgrade" in the transparency that the Patent Act requires by forcing patentees to describe the product so as to permit its generic replication at the end of the patent's exclusivity period, is a presumptively pro-competitive benefit of Warner's shift from Doryx capsules to Doryx tablets. *See Image Tech Servs., Inc. v. Eastman Kodak Co.*, 125, F.3d 1195, 1219 (9th Cir. 1997); *see also Barry Wright Corp. v. ITT Grinnell Corp.*, 724 F.2d 227, 230 (1st Cir. 1982) (Breyer, J.) (acknowledging in dicta that "patents" are a "legitimate means" of acquiring and maintaining monopoly power), and *Hartford-Empire Co. v. United States*, 323 U.S. 386, 431-432 (1945) (eliminating provisions of an antitrust decree that prevented defendants from patenting improvements to already patented machines).

U.S.C. § 154(a)(1)) explain why the *Namenda* opinion is incorrect and why the district court in the instant case correctly ruled for Warner.[6] The Second Circuit's ruling in *Namenda* was squarely inconsistent with that Court's previous holding that, where a patent has been lawfully acquired, subsequent conduct permissible under the patent laws *cannot trigger any liability under the antitrust laws*." *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1206 (2d Cir. 1981) (emphasis added). In this context, the Patent Act allowed Warner to take steps ancillary to pursuing the fruits of its patent for Doryx tablets, i.e., discontinuing its sale of Doryx capsules.

One of the rights that Warner unquestionably acquired as the owner of a valid patent for Doryx tablets is the right to elect not to produce, distribute, market, or sell patented products. "The essential rights of a patentee … include[] the right to suppress the invention." *United States v. Studiengesellschaft Kohle, m.b.H*, 670 F.2d 1122, 1127 (D.C. Cir. 1981). The proposition that "[a] patent owner … has no obligation either to use [the patent] or to grant its use to others" has "been settled doctrine since at least 1896." *Hartford-Empire Co. v. United States*, 323 U.S. 386, 432-33 (1945). Congress amended the Patent Act in 1988 to provide that "refus[ing] to … use any rights to the patent" cannot constitute "misuse or illegal extension of the patent right." 35 U.S.C. § 271(d)(4) (1988). The amended

[6] "Where a patentee's conduct in exercising a valid patent is challenged under the antitrust laws, the 'threshold question' is thus whether the challenged conduct "exceeds the scope of the patent grant." *See In re Indep. Serv. Orgs.* (*"ISO") Antitrust Litig.*, 203 F.3d 1322, 1327, 1328 (Fed. Cir. 2000).

language added by Congress even more clearly insulates a patent owner from antitrust liability for its alleged refusal to make its patented product. *See ISO*, 203 F.3d at 1326.[7] So much clearer then, is the right of Warner to discontinue unpatented Doryx capsules in order to fully commit to production and promotion of its Doryx patented tablets.

The Federal Circuit has explicitly ruled that manufacturers such as Warner can refuse to develop a product which it has patented: "[a] court should not presume to determine how a patentee should maximize its reward for investing in innovation. [….] The market may well dictate that the best use of a patent is to exclude infringing products, rather than market the invention." *King Instruments Corp. v. Perego*, 65 F.3d 941, 950 (Fed. Cir. 1995).[8] This principle, by extension,

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[7] Where Congress did not create antitrust liability under the Patent Act, it intended not to do so. Congress expressly imposed potential antitrust liability for certain tying agreements that may be "misuse or illegal extension of the patent right" if the patentee has "market power in the relevant market." *See* 35 U.S.C. § 271(d)(5). Congress's "use of explicit language" in § 271(d)(5) "confirm[s]" the lack of a comparable limitation in Section 271(d)(4)." *Marx v. Gen. Revenue Corp.*, 133 S. Ct. 1166, 1177 (2013). Congress intended § 271(d)(4) to codify the Second Circuit's holding in *SCM* that a patentee's unilateral refusal either to use or license a patented product cannot violate antitrust law. *See* 134 Cong. Rec. H10646, H10648-02 (Oct. 20, 1988) (statement by primary sponsor, Rep. Kastenmeier).

[8] *Special Equip. Co. v. Coe*, 324 U.S. 370, 378 (1945) (Congress "did not" "condition[] [patents] upon the use of the patented invention); *Ethyl Gasoline Corp. v. United States*, 309 U.S. 436, 457 (1940) (patentees have "right to refuse to sell … patented products"); *Cont'l Paper Bag Co. v. E. Paper Bag Co.*, 210 U.S. 405, 429 (1908) (patentees can "use or not use [their patents],

supports the rights of patentees such as Warner to discontinue a product that it has *not patented*, and for which generic market entry is always permitted. Thus, the Patent Act and well-established precedent applying it to production decisions of patentees implicitly granted to Warner an unfettered right in 2005 to sell (or not sell) its *unpatented* Doryx capsules, while Warner re-focused its sales and marketing in favor of its next generation patented Doryx tablets.

2. Antitrust law does not require pharmaceutical manufacturers to compete against themselves for purposes of advancing competitor's market opportunities

From a scholar's perspective, Mylan's efforts to use patent law and antitrust law to penalize a manufacturer such as Warner unless Warner continues to sell an unpatented product in competition with its other products make no sense. To the contrary, established precedent permits a patentee to replace an older drug with a patented and improved version during the original product patent's exclusivity period, even if it would impede competitors' market entry once the original patent expires. *E.g., Cal. Computer Prods., Inc. v. IBM*, 613 F.2d 727, 744 (9th Cir. 1979) (IBM "had the right to redesign its products.… It was under no duty to help [competitors reliant on its older products] survive or expand.").

It is settled law that companies are not required to compete against themselves in order to comply with the Sherman Act. The very notion of successful

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without question of motive"); *see also Rite-Hite Corp. v. Kelley Co., Inc.*, 56 F.3d 1538, 1547 (Fed. Cir. 1995) (*en banc*).

competition by a market participant requires that it coordinate its production and marketing of its products:

> The point is that antitrust law permits, indeed encourages, cooperation inside a business organization the better to facilitate competition between that organization and other producers. To say that participants in an organization may cooperate is to say that they may control what they make and how they sell it: the producers of *Star Trek* may decide to release two episodes a week and grant exclusive licenses to show them, even though this reduces the number of times episodes appear on TV in a given market, just as the NBA's superstation rules do.

Chi. Prof'l Sports Ltd. P'ship v. NBA, 95 F.3d 593, 598 (7th Cir. 1996)[9].

In particular, federal courts have articulated a right of market participants to internally organize a successful market strategy:

> There is no provision of law that would have required Biovail and Forest to sell or continue selling a generic version of [its product] in competition with Biovail's branded product once it became clear, as it would have done in early 2001, that [a competitor] could not get FDA approval to enter the market. . . . These gaps are fatal to the plaintiff's case.

Meijer, Inc. v. Biovail Corp., 533 F.3d 857, 867 (D.C. Cir. 2008) (Ginsburg, J.)

[9] "Conflicts are endemic in any multi-stage firm, such as General Motors or IBM, but they do not imply that these large firms must justify all of their acts under the Rule of Reason." *Id.*

Antitrust scholars such as the amici here agree with the right of market participants to pursue market share and financial success by not dividing its house against itself through internal product competition:

> Until the threat of patent expiry and entry of competitors is timely, the branded drug industry does not expend its scarce research and development efforts on drugs, because to do so would mean it would develop a drug to compete against itself, which is not profit maximizing.

Michael S. Wroblewski and Elizabeth A. Jex, *The Promise of Follow-on Biologics to Spur Both Biologic Drug Innovation and Competitive Prices*, 7 J. GENERIC MEDS. (2010). This Court cannot expect patentees to maintain and compete against their own product lines to the detriment of their own financial success. Mylan seeks to simply structure Warner's product lines in a manner best suited to Mylan's market participation after Mylan passed on opportunities to introduce and compete with a generic version of Doryx capsules.

II. Rejecting Mylan's Legal Arguments in Turn Supports Dynamic Efficiencies Protected and Encouraged by the Patent Act and Patent Law, Generally

A. Dynamic Economic Efficiency is Vital to Consumer Welfare

The economic concepts of dynamic and static efficiency are central to understanding the potential adverse impact of reversal of the district court's ruling upon pharmaceutical innovation: "[i]n economic parlance, antitrust is principally concerned with static efficiency—the allocation of goods and services over the short run. Dynamic efficiency…refers to the ability of a market or an economy to

produce innovation…." Thomas Cheng, *Putting Innovation Back in the Patent-Antitrust Interface*, 11 NW. J. TECH. & INTELL. PROP. 385, 388 (2013).

Congress balanced static and dynamic efficiencies by carving out safe harbors in the Patent Act for protection from competition. Keith Leffler and Cristofer Leffler, *Efficiency Trade-Offs in Patent Litigation Settlements? Analysis Gone Astray*, 39 SAN. FRAN. L. REV. 1 (2015).[10] Congressional motivation for doing so is clear: innovation through dynamic efficiency is a keystone to consumer welfare. "Professor William Baumol estimates that innovators are able to capture only 20% of the value created by their innovations; the remaining 80% of the value benefits the rest of society." Cheng, *supra*, at 400.

Indeed, Congress is best positioned to protect consumer interests by encouraging innovation through patent laws:

> Currently, neither economic theory nor empirical evidence suggest that antitrust agencies or courts have reliable knowledge concerning the types of conduct implicating innovation that are systematically likely to make consumers worse off.

Joshua D. Wright, *Antitrust, Multi-Dimensional Competition and Innovation: Do We Have an Antitrust-Relevant Theory of Competition Now?*, p. 31 (http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1463732). The U.S. Patent and Trademark Office is also better equipped than courts to make changes to antitrust or patent

[10] "The tradeoff […] is said to be implicitly struck by Congress when it set the length and breadth of patent rights." Cheng, *supra*, at 390.

procedures: "Like Congress, the PTO is in a better position than the courts to solicit and balance the concerns of all stakeholders, through practices such as notice and comment rulemaking." Christopher M. Holman, *Unpredictability in Patent Law and its Effect on Pharmaceutical Innovation*, 76 MO. L. REV. 645, 689 (2011).[11]

B. Unfettered Pursuit of Patent Act Rights by, *Inter Alia*, Suspending Sale of Earlier Product Versions, Advances the Interests of Dynamic Efficiency, Which Mylan's Requested Reversal of the District Court Would Undermine

What both Mylan and the Second Circuit in *Namenda* did not acknowledge is that patent law is a targeted mechanism for exactly such dynamism in product innovation: "[v]alid patents can nonetheless be efficient in a 'dynamic' sense because the possibility of monopoly profits spurs incentives to develop new products." Leffler and Leffler, *supra*, at 1 (internal citations omitted). Patent law embodies core concepts of dynamic efficiency's promotion of consumer welfare through innovation, as opposed to short-term advantages from consumer price reduction sought by antitrust law: "in the long run, the greatest enhancement to consumer welfare comes […] from the emergence of new technology and new

[11] "In other contexts, such as the regulation of drugs and medical devices, the courts have recognized the heightened institutional competency of Congress and administrative agencies like FDA to weigh competing, technically complex policy concerns." Holman, *supra* at 686 (citing Lars Noah, *Rewarding Regulatory Compliance: The Pursuit of Symmetry in Products Liability*, 88 GEO. L.J. 2147, 2147 (2000)).

products." Cheng, *supra* at 390. [12] Commitment to dynamic efficiency is particularly necessary in pharmaceutical innovation, since the time from commencing research to FDA approval and market introduction can take a decade or more. Dan L. Burk and Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1657 (2003).

As a result of that legislative balancing, the courts traditionally concur with the Congress that dynamic efficiency interests supersede static efficiency claims of temporary consumer benefit. *See CSU v. Xerox Corp.* 203 F.3d 1322 (Fed. Cir. 2000). Contrary to the Second Circuit's *Namenda* decision and Mylan's arguments, federal courts regularly adopt innovation protections by deferring to the Patent Act's safe harbors. Indeed, a "deferential judicial attitude toward innovation" is also evident in other important patent-antitrust cases. Cheng, *supra*, at 398 (citing: *United States v. General Elec. Co.*, 272 U.S. 476 (1926); *Standard Oil Co. v. United States*, 283 U.S. 163 (1931); *Rambus, Inc. v. FTC*, 522 F.3d 456 (D.C. Cir. 2008); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005); *Matsushita Elec. Indus. Co. v. Cinram*, 299 F.Supp.2d 370 (D. Del. 2004); *In re Indep. Serv. Orgs. Antitrust Litig.* (*Xerox*), 203 F.3d 1322 (Fed. Cir. 2000); *Filmtec Corp. v. Hydranautics*, 67 F.3d 931 (Fed. Cir. 1995); *Brunswick*

[12] Dynamic efficiency at times unavoidably conflicts with antitrust law's promotion of static efficiency: "[t]he conflict between these two areas of law is the most acute when antitrust policy may undermine innovation incentives by limiting a patentee's ability to exploit its patent." Cheng, *supra* at 390.

Corp. v. Riegel Textile Corp., 752 F.2d 261 (7th Cir. 1984); *Foremost Pro Color, Inc. v. Eastman Kodak Co.*, 703 F.2d 534 (9th Cir. 1983); and *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263 (2d Cir. 1979)).

The district court did exactly that here and deferred to clear statutory language and to Warner's well-earned right to compete by terminating Doryx capsules. This Court should not disturb that result.

III. Mylan's Appeal Ignores Traditional Judicial Respect for Congressional Protection of Dynamic Efficiency through the Patent Act's Exceptions to the Sherman Act

A. Mylan's Requested Interpretative Intersection of Liability Between the Sherman Act and Patent Act, Especially in Light of State Substitution Laws, Represents an Unconstitutional Burden Upon Warner's Patent Rights

Mylan improperly asks this Court to engage in estimating the medical value of Doryx tablets. By doing so, this Court would introduce judicial speculation and investor uncertainty into the pharmaceutical industry and the development of patented drugs (Cheng, *supra* at 413) and interject itself into a legislative function:

> The Second Circuit in *Namenda* has joined other courts in a recent disquieting trend of rewriting the Patent Act: "[m]uch of the problematic uncertainty in patent law stems from the fact that courts, primarily the Federal Circuit, have taken on the leading role in creating U.S. patent law."

Holman, *supra* at 685 (citing Ryan Vacca, *Acting Like an Administrative Agency: The Federal Circuit En Banc*, 76 MO. L. REV. 733, 734 (2011)); *see also* David L.

Schwartz, *Practice Makes Perfect? An Empirical Study of Claim Construction Reversal Rates in Patent Cases*, 107 MICH. L. REV. 223, 266 (2008).

The result is to burden Warner's and any other drug manufacturer's constitutionally-protected patent rights under the Patent Clause (U.S. Const. art. I, § 8, cl. 8). The Supreme Court, in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002), ruled that courts should not engage in retrospective application of new rules to existing patents, or else the courts will "destroy[] the legitimate expectations of inventors in their property." *Id.* at 739. Mylan fails to acknowledge Warner's constitutional interest in its patent rights, nor does Mylan defend its appeal under any level of requisite constitutional scrutiny.

B. Mylan's Request that the Third Circuit Reverse the District Court Invites Harm to Important Pharmaceutical Innovation Otherwise Protected by Patent Law

Consistent judicial enforcement of rights ancillary to the Patent Act's exclusionary period, such as a patentee's decision to extinguish prior obsolete drug versions, is critical to protecting commercial pharmaceutical innovation. Providing a predictable means to recover the sunk costs of research and development helps overcome the inherently high risk to pharmaceutical investors.[13]

[13] In particular, pharmaceutical research and development (R&D) enhances consumer welfare through inadvertent innovative discoveries:

> [I]t remains true that serendipitous innovation often emerges in the context of a routinized innovation project. [Footnote omitted] A

Financial investment in a prospective pharmaceutical drug through the entire process of "development, clinical trials, and onto the market is a notoriously expensive and high risk gamble." Holman, *supra* at 649.[14] Balancing the "costs of creative destruction" is particularly challenging for manufacturers who continue to innovate from their existing line of pharmaceutical products, such as Doryx tablets replacing Doryx capsules:

> Another social cost is [....] the cost imposed by a new innovation on the producers of an existing product, and is sometimes known as the costs of creative destruction. To the extent that the new innovation renders existing products in the market obsolete, the machineries that these firms have installed, and the plants that these firms have constructed, to produce their now-obsolete products may become redundant.

Cheng, *supra* at 400 (citation omitted). The Patent and Trademark Office particularly considers the costs of creative destruction, or collateral obsolescence,

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> research team may have accidentally discovered a chemical that turns out to be highly valuable. [Footnote omitted] The team probably has incurred considerable costs to put itself in a position to make the accidental discovery.

Cheng, *supra*, at 411.

> Studies of pharmaceutical R&D estimate that if one were to screen 5,000 to 10,000 chemical compounds for possible therapeutic value, roughly 250 of them will show sufficient promise for further testing. Out of these 250 molecules, about five of them will be put through clinical testing. And 80% of the drugs that are clinically tested end up in failure.

Cheng, *supra at* 412, footnote 127.

in discouraging judicial intervention into the legislative balance struck between dynamic and static efficiency in patent law:

> Federal agency officials have also demonstrated a concern for antitrust policy that overreaches by attempting to increase short run product market competition at the expense of dynamic efficiencies created by innovation.

Wright, *supra* at 3 (Footnote omitted). Courts should not unnecessarily burden a company's efforts to recover it sunk costs of R&D through antitrust policy. Cheng, *supra at* 397-398.

C. A Main Appeal of Patent Law is Predictability, Which Allows Pharmaceutical Manufacturers to Make Their Own Estimates of Recoverable Costs and Undertake Research at Their Own Risk

Patent protection, including the right to engage in termination of prior drug versions, is key to dynamic efficiency by encouraging investment in pharmaceutical research and development: "[i]t is widely accepted that patents play an essential role in motivating private investment in pharmaceutical R&D, and those investments have yielded tremendous social gains through the resulting introduction of new drugs. For this reason, pharmaceutical innovation is thought to be the patent system's greatest success story." Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503, 504 (2009).

With investor realities in mind, judicial presumptions must protect the balance achieved by Congress between dynamic efficiency of patent law innovation and static efficiency of price competition by antitrust laws. "It is critical

that antitrust policy not adopt an analytical framework that presumes harm to competition when the procompetitive rationale for the conduct is not facially obvious." Wright, *supra* at 31. Judicial assumption of harm to competition by dynamic efficiency actually harms innovation and consumer welfare. Wright, *supra* at 4. Indeed, in any competent economic model, rational actors will not invest in R&D "[a]fter witnessing repeated cases where a drug company has its patent rights negated based on unpredictable and unanticipated applications of the law…" Holman, *supra* at 651.

IV. Application of the Sherman Act § 2 to Warner's Manufacture of Doryx Tablets Improperly Makes Pharmaceutical Manufacturers Vulnerable Under the Sherman Act to Inconsistent State Drug Substitution Laws, Which Have Nothing to do With Federal Antitrust Statutes

State drug substitution laws and the Federal Hatch-Waxman Act say nothing about antitrust prohibitions, and Mylan's attempt to convert essentially medical practice regulations into federal antitrust laws is improper. Specifically, Congress did not pass the "Abbreviated New Drug Application" standards (21 U.S.C. § 355(j)) as part of the Hatch-Waxman amendments (21 U.S.C. § 355(j)(2)(A)(ii) to allow courts to interpret the Patent Act or the Sherman Act differently in fifty separate states. And yet, Mylan urges this Court to adopt geographically shifting definitions of antitrust liability, and thus treble damages, under non-antitrust state substitution laws, which should not be given effect under the antitrust laws. *See, e.g.*, *Mid-S Grizzlies v. NFL*, 720 F. 2d 772 (3d. Cir. 1983).

Amici do not contest that states are entitled to craft the scope of medical practice laws, often to protect the "turf" of each profession's scope of practice. For instance, in *Namenda*, the New York State's "scope of practice" statutes limit pharmacists' dispensing discretion for bio-equivalent prescription drugs under N.Y. Education Law § 6816-a(1). But the Second Circuit in *Namenda* interpreted New York State's prohibition of pharmacies dispensing generic, immediate release tablets in *lieu* of brand-name, extended release ones, and thereby improperly converted a manufacturer's cessation of an obsolete drug (Namenda IR) from conduct protected by the Patent Act's safe harbor into Sherman Act violations. Both the Second Circuit in *Namenda* and Mylan have failed to realize that any consumer inconvenience through, for instance, increased prices, is unquestionably attributable not to a patentee's legitimate decision as to which products to produce and which to forego, but to state restrictive scope of practice laws that do not permit broader substitution of authority to the pharmacists. Mylan's legal arguments in this appeal are equally, legally incorrect.

CONCLUSION

For these reasons, these *amici curiae* urge this Court to reject the legal arguments underpinning the brief of appellant Mylan Pharmaceuticals, Inc.

Respectfully submitted,

James B. Reed
Baird, Williams & Greer, LLP
6225 N. 24th Street, Suite 125
Phoenix, Arizona 85016
602-256-9400
jreed@bwglaw.net
Counsel of Record for Amici Curiae

December 21, 2015

COMBINED CERTIFICATES – CASE 15-2236
BRIEF OF AMICUS CURIAE ANTITRUST PROFESSORS GREGORY DOLIN AND ADAM MOSSOFF SUPPORTING DEFENDANTS APPELLEES

Undersigned counsel for *amici* hereby certifies that:

1. This brief complies with the type-volume limitation of Fed. R. Civ. P. 32(a)(7)(B) and L.A.R. 29.1(b). It has 5,345 words as counted by Microsoft Word 2010.
2. This electronic version of this brief is identical to the version sent in hard copy to this Court.
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6. I am a member of the Bar of this Court.

DATE: December 21, 2015 ***/s/ James B. Reed***
James B. Reed