Appeal No. 14-4624

UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

STATE OF NEW YORK, BY AND THROUGH ERIC T. SCHNEIDERMAN, ATTORNEY GENERAL,

Plaintiff-Appellee,

v.

ACTAVIS PLC AND FOREST LABORATORIES, LLC,

Defendants-Appellants

From The United States District Court
For The Southern District Of New York

Case No. 14-CV-7473 (RWS)

BRIEF OF PROFESSORS DOLIN, HOLTE, LANDE, MOSSOFF AND OSENGA AS *AMICI CURIAE* IN SUPPORT OF DEFENDANTS-APPELLANTS AND URGING REVERSAL

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Gregory Dolin, M.D., J.D., Ryan T. Holte, J.D., Robert H. Lande, J.D., Adam Mossoff, J.D. and Kristen J. Osenga, J.D. together submit this brief as *amici curiae* in support of appellants-defendants Forest Laboratories, LLC and Actavis plc (referred to collectively herein as "Forest").[1] For reasons set forth below, *amici* urge this Court to reverse the district court injunction that will require Forest to "continue to make" Forest's patented drug and to make it available for purchase "on the same terms and conditions applicable since July 21, 2013." SA-137.

Interest of the *Amici*

These *amici* are professors who have a strong interest in intellectual property law generally and especially as it relates to heath care and patented drugs or medical products. Each of the professors teach classes at their law schools in intellectual property law or antitrust law. Dr. Dolin and Professor Mossoff are also directors of academic centers whose mission is focused upon issues that are strongly impacted by the injunction. Dr. Dolin is a co-director of the Center for Medicine & Law, a center focused upon the interplay between law and medicine. Professor Mossoff is a co-director of academic programs at the Center for the Protection of Intellectual Property.

[1]Pursuant to FRAP 29(c)(5) and 2d Cir. L.R. 29.1, amici curiae state that no party's counsel has authored this brief either in whole or in part; that no party or its counsel contributed money that was intended to fund preparing or submitting the brief; and that no person other than these amici curiae and their counsel have contributed money intended to fund preparing or submitting the brief.

Accordingly, all of the professors have a strong interest in ensuring that the antitrust laws and the legal precedent applying those laws 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.

Specifically, the amici who file this brief are:

▪ Gregory Dolin, M.D., J.D.: Dr. Dolin is an Associate Professor of Law at the University of Baltimore School of Law. He is an Adjunct Associate Professor of Emergency Medicine at The Johns Hopkins University. He is an Adjunct Associate Professor of Law teaching Intellectual Property law at the New York Law School. He is also a Co-Director of the Center for Medicine & Law.

▪ Ryan Holte, J.D.: Professor Holte is an Assistant Professor of Law at Southern Illinois University School of Law.

▪ Robert Lande, J.D.: Professor Lande is Venable Professor of Law at the University of Baltimore School of Law. He is a Director of the American Antitrust Institute.

▪ Adam Mossoff, J.D.: Professor Mossoff is a Professor of Law at George Mason University School of Law. He is also a Co-Director of Academic Programs and a Senior Scholar at the Center for the Protection of Intellectual Property.

▪ Kristen Osenga, J.D.: Professor Osenga is a Professor of Law at University of Richmond School of Law.

Authority Under Which the Brief is Filed

Both the State of New York, Plaintiff-Appellee, and Forest Laboratories, LLC and Actavis plc, Defendants-Appellants, have consented to these amici's filing of this brief. Amici thus file their brief under Fed. R. App. P. 29(a), second sentence.

Introduction and Summary of the Argument

Despite the district court's finding that the public interest favored entry of the injunction, that injunction (if permitted to stand) will do grave harm to consumers in both the short- and long-term and with respect to consumers of Alzheimer's drugs and of other patented products as well. Forcing a patentee to manufacture its patented product is contrary to the Patent Act, the case law applying it and the public policy purposes of federal patent protection. This Court should reverse the district court's injunction.

ARGUMENT

I. THE DISTRICT COURT'S INJUNCTION WILL DO GRAVE HARM TO CONSUMERS

While antitrust law and patent law are frequently thought to exist in conflict with one another, in truth when properly applied they are complementary. Both serve the same ultimate goal: the promotion of overall consumer welfare. *See* Greg Dolin, *Resolving the Patent-Antitrust Paradox: Promoting Consumer Welfare Through Innovation*, *available at* http://cpip.gmu.edu/wp-

content/uploads/2013/08/Dolin-Patent-Antitrust-Paradox.pdf. The relationship between competition and consumer welfare is complex and multi-variable. Consumers benefit not just from the lower prices that competition along the price axis brings but also from the improved products and services – or indeed the introduction of wholly new categories of products or services – that come from competition along the innovation axis. *See id.* at 2 ("Although a patent *may* provide the patent owner with an opportunity to charge super-competitive process 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. From pioneering pharmaceuticals to revolutionary electronic devices, patents have allowed consumers to increase their quality of life at a faster pace than would have been available absent patent-based protections."); *see also id.* at 3 ("Not only do patents spur innovation by rewarding those making scientific advances or discoveries, they push competitors to out-innovate each other and thus compete not solely on price, but also such things as product features[.]") The protections to innovators offered by patents thus promote consumer welfare and serve the same ultimate goal as antitrust law – the promotion of consumer welfare.

Here, it is the district court's injunction, rather than any actual or contemplated action by Forest, that threatens harm to consumers. The district

court's injunction forces Forest to continue to make and offer for sale its patented drug for the treatment of Alzheimer's, twice-a-day Namenda IR. The injunction does so despite Forest's development of a superior treatment for Alzheimer's that is already available today (once-daily Namenda XR) and its development of a third treatment for Alzheimer's, Namzaric (a single-dose combination of two drugs prescribed to treat symptoms found in Alzheimer's patients) which Forest will offer for sale once it receives final regulatory approval.

The district court's remedy is simply unprecedented. It is unprecedented for good reason. If affirmed and approved by this Court, that injunction will result in grave harm to consumers in both the short-term and the long-term with regard to Alzheimer's drugs and other patented products.

A. The Injunction Will Cause Short-Term Consumer Injury: Reduced Access to Next Generation NMDA Drugs

Namenda IR and Namenda XR are both so-called NMDA drugs (they are NMDA (N-methyl-D-aspartate) receptor antagonists). However, the XR version has fewer side effects. Forest is also developing an improved single-dose combination drug (Namzaric) that will combine an NMDA drug with donepezil (a cholinesterase inhibitor, another class of drug used for Alzheimer's patients) and thus provide an even greater treatment option for this disease.

Higher-dose drugs like Namenda XR and combination drugs like Namzaric benefit patients by reducing the total number of pills the patient must take daily,

thus improving patient (and caretaker) compliance. That benefit is especially important to Alzheimer's patients whose impaired cognitive function makes following more-elaborate medicinal regimes even more arduous.

The injunction has injured and will injure consumers in the short term by reducing the supply of, or completely eliminating access to, these next-generation NMDA drugs. There is only a single facility in the world where Namenda IR, Namenda XR and Namzaric can be manufactured. JA_ (Stewart_12/14/14_Decl_2-3_). In order to comply with the district court command that it continue to make Namenda IR, Forest has reallocated production resources that would have been devoted to producing Namenda XR and/or Namzaric. As a consequence, the injunction has reduced Namenda XR production and completely halted the production of Namzaric. Id.; JA__ (Meury_12/12/14_Decl_7).

By ordering Forest to use its finite resources to produce Namenda IR, the district court has thus deprived and will deprive consumers and Alzheimer's sufferers of important benefits from these next-generation treatments. That deprivation is particularly unjustified and inappropriate in light of the fact that the State of New York's own expert has conceded that there is no longer any market need for the original Namenda IR.JA__ (Lah_11/10/14/Hr'g_85).

B. The Injunction Will Cause Long-Term Consumer Injury: Reduced Medical and Overall Innovation

Beyond the immediate injury that the injunction is causing and will cause to Alzheimer's patients and their caretakers, the injunction threatens long-term injury to all consumers in the form of reduced innovation. The district court's order approves a remedy no court has ever ordered. If endorsed by this Court, that remedy will set a dangerous precedent that would not only contravene decades of clearly-established law but would also substantially impede long-term investment in innovation.

At the core of this injunction is the Court's endorsement of the radical proposition that, in the final period of a patent's life, the antitrust laws require patent holders to take affirmative steps to assist future competitors by making it easier for consumers to transition from the patent holder's products to its competitor's generic products in advance of the generic products becoming available. This proposition is obviously at odds with this Court's ruling in *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1206 (2d Cir. 1981), which held that a patent holder's exercise of its core rights under a lawfully-acquired patent does not and cannot create antitrust liability.

More than that, however, the district court's injunction, if allowed to stand by this Court, will substantially chill new innovations. Potential developers of innovative drugs or other technologies, as well as the sources of capital that might

consider funding such innovators, will now have to grapple with this novel, judicially-created obligation that requires them to assist their own competitors in competing with them by, if necessary, continuing to make outmoded product lines, against their own interests and the interests of their consumers. This ruling will thus reduce the rewards of innovation protected in U.S. patent law. That result, in turn, will also predictably reduce both the quantity and quality of innovation in the market.

II. THE DISTRICT COURT'S ORDER FORCING A PATENTEE TO MANUFACTURE ITS PRODUCT VIOLATES CLEAR STATUTORY LAW AND PUBLIC POLICY EMBODIED IN THE PATENT LAW

The district court's order entering an injunction that forces Forest to manufacture its patented product in order to assist its competitors is not only bad for consumers but that order also violates black letter law that grants a patent owner the right to suppress or withhold its patented product from the market and also insulates the patent owner from antitrust liability for exercising that right (or other rights) granted to it by its patent.

Patent law grants a patent owner "the right to exclude others from making, using, offering for sale, or selling the invention . . . ."35 U.S.C. § 154(a)(1). Thus, 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). And while tying or restrictive licensing terms may be subject to antitrust scrutiny, the State of New York has not alleged Forest engaged in such conduct. Accordingly, as this Court has previously held, "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).

One of the rights Forest acquired as the owner of valid patents for these drugs was its right to elect not to produce, distribute, market, or sell its 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). Stated directly, 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).[2] In sum, the Patent Act and the well-established precedent applying it give Forest an unfettered right to make (or not make) and to sell (or not sell) Namenda IR.

Furthermore, 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 language added by Congress even more clearly insulates a patent owner from antitrust liability for its alleged refusal to make its patented patent. *See ISO*, 203 F.3d at 1326.[3]

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

[3]Where it has elected to do so, Congress can create and has created express statutory language imposing potential antitrust liability. For example, another subsection of the act provides that certain tying agreements 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' "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.*, ___ U.S. ___, 133 S. Ct. 1166, 1177 (2013). Congress intended § 271(d)(4) to codify this Court'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).

Similarly, established precedent permits a patentee to replace an older product with a newer one during the exclusivity period, even if doing so would impede competitors' market entry once the old 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.").

Curiously, the district court's order fails even to discuss the import of Forest's patent rights over Namenda IR and XR and this long-established precedent insulating a patent owner from antitrust liability for exercising its patent rights, including its right not to manufacture the patented product. Instead, the district court's order utterly ignores this black-letter law. The district court thus entered the instant injunction in a case where the Appellees cannot demonstrate the requisite probability of their success on the merits and in a manner that has eviscerated Forest's patent rights. This Court should thus reverse the injunction.

Respectfully Submitted,

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CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) as modified for amici by Fed. R. App. P. 29(d) because this brief contains 2,526 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

2. This brief complies with the typeface limitation of Fed. R. App. P. 32(a)(5) and the style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word 2010 in 14 point Times New Roman font. The electronic version of this brief has been scanned for viruses and is virus-free.

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