The American Antitrust Institute

July 14, 2016

The Honorable Ian H. Gershengorn
Acting Solicitor General
950 Pennsylvania Ave., NW
Washington, DC 20530

Re: *SmithKline Beecham Corp. et al. v. King Drug Co. of Florence, Inc. et al.*, No. 06-1055.

Dear Mr. Gershengorn,

We write on behalf of the American Antitrust Institute ("AAI")[1] to urge you to advise the Supreme Court not to grant the petition for a writ of certiorari in the above-referenced matter. This case does not present the question as to which the Petitioners seek review. Petitioners ask review of whether "the patentee's grant of an exclusive license must undergo antitrust scrutiny." But the Court of Appeals made no such holding. Instead, the Court held that a patentee's agreement not to compete with a licensee is subject to scrutiny when the licensee (1) is a potential competitor,[2] and (2) agrees in exchange to delay competing against the patentee.

[1] AAI is an independent, nonprofit organization devoted to promoting competition that protects consumers, businesses, and society. It serves the public through education, research, and advocacy on the benefits of competition and the use of antitrust enforcement as a vital component of national and international competition policy. AAI is managed by its Board of Directors, with the guidance of an Advisory Board that consists of over 130 prominent antitrust lawyers, law professors, economists, and business leaders. See http://www.antitrustinstitute.org. AAI has filed briefs amicus curiae in some dozen cases involving exclusion payments in the pharmaceutical industry, including the Third Circuit decision at issue here. *See* AAI Asks Third Circuit for Common Sense in the Wake of Actavis (In re Lamictal Direct Purchaser Antitrust Litigation) (April 29, 2014), http://www.antitrustinstitute.org/aai_activities/amicus-program?page=2.

[2] It is unlawful to allocate a market with a *potential* competitor as well as with a competitor. *See, e.g., Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46, 49-50 (1990); *cf. United States v. Microsoft*, 253 F.3d 34, 79 (D.C. Cir. 2001) (en banc) ("the exclusion of nascent threats is the type of conduct that is reasonably capable of contributing significantly to a defendant's continued monopoly power"). The Court in *FTC v. Actavis, Inc.,* 133 S. Ct. 2233, 2236 (2013), made clear that an agreement is subject to antitrust scrutiny if it "prevent[s] the risk of competition" which is "the relevant anticompetitive harm."

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These two facts dispositively distinguish the economic circumstances—and therefore the applicable patent/antitrust principles—from those that Petitioners ask the Supreme Court to review. The two key facts are the very core of what made Petitioners' agreement anticompetitive and not immunized by the Patent Act. Asking the Supreme Court to grant review of the propriety of a patentee granting an exclusive license, divorced from these two key aspects of the agreement, is like asking the Court to review the propriety of a man swinging a bat, isolated from the integral facts of whether he did so in a baseball game or a bar fight. These are not peripheral aspects of Petitioners' agreement—they are constitutive of the relevant conduct.

In short, the Court of Appeals did not hold that exclusive licenses are subject to antitrust scrutiny. It instead held that a reciprocal non-compete agreement between competitors was subject to scrutiny.[3] That holding is plainly not *cert*-worthy. Any other holding would have overturned a century of antitrust and patent-law jurisprudence.

AAI expects that the parties and other commentators will discuss in detail many of the other issues that Petitioners raise. AAI therefore focuses its comments on the economic legal significance of the fact that Glaxo agreed not to compete with a licensee that (1) was a potential competitor, and (2) agreed in exchange to delay competing against Glaxo.[4]

I. *Vertical* Licenses Are Often Competitively Benign.

Vertical patent licenses—licenses between parties that do not compete against each other on the same level of distribution—are often competitively benign and increase consumer welfare.[5] They can improve efficiency in production or distribution by getting

[3] The type of agreement at issue here has picked up the informal name "No-Authorized-Generic" or "No-AG" agreement. The nickname is unfortunate because it does not capture the essence of the conduct that generates antitrust concern, i.e., that the brand manufacturer has agreed not market an authorized generic *in exchange for the generic manufacturer's agreement to delay entry into the market*.

[4] In a payment-free, competitively benign early-entry settlement agreement, the brand manufacturer also grants a license to a potential competitor in exchange for its agreement to delay entry. Such an agreement can be benign precisely because it lacks the element of a payment from the brand manufacturer to the generic. What creates the antitrust problem is the combination of three elements: (a) a payment (here, a reciprocal agreement not to compete) (b) from one competitor to another (c) in exchange for not competing. The point of AAI's comments is that, *given Glaxo's agreement not to compete against Teva with an authorized generic*, *i.e.*, given the presence of element (a), antitrust concern arises when elements (b) and (c) are also present.

[5] A principal goal of the Sherman Act is to advance consumer welfare. *See, e.g., NCAA v. Bd. of Regents of Univ. of Okla.,* 468 U.S. 85, 107 (1984); *Arizona v. Maricopa County Med. Soc'y*, 457 U.S. 332, 367 (1982); *Reiter v. Sonotone Corp*., 442 U.S. 330, 343 (1979).

the intellectual property into the hands of a party that is better situated than the patentee to exploit it.

In essence, the patentee/licensor "hires" more efficient parties to produce or distribute the product. The licensees pay a fee or royalty to the patentee, keeping the difference between the fee/royalty and the amount they collect as revenue by using the patent. The patentee gets the fee/royalty. These economic arrangements work for both the patentee and the licensees (and consumers, too) when the latter can produce or distribute the product more efficiently than the patentee can.

This holds true even for vertical *exclusive* licenses. The element of exclusivity in a vertical license can create an added incentive for the licensee to devote itself to the business of exploiting the patent. The patentee will choose an exclusive license arrangement when the licensee can produce or distribute the product more efficiently than the patentee and more efficiently than a network of multiple licensees. Vertical licenses can "benefit[] consumers through the reduction of costs and the introduction of new products." DOJ & FTC, *Antitrust Guidelines for the Licensing of Intellectual Property* § 2.3 (1995) (*IP Licensing Guidelines*).

Benign *vertical* licenses are routine in the pharmaceutical industry. For example, Prasco Laboratories' principal business is marketing and distributing the brand's "authorized generic" once the brand's generic competitors are ready to enter the market. *See* http://www.prasco.com/index.php/what-we-do/authorized-generics/. Prasco's message is that it is more efficient than the brand manufacturers in marketing authorized generics. *See id*. ("we invest in resources – human and material – that make our company smarter, faster and more imaginative"). Prasco and the brand manufacturers typically agree on a split of the revenue generated by Prasco's sales of the authorized generic—effectively, a royalty.

Importantly, the relationship between the brand manufacturer and Prasco is *entirely vertical*. Prasco does not participate in Hatch-Waxman Paragraph IV litigation against its brand-manufacturer partners: it instead is "[a] trusted partner who understands that the solution to the generic dilemma is product lifecycle management, not PIV [Paragraph IV] challenges." *See* http://www.prasco.com/index.php/what-we-do/authorized-generics/authorized-generics-for-brand-pharmaceutical-companies/.[6] We are unaware of any antitrust challenges having been brought against the brand/Prasco licenses or other such vertical authorized-generic licenses in the pharmaceutical industry.

[6] Other manufacturers/distributors of authorized generics are similarly in wholly vertical relationships with brand manufacturers. These include Sandoz Pharmaceuticals—a division of Novartis, for which Sandoz produces and markets authorized generic versions of many Novartis brand products—and Greenstone LLC, which does the same for its parent corporation, Pfizer, Inc. *See* http://www.sandoz.com/about_us/our_company.shtml and http://www.greenstonellc.com. There are several others as well.

II. Granting a License to a Potential Competitor In Exchange for Delayed Competition Is Dispositively Different.

There is a crucial difference between, on the one hand, Prasco and its business partners, and, on the other hand, Teva and Glaxo in this case. Teva and Glaxo were in a *horizontal* relationship, i.e., they were competitors. Teva was not merely standing by, ready to market Glaxo's authorized generic if some other generic manufacturer busted Glaxo's patent. Teva was trying to bust the patent itself and thereby compete against Glaxo immediately and royalty-free. *Teva was a potential competitor with respect to Lamictal*.[7]

Teva's active challenge to Glaxo's patent created the potential for Teva to enter the market and compete against Glaxo before the end of the patent term. In exchange for Glaxo's agreement not to compete against Teva with an authorized generic, Teva agreed not to enter the market until July 2008. This is later than the date that Glaxo believed that Teva could achieve through the patent litigation—otherwise Glaxo would not have agreed to forgo competing against Teva with an authorized generic.[8] *Glaxo granted the license to Teva in exchange for its agreement to delay competing against Glaxo*.[9]

The *Actavis* Court itself made the key points that the defendants there were potential competitors and that, in exchange for the license, the generic manufacturer agreed to delay entry. The Court emphasized that the generic manufacturer was not a mere vertical licensee, but was instead a potential competitor: "The patent here may or may not be valid, and may or may not be infringed . . . . The paragraph IV litigation in this case put the patent's validity at issue, as well as its actual preclusive scope." 133 S. Ct. at 2231. Given this horizontal relationship, it was reversible error "to refer . . . simply to what the holder of a valid patent could do." *Id*. at 2230-31.

The Court likewise emphasized that "the relevant anticompetitive harm" was that the generic manufacturer had agreed to delay entry into the market. 133 S. Ct. at 2226. The generic manufacturer's agreement to withdraw the challenge to the patent and delay

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[7] Antitrust authorities have long recognized that license agreements warrant significant antitrust scrutiny when "the licensor and its licensees[] are in a horizontal relationship." *IP Licensing Guidelines* § 4.1.2; *see also id.* at § 5.1 ("horizontal restraints often will be evaluated under the rule of reason" but may in some circumstances be condemned under a per se or truncated analysis).

[8] *See, e.g.*, Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 Rand J. Econ. 391, 408 (2003).

[9] A leading treatise explains this key fact: "Clearly a reverse payment settlement is not a 'license' but at most an agreement to license at some time in the future. The anticompetitive consequences take effect immediately, however. Pending the commencement of production by the generic under a license, such an agreement is simply a naked restraint on trade." Phillip E. Areeda & Herbert J. Hovenkamp, *Antitrust Law* ¶ 2046d1.26 (Supp. 2015).

entry required antitrust scrutiny because it "prevent[ed] the risk of competition." *Id*.; *see also id.* ("maintain[ing] supracompetitive prices to be shared among the patentee and the challenger rather than fac[ing] what might have been a competitive market … [is] the very anticompetitive consequence that underlies the claim of antitrust unlawfulness").[10]

III. The Agreement Here Fits Comfortably Within the *Actavis* Framework.

No relevant economic difference separates the reciprocal non-compete pact at issue here from the type of agreement at issue in *Actavis*. Colluding firms have two basic ways to unlawfully allocate a market and split the resulting ill-gotten profits. The first way, as in *Actavis*, is for the two firms to agree to allocate the entire market to one of them, with the firm that receives the market (the brand manufacturer) paying the other firm (the generic manufacturer) a share of the excess profits that the agreement unlawfully extracts from consumers.

A second way is for the two firms to allocate a part of the market to each of them, with their reciprocal agreements not to compete in each other's part of the market serving as compensation from each to the other. Each conspiring firm keeps the excess profits that unlawfully accrue to it from the sales it makes in its allocated part of the market. In short, the twist with a reciprocal non-compete agreement is that the brand's payment to the generic manufacturer takes the form of higher generic prices that the generic manufacturer extracts directly from its customers, rather than the brand manufacturer first extracting them and then transferring them to the generic manufacturer.

Both ways of unlawfully allocating a market (1) create or preserve prices above competitive market levels and (2) provide a means for the conspirators to share the extra profits unlawfully extracted from consumers. Consequently, courts have readily concluded that it is irrelevant whether the conspirators allocate the entire market to one of them, in exchange for cash or some other payment, or the conspirators allocate the market between themselves, with the payments coming via reciprocal non-competition pledges. In the words of the leading case, twice cited in *Actavis*, 133 S. Ct. at 2227, 2230, "[s]uch agreements are anticompetitive regardless of whether the parties split a market within which both do business or whether they merely reserve one market for one and another for the other." *Palmer,* 498 U.S. at 49-50.[11]

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[10] *See also Actavis,* 133 S. Ct. at 2236 (the antitrust concern is "that a patentee is using its monopoly profits to *avoid the risk* of patent invalidation or a finding of noninfringement") (emphasis added); *id*. (patentee cannot lawfully pay to avoid "even a small risk of invalidity," because "the payment (if otherwise unexplained) likely seeks to prevent the risk of competition. And, as we have said, that consequence constitutes the relevant anticompetitive harm.").

[11] See also, for example, *United States v. Topco Associates, Inc.*, 405 U.S. 596, 608 (1972) ("an agreement between competitors at the same level of the market structure to allocate territories in order to minimize competition" is plainly anticompetitive); *United*

Rather than allocating the market geographically, GSK and Teva allocated it *in time.* This is seen most clearly by imagining that Teva had agreed, as it did, to stay out of the market from February 2005 until July 2008, and that in exchange GSK had granted Teva a truly exclusive license that precluded GSK from competing by offering an authorized generic *and* by offering branded Lamictal for the period July 2008 to January 2009. It would then be crystal clear that the competitors had simply allocated the entire market for the period February 2005 to January 2009, with each of them extracting monopoly profits during their allocated time periods. The only difference here is that Teva's allocated time period was not entirely exclusive—GSK was permitted to continue to compete by offering branded Lamictal.

IV. Any Protection Afforded by the Patent Act Does Not Immunize an Agreement Not to Compete Against a Potential Competitor In Exchange for Delayed Competition.

Contending that their agreement is nothing more than an exclusive license, Petitioners invoke 35 U.S.C. § 261 as a talisman against antitrust scrutiny. But Glaxo did not merely grant a (semi-) exclusive license; it agreed to restrict its own competition against a license that (1) was a competitor, and (2) agreed in exchange to delay competing against Glaxo. *Actavis* is the relevant authority for determining the antitrust treatment of such an agreement.

Petitioners cite no authority that comes anywhere near granting antitrust immunity to a reciprocal non-compete agreement like that at issue here. They rely principally on *United States v. General Elec. Co.*, 272 U.S. 476 (1926), which held that General Electric did not violate the Sherman Act by granting a license to Westinghouse Electric on the condition that "with regard to lamps manufactured by it under the license, [Westinghouse would] adopt and maintain the same conditions of sale as observed by the Electric Company in the distribution of lamps manufactured by it." *Id*. at 479.

General Electric involved a vertical license in which the licensee was *not* a potential competitor[12] and did *not* agree in exchange to refrain from competing against

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States v. Addyston Pipe & Steel Co., 175 U.S. 211, 241 (1899) ("If dealers in any commodity agreed among themselves that any particular territory … should be furnished with such commodity by certain members only of the combination, and others would abstain from business in that territory, would not such agreement be regarded as one in restraint of interstate trade?"); *Engine Specialties, Inc. v. Bombardier, Ltd.*, 605 F.2d 1, 11 (1st Cir. 1979) ("Bombardier is free of Agrati's competition in both sales and manufacturing in North America and Agrati is free of Bombardier's competition in manufacturing outside North America. This, we think, rises to the level of a territorial allocation of markets.").

[12] Westinghouse was not a potential competitor with respect to lamps with tungsten filaments merely because it was in the same industry as General Electric. A "potential

General Electric. General Electric had patents on "the use of tungsten filaments in the manufacture of electric lamps." *Id*. at 480. Westinghouse did not dispute the validity or scope of those patents. Instead, "[t]he validity of these patents has been sustained against all infringers, and no one may make or sell this type of lamp except with [General Electric's] permission" and "all makers not having licenses have been enjoined." *United States v. General Elec. Co.*, 15 F.2d 715, 716, 718 (N.D. Ohio 1925). Nor did Westinghouse agree to refrain from competing with General Electric by designing around the patent or selling lamps made without a tungsten filament.[13]

The Court in *General Electric* distinguished a series of prior cases on the specific ground that they did not "consider or condemn a restriction put by a patentee upon his licensee as to the prices at which the latter shall sell articles *which he makes and only can make legally under the license*." 272 U.S. at 494 (emphasis added); *see also* 15 F.2d at 717 ("Upon the facts as stipulated, the Westinghouse Company would have no trade . . . to restrain except for the license agreement."). In short, *General Electric* stands for the unremarkable proposition that a patentee that has the *undisputed exclusive right* to sell the patented product may instead (or in addition) license another to sell on condition that it make the sales at a stipulated price.[14]

That holding has nothing to do with this case, where Teva *did* dispute Glaxo's patent rights and was thus a potential competitor, and where in exchange for Glaxo's agreement not to sell an authorized generic Teva agreed to delay entry into the market. Thus, after specifically discussing *General Electric* the Court in *Actavis* concluded that it was "novel" to suggest, as the dissent contended, that "a patent holder may simply 'pa[y] a competitor to respect its patent' and quit its patent invalidity or noninfringement claim without any antitrust scrutiny . . . ." 133 S. Ct. at 2234.

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competitor" is one whose entry is "reasonably probable in the absence of the relevant agreement." FTC and DOJ, *Antitrust Guidelines for Collaborations Among Competitors* 2 n.6 (April 2000). Just like Prasco, Westinghouse was in the same industry as the patentee but did not challenge the patents' validity.

[13] The same is true of the other case on which Petitioners rely, *E. Bement & Sons v. National Harrow Co*., 186 U.S. 70 (1902). The licensee there was not challenging the patents, and the Court construed the agreement not to prevent the licensee from competing with non-infringing products. *Id*. at 93, 94. Petitioners' reliance on *U.S. v. Line Material Co.*, 333 U.S. 287 (1948), is odd, given that the Court there found an antitrust violation. True, the Court reiterated the *General Electric* holding, but specifically noted that in *Line Material* "[i]t is stipulated by the United States that the validity of the patents is not in issue." *Id*. at 305.

[14] General Electric made money on the Westinghouse deal the way that patentees legitimately make money on wholly vertical licenses—from royalty payments. *See* 15 F.2d at 718.

We trust that this presentation has been useful in helping you reach the conclusion that the Third Circuit's decision was unremarkably correct, and that the United States should urge the Court to deny certiorari.

Sincerely,

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