Federal Trade Commission

Recent Antitrust Enforcement and Policy Initiatives at the U.S. Federal Trade Commission

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at the

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Good morning. It is my pleasure to be here today with my distinguished colleagues from antitrust enforcement agencies in China and around the world. It is also a distinct pleasure to be back in Beijing. I would like to thank the ABA's Section of

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International Law, Beijing Foreign Studies University, and especially Dr. Elizabeth Wang and Ms. YeeWah Chin, for the invitation to speak with you today.

This morning I would like to share with you two recent antitrust enforcement and policy initiatives at the United States Federal Trade Commission ("FTC"). Before I begin, I should note that the views I express here are my own and not necessarily those of the Commission or any other Commissioners.

I. Challenging Anticompetitive Pay-For-Delay Agreements

The first recent development I'd like to highlight involves the FTC's continued efforts to identify and challenge anticompetitive pay-for-delay agreements. Pay-for-delay agreements, sometimes referred to as reverse payments, involve a brand-name drug manufacturer compensating a potential generic entrant to abandon its patent challenge and agree not to sell its generic drug product for a number of years.

Anticompetitive pay-for-delay agreements violate the antitrust laws and undermine the goals of the Hatch-Waxman Act, legislation that aims to prevent weak patents from obstructing the development of competition between branded and lower-cost generic pharmaceuticals. These agreements may lead to higher prices for pharmaceuticals by deterring generic entry, and contribute to increased health care costs that consumers, employers, and federal and state governments are struggling to

contain. For these reasons, challenging anticompetitive pay-for-delay agreements has been one of the Commission's top priorities for many years.

In June of this year, the FTC won a significant victory in the Supreme Court on a matter involving pay-for-delay agreements that set forth a legal standard for evaluating these agreements and will shape the FTC's future enforcement efforts. In *FTC v. Actavis*, the Court in a 5-3 opinion reversed a lower court dismissal and held that pay-for-delay agreements are subject to antitrust scrutiny. The Supreme Court explained, "there is reason for concern that settlements taking this form tend to have significant adverse effects on competition."[1] The core concern with these agreements, and what the Court termed "the relevant anticompetitive harm," is that they may allow the brand to "prevent the risk of competition" by splitting monopoly profits with the prospective entrant.[2] Moreover, the Court ruled that pay-for-delay agreements are to be evaluated under the traditional antitrust "rule of reason," the standard applied in most antitrust actions in the United States, under which courts consider evidence that the agreement harms consumers as well as possible efficiency justifications.

An important feature of the Court's ruling is that it provided useful guidance to lower courts and competition agencies analyzing pay-for-delay agreements in the first

[1] Federal Trade Commission v. Actavis, Inc., No. 12-416, slip op. at 8 (U.S. June 17, 2013).

[2] *Id.* at 19.

instance. The Supreme Court laid out the conditions under which an analytical framework for understanding when pay-for-delay agreements violate the Sherman Act.

First, the Court was clear that reverse payment settlements have the potential for "genuine adverse effects on competition."[3]

Second, and importantly, the Supreme Court also explained the need to assess the efficiency justifications offered for the payment.[4] The Court observed, "Where a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of non-infringement."[5] Thus, companies "may show in the antitrust proceeding that legitimate justifications are present."[6] The Court's decision brings pay-for-delay agreements within the traditional rule of reason framework and rejects the FTC's argument that these arrangements should receive "quick look" treatment.[7]

Third, while the Supreme Court endorsed rule of reason analysis, it left considerable room for lower courts to structure the contours of that analysis. With respect to analyzing the likelihood of anticompetitive effects arising from a pay-for-delay agreement, the Court noted a number of potentially relevant factors, including

[3] *Id.* at 14.

[4] *See id*. at 17.

[5] *Id*.

[6] *Id*. at 18.

[7] *Id.* at 20-21.

the reverse payment's "size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification."[8]

Fourth, the Supreme Court recognized that a brand-name drug manufacturer likely has the power to bring about anticompetitive harm in practice—i.e., it likely has market power.[9] As the Court explained, "a firm without that power" is unlikely "to pay 'large sums' to induce 'others to stay out of its market.'"[10]

Fifth, the Supreme Court held – over vigorous dissent from three Supreme Court Justices – that "it is normally not necessary to litigate patent validity" to determine the anticompetitive effects of the settlement.[11] As the Court explained, "prevent[ing] the risk of competition"—even where the patentee's risk of losing the patent suit may be small—is "the relevant anticompetitive harm."[12] Consequently, companies cannot defend their agreements by merely arguing that the brand-name drug company would likely have prevailed had the patent case been fully litigated or that the settlement provided for entry prior to patent expiration.[13]

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[8] *Id.* at 20. The Court also noted that "[t]he existence and degree of any anticompetitive consequences may also vary among industries." *Id*.

[9] *Id*. at 18.

[10] *Id*. (citing 7 AREEDA & H. HOVENKAMP, ANTITRUST LAW ¶2046, at 351 (3d ed. 2010)).

[11] *Id*.

[12] *Id*. at 19.

[13] In dissent, Chief Justice Roberts, joined by Justice Scalia and Justice Thomas, take issue with the notion that the merits of the patent can be so easily divorced from the relevant antitrust analysis. *Id*. at 4

Finally, the Supreme Court recognized that parties in the pharmaceutical industry can and routinely do settle patent litigation without reverse payments, specifically rejecting the defendants' argument that such payments are necessary for settlement.[14] Over 75 percent of patent settlements since fiscal year 2005 have not contained both compensation to the generic and the generic's agreement to delay entry.[15] The Court recognized that parties "may, as in other industries, settle in other ways, for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point."[16]

Let me turn briefly to the FTC's post-*Actavis* pay-for-delay enforcement agenda. Following the Supreme Court's decision, the Commission will continue to protect consumers from anticompetitive drug settlements that result in higher drug costs and will continue to bring two pending pay-for-delay settlement cases under the rule of reason. The FTC will now proceed with its litigation against Actavis, the maker of the drug AndroGel, and two generic drug manufacturers, charging that the companies

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(Roberts, C.J., dissenting) ("[t]he difficulty with [the majority's approach] is that a patent holder acting within the scope of its patent has an obvious defense to any antitrust suit: that its patent allows it to engage in conduct that would otherwise violate the antitrust laws. But again, that's the whole point of a patent: to confer a limited monopoly.").

[14] *Id*. at 19 (majority opinion).

[15] Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug Improvement and Modernization Act of 2003: Overview of Agreements Filed in FY 2012, *available at* http://www.ftc.gov/os/2013/01/130117mmareport.pdf.

[16] *Actavis*, slip op. at 19.

agreed that the generic manufacturers would abandon their patent challenges relating to AndroGel and delay for nine years the marketing of a generic formulation of the testosterone replacement drug in return for certain "exclusion payments."

The FTC will also continue its challenge in federal court a pay-for-delay agreement by Cephalon with four generic rivals for its branded drug Provigil, a treatment for sleep apnea, narcolepsy, and shift-work sleep disorder. The case had been on hold in federal district court pending the Supreme Court's decision in *Actavis*.

Finally, in light of *Actavis*, the FTC will continue pending investigations into pay-for-delay agreements between branded and generic drug manufacturers, examine new settlements that companies file with the Commission pursuant to the Medicare Modernization Act of 2003 and investigate those that raise anticompetitive concerns, and consider and analyze potential procompetitive efficiencies for these settlements. The Commission will continue to actively challenge anticompetitive patent settlements and seek relief for consumers as appropriate.

II. Understanding Patent Assertion Entities

The second topic I will briefly discuss today is the FTC's recent activities related to understanding Patent Assertion Entities ("PAEs") and their potential impact on the economy and innovation.[17]

[17] I have previously spoken on PAEs and the appropriate role of antitrust in regulating those activities. *See* Joshua D. Wright, Commissioner, Fed. Trade Comm'n, *What Role Should Antitrust Play in Regulating*

There are many different definitions of a PAE,[18] but the one my agency has adopted – and the one I will use now for ease of reference – is that these are "firms whose business model primarily focuses on purchasing and asserting patents."[19] In short, PAEs purchase patents, usually along with a business model to monetize these assets through licensing and patent infringement suits against manufacturers.

Patent holders may sell their patents to PAEs because they lack the capabilities, financial or otherwise, to exploit the patented technology in the marketplace. PAEs may purchase patents because their business model is to monetize these intellectual property assets via licensing. When infringers reject their license offers – for example, manufacturers who are already using the patent technology – PAEs sue them for patent infringement. Generally speaking, PAEs do not conduct research, development, technology transfer, or engage in manufacturing activities. Their competitive advantage is in commercial licensing and legal enforcement, not development.[20]

Recently, PAEs and their business model as defined here have drawn a lot of attention in the United States. Just over two years ago, the FTC issued a report that

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the Activities of Patent Assertion Entities? (Apr. 17, 2013), *available at* http://www.ftc.gov/speeches/wright/130417paespeech.pdf.

[18] *See, e.g.*, eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 396 (2006) (Kennedy, Concurring) ("An industry has developed in which firms use patents not as a basis for producing and selling goods but, instead, primarily for obtaining licensing fees.").

[19] FED. TRADE COMM'N, THE EVOLVING IP MARKETPLACE: ALIGNING PATENT NOTICE AND REMEDIES WITH COMPETITION, 8 n.5 (Mar. 2011) [hereinafter IP Report], *available at* http://www.ftc.gov/os/2011/03/110307patentreport.pdf.

[20] *Id*. at 63.

identified several problems with the patent system at that time, and further suggested ways for the US Patent and Trademark Office and the courts to improve patent notice and patent remedies.[21] That 2011 report was the first time the FTC offered its views on PAEs and their activities.

The FTC again took notice of the PAE business model this past December, when it joined with the US Department of Justice ("DOJ") in holding a public workshop to explore the impact of PAE activity on innovation and competition.[22] The workshop drew upon, and solicited advice from, industry leaders, academics, economists, regulators, and over a dozen other organizations.[23] The FTC and DOJ also received public comments in conjunction with the workshop.

Some commentators have noted that PAEs are efficiency-generating specialist who facilitate licensing and innovation. PAEs can generate efficiencies in the market for patents as well as the market for ideas. PAEs contribute to a more active secondary market for patents, increasing patent liquidity, allowing patent holders to dispose of portfolios they cannot or will not maintain, and permitting companies to recoup immediately some research and development costs. Each of these functions in turn permits practicing entities to focus on invention, manufacture, and further research,

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[21] *Id. passim.*

[22] Information about the workshop, including the panelist presentations, is available at http://www.ftc.gov/opp/workshops/pae/.

[23] The workshop public comments are available at http://www.ftc.gov/os/comments/pae/index.shtm. The Agencies accepted public comments through April 5, 2013.

which enhances welfare.

On the other hand, PAE critics argue that the PAE business model creates asymmetrical risks and greater incentives for patent enforcement in court. Because PAEs do not manufacture or sell products, they face little risk of countersuits for patent infringement and do not have to be concerned about disruptions to other businesses or customer relations from litigation. With respect to reputational costs, and unlike most firms, PAEs benefit from having a reputation for being aggressive litigators. PAEs incur hardly any discovery costs, and benefit from a lower cost of litigation due to contingency arrangements. Consequently, PAEs can profitably sue on marginal infringement claims that practicing entities would ordinarily disregard. As a result some argue the number of PAE suits as a share of all IP infringement suits has doubled,[24] and some claim PAEs now account for the majority of new patent infringement suits in the United States.[25] In contrast, the U.S. Government Accountability Office ("GAO"), at the direction of Congress, recently studied patent infringement litigation, including those brought by nonpracticing entities ("NPEs") such as PAEs.[26] Among other things, the GAO found that companies that make

[24] Colleen Chien, Patent Assertion Entities 23-24 (Dec. 10, 2012), *available at* http://www.ftc.gov/opp/workshops/pae/docs/cchien.pdf ("Traditional patent litigation economics are stacked against enforcement.").

[25] *Id*. (citing data from RPX Research and PACER).

[26] U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-13-465, INTELLECTUAL PROPERTY: ASSESSING FACTORS THAT AFFECT PATENT INFRINGEMENT LITIGATION COULD HELP IMPROVE PATENT QUALITY (2013), *available at* http://www.gao.gov/products/GAO-13-465.

products brought most of the lawsuits and that NPEs brought only about a fifth of all lawsuits.

There is also some evidence PAEs send a large number of demand letters to potential infringers compared to practicing entities. The FTC's 2011 IP Report stated that "most PAE suits are against large companies,"[27] while more recent data suggest that the primary targets of PAE suits are now small companies and start-ups.[28]

While policymakers, academics, participants of the workshop, and other commenters have identified potential harms and efficiencies of PAE activity, they noted a lack of empirical data in this area, and recommended that the FTC use its FTC Act Section 6(b) authority to collect information on PAE acquisition, litigation, and licensing practices. Empirical data in this area is particularly important because while both proponents and critics of the PAE business model claim to rely on facts, there is little empirical evidence to support their assertions or to distinguish between conflicting predictions.

Recognizing the FTC's role in competition research and development and advocacy, the Commission is now considering using its 6(b) authority to conduct an empirical study regarding PAE activity. The FTC has a long history of using its 6(b) authority to engage in careful industry study to inform its activities. Section 6(b) of the

[27] IP Report, *supra* note 19, at 61.

[28] Chien, *supra* note 24, at 39 ("Although suits against large tech companies get the most attention, defendants revenue/industry profiles vary widely"), 50 ("The majority of PAE defendants (at least 55%) have less than $10M in revenue.").

FTC Act gives the Commission the authority to subpoena data and information from relevant firms, subject to a set of guidelines, and if authorized by the Commission, would allow the agency to collect, analyze, and report upon PAEs and their activities. Section 6(b) of the FTC Act is an important part of the Agency toolkit, and its appropriate use can facilitate the development of an evidence-based understanding of business practices and strategies which is an important prerequisite to promoting the Agency's mission to protect competition.

Thank you very much for your time.