FTC RESEARCH, ENFORCEMENT, AND ADVOCACY AT THE INTERSECTION OF ANTITRUST AND IP

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Keynote Remarks of Commissioner Terrell McSweeny[1]

Good morning. Thank you very much for having me here this morning for the 3rd Annual IP and Antitrust USA Conference. The agenda today is filled with a number of hot topics at the intersection of IP and competition law – including conduct by patent assertion entities (PAEs), patent hold-up, and FRAND obligations. This morning I'd like to talk about my view on these topics as a competition enforcer.

It is generally acknowledged that a careful balance is required between competition and intellectual property protections to optimize innovation.[2] As Judge Posner has explained, "[t]he patent and copyright laws try to strike the output-maximizing balance by giving the creator of intellectual property some but not complete protection from competition."[3]

The fundamental question comes down to how much the government should intervene on either side – where we should draw the lines. How strong should our intellectual property protections be?[4] Ultimately, this is a choice for Congress. But it is the job of courts and agencies to seek an accommodation between antitrust and intellectual property protections in individual instances. A lawful patent or other IP right may nonetheless be used or extended in unlawful ways.

The FTC is confronting the question of how and when to draw the lines between competition and IP on a number of fronts – challenging anticompetitive reverse payments, studying the role played by PAEs, and ensuring that standard essential patents (SEPs) are used to encourage standard-setting and not to engage in "hold-up." Getting the balance right on these issues is important to promoting the dual goals of innovation and competition.

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[1] The views expressed in this speech are my own and do not necessarily reflect those of the Commission or any other Commissioner.

[2] *See United States v. United States Gypsum Co.*, 333 U.S. 364, 390-91 (1948) (observing that courts must "balance the privileges of [the patent holder] and its licensees under the patent grants with the prohibitions of the Sherman Act against combinations and attempts to monopolize"); *quoted in Federal Trade Commission v. Actavis, Inc.*, 570 U.S. __ at *9 (2013).

[3] Richard A. Posner, ANTITRUST LAW 247 (2d ed. 2001).

[4] *See, e.g.*, Richard Gilbert & Carl Shapiro, *Optimal Patent Length and Breadth*, 21 RAND J. ECON. 106, 107 (1990).

FTC Conduct Enforcement

I want to begin by touching on the FTC's established enforcement regime combatting reverse payment settlements (or "pay-for-delay" agreements) in the pharmaceutical industry. Through the Hatch-Waxman Act (1984), Congress struck a balance between intellectual property protection and antitrust law. It did this by setting the period of exclusivity during which a new drug is protected from competition, and by establishing the framework for entry by generics.

However, there is often a financial incentive for a branded patent holder to pay a potential generic rival to drop its patent challenge and delay entering the market – to pay for delay. Likewise, there is a financial incentive for the generic entrant to agree and accept the payment. In this situation, the brand and generic *each* stand to make more money by sharing in the brand's monopoly profits rather than competing. This conduct extends the brand's monopoly power beyond the balance struck by Congress under Hatch-Waxman and harms consumers who pay higher prices for prescription drugs.

As many here know, for nearly two decades the FTC has worked to stop anticompetitive reverse payment settlements. The Supreme Court's 2013 decision in *Actavis* was a major victory for the FTC because it confirmed the potential harm to competition from reverse payments. Developments since have been positive – the number of reverse payment settlements has decreased and more patent disputes are now being settled without reverse payments.[5]

The main questions are ones of interpretation – such as whether *Actavis* is limited to cash payments. I'm encouraged that both the Third Circuit and the First Circuit have adopted the FTC's view that non-cash patent settlement payments can harm competition.[6]

The FTC will continue to act when there is evidence that these types of reverse payments are anticompetitive. Just last month, the FTC filed suit against Endo and several generic firms for entering into illegal reverse payment agreements to delay entry of generic versions of two drugs, Opana ER and Lidoderm. Endo is the first FTC case that challenges a no-authorized generic (no-AG) commitment as a form of reverse payment. When a generic enters a market, the branded firm commonly introduces an "authorized generic" version of the drug, which it sells at a discount to the branded price as a way of recapturing some of the sales that it would otherwise lose to the generic entrant. By making a no-AG commitment, a branded firm gives up its right to

[5] Press Release, Fed. Trade Comm'n, FTC Report on Drug Patent Settlements Shows Potential Pay-for-Delay Deals Decreased Substantially in the First Year Since Supreme Court's Actavis Decision (Jan. 13, 2016), https://www.ftc.gov/newsevents/press-releases/2016/01/ftc-report-drug-patent-settlements-shows-potential-pay-delay.

[6] *See King Drug Company of Florence, Inc. v. Smithkline Beecham Corp*., 791 F.3d 388 (3d Cir. 2015); *In re Loestrin 24 FE Antitrust Litig*., __ F. 3d. ___, 2016 WL 698077 (1st Cir. Feb 22, 2016).

market an authorized generic in competition against the entrant following the agreed-upon generic entry date.

Another way for branded drug companies to delay generic competition is by denying generic companies the drug samples needed to complete FDA-required bioequivalence testing. Certain brand drugs are subject to restricted distribution programs implemented as part of FDA-mandated "REMS" safety protocols.[7] Branded manufacturers may use these safety procedures and other closed distribution systems opportunistically to preclude generic entry. Once again, this type of conduct can undermine the Hatch-Waxman balancing of competition and intellectual property principles.

The main question for competition enforcers in these cases is whether the facts support a finding of exclusionary conduct under Section 2 of the Sherman Act. Does a branded drug company's decision not to provide a drug sample to a generic entrant in a specific case constitute a refusal to deal under Supreme Court precedent?[8] The FTC has investigated allegations that branded distribution restrictions prevent generic firms from competing and continues to monitor this area. While the Commission has not initiated any law enforcement actions to date, the FTC has filed amicus briefs in two private actions explaining that such conduct can violate the antitrust laws and weaken the goals of Hatch-Waxman.[9]

SEPs and Hold-up

The statutory and regulatory aspects of the pharmaceutical sector are unique. But the role of competition enforcers in striking a balance between IP and competition is not. While the FTC has invested considerable resources in promoting consumer welfare in that sector, the agency has also been actively involved in study, advocacy, and enforcement in the standard-setting context. Our work in this area has focused on standard essential patents and the issue of hold-up.

A FRAND commitment is a voluntary commitment by a patent holder to license its intellectual property on fair, reasonable, and non-discriminatory terms in exchange for the inclusion of its technology in a standard. It is important to recognize that FRAND commitments

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[7] REMS stands for "risk evaluation and mitigation strategies."

[8] The Supreme Court has addressed the circumstances under which a refusal to deal may violate Section 2 in *Otter Tail Power Co. v. United States*, 410 U.S. 366 (1973), *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585 (1985), and *Verizon Commc'ns, Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398 (2004).

[9] FTC Brief as Amicus Curiae, *Mylan v. Celgene*, Case No. 2:14-CV-2094 (D.N.J. June 17, 2014), https://www.ftc.gov/system/files/documents/amicus_briefs/mylan-pharmaceuticals-inc.v.celgene-corporation/140617celgeneamicusbrief.pdf; FTC Brief as Amicus Curiae, *Actelion Pharms Ltd. v. Apotex Inc.*, Case No. 1:12-cv-05743 (D.N.J. Mar. 11, 2013), https://www.ftc.gov/sites/default/files/documents/amicus_briefs/actelion-pharmaceuticals-ltd.et-al.v.apotex-inc./130311actelionamicusbrief.pdf.

arose organically among standard-setting organizations (SSOs) in order to mitigate hold-up, and were not imposed on SSOs by governments or other outside parties.[10]

"Hold-up" refers to the fact that the bargaining position of a patent-holder may increase considerably after a patent is included in the standard. Once firms begin to make investments to practice the standard, they become locked-in.[11] By taking advantage of this enhanced bargaining position, a standard-essential patent (SEP) holder can demand higher royalty rates, or other more favorable licensing terms, than it could have obtained before lock-in occurred. As Dennis Carlton has explained, once a patent is included in a standard, "the patent owner definitely has some additional market power conferred on him that he can exploit in the absence of a constraint on him."[12] That added market power derives from the value of the standard itself, rather than the value of the underlying intellectual property.[13]

Hold-up is a standard, straightforward concept in economics. Oliver Williamson won the Nobel Prize in economics in 2009 due in no small part to his work showing how opportunistic behavior such as hold-up can lead to inefficient economic outcomes.[14] Patent hold-up can hamper standard-setting efforts, distort incentives for innovation, and potentially lead to higher prices and reduced output for consumers.[15] Hold-up becomes an antitrust issue when parties obtain their leverage as a result of the standard-setting process, which substitutes collective decision making for market forces.

By making a FRAND commitment, an SEP-holder chooses to monetize its technology through licensing rather than through exclusion. This makes it inappropriate, in most circumstances, for an SEP-holder to seek injunctive or exclusionary relief. As Carl Shapiro has explained, "[t]he economics here clearly teaches us that exclusion orders or injunctions tip the

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[10] U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, ANTITRUST ENFORCEMENT AND INTELLECTUAL PROPERTY RIGHTS: PROMOTING INNOVATION AND COMPETITION 42 (April 2007) (describing FRAND licensing as an "SSO Method[] to Avoid or Mitigate Hold Up").

[11] *See, e.g.*, FED. TRADE COMM'N, THE EVOLVING IP MARKETPLACE: ALIGNING PATENT NOTICE AND REMEDIES WITH COMPETITION 22 (March 2011).

[12] Economists' Roundtable on Hot Patent-Related Antitrust Issues, 27 ANTITRUST 11 (Sum. 2013).

[13] As a general principle, a FRAND rate should reflect value that the patented technology brings to consumers, relative to the other technologies available when the technology was chosen for the standard. *See, e.g., Ericsson, Inc. v. D-Link Systems, Inc.* 773 F.3d 1201, 1235 (Fed. Cir. 2014) ("We further hold that district courts must make clear to the jury that any royalty award must be based on the incremental value of the invention, not the value of the standard as a whole or any increased value the patented feature gains from its inclusion in the standard").

[14] *See* Avanish Dixit, Remarks at the AEA 2011 Nobel Lunch Honoring Elinor Ostrom and Oliver Williamson, January 8, 2011, at 3, https://www.princeton.edu/~dixitak/home/NobelLunchTalkJan2011.pdf.

[15] *See, e.g., Innovatio IP Ventures, LLC Patent Litigation*, MDL No. 2303, 2013 U.S. Dist. LEXIS 144061 *64 (N.D. Ill. Oct. 3, 2013) ("In light of all of the testimony, and particularly the evidence about Broadcom's real-world concerns about patent hold-up, the court concludes that patent hold-up is a substantial problem that RAND is designed to prevent"); *Microsoft Corp. v. Motorola, Inc.*, 2013 U.S. Dist. LEXIS 60233 *38 (W.D. Wash. Apr. 25, 2013) ("Hold-up can threaten the diffusion of valuable standards and undermine the standards-setting process).

balance of power in negotiations towards royalties that are excessive rather than just reasonable."[16]

The good news is that the SEP system works well overall. The vast majority of SEP licenses are successfully negotiated by parties without involving the courts or the agencies. There is little reason to think that that will change. In the U.S., the courts are there to make a determination when private parties are unable to reach agreement on what a negotiated FRAND rate should be. This is not particularly different from the role courts play when parties are unable to agree on any other aspect of contract interpretation.

When courts have been asked to determine FRAND rates, their findings have tended to be substantially lower than the rates sought by the FRAND-encumbered SEP holders. For example, in *Microsoft Corp. v. Motorola, Inc.* (W.D. Wash. Apr. 25, 2013), Motorola sought to exclude Microsoft's gaming consoles from the United States and demanded that Microsoft pay royalties of between $6–8 per console for the use of patents reading on the 802.11 and H.264 standards. The court determined that the F/RAND rate was less than four cents per unit for the 802.11 standard, and less than one cent per unit for the H.264 standard. The cumulative RAND royalty found appropriate by the court was approximately 1/150th the royalty sought by Motorola.[17] In *Realtek Semiconductor Corp. v. LSI Corp.*, (N.D. Cal. June 16, 2014), LSI filed an action with the U.S. International Trade Commission (ITC) seeking an exclusion order and then offered to license Realtek the underlying SEPs in exchange for a royalty that exceeded the selling price of Realtek's standard-compliant products. The federal district court determined that the cumulative F/RAND royalty to which LSI was entitled was 0.19% of the selling price – less than 1/500th the amount that LSI had been seeking.[18] In both cases, the F/RAND royalty rates offered by SEP-holders were orders of magnitude higher than what a neutral arbitrator found to be fair and reasonable.

When a licensing commitment to an SSO and its members is not honored, there may be a role for competition law. For example, in 2012, the FTC resolved an investigation involving Google/Motorola Mobility in which Motorola Mobility allegedly undermined the procompetitive

[16] Economists' Roundtable on Hot Patent-Related Antitrust Issues, *supra note* 12, at 12. In the same roundtable, Dennis Carlton stated that "[a]llowing somebody to get an injunction or go to the ITC and get an exclusion order undercuts the whole purpose of FRAND. So except in special circumstances we should not allow it." *Id*.

[17] *Microsoft Corp. v. Motorola, Inc., 2013 U.S. Dist. LEXIS 60233** 303 (W.D. Wash. Apr. 25, 2013). The cumulative royalty of 4.026 cents was 1/149th the FRAND rate sought by Motorola. The court also calculated ranges of RAND rates. The sum of the "upper bound" of these ranges was just under 36 cents. This upper bound was less than 1/16th of the FRAND rate sought by Motorola.

[18] *Realtek Semiconductor Corp. v. LSI Corp*., 2014 U.S. Dist. LEXIS 81673 * 23 (N.D. Cal. June 16, 2014).

standard-setting process by committing to license on FRAND terms, and then seeking injunctions and exclusion orders against willing licensees.[19]

The U.S. antitrust agencies have been actively involved in efforts to contribute to an understanding of the standard-setting process and the role of FRAND commitments. The agencies published a joint report on antitrust and intellectual property in 2007.[20] The FTC published a further report on patent remedies in 2011.[21] The agencies have also provided Congressional testimony and the FTC has filed statements with courts and the U.S. International Trade Commission on issues related to standard-essential patents. [22]

Patent Assertion Entities

Another area potentially at the intersection of antitrust and intellectual property law involves the activities of patent assertion entities (PAEs). I say "potentially" because currently there is much we do not understand about PAEs and their impact on competition and innovation.

The activity of PAEs differs from the classic activity of other non-practicing entities (NPEs). NPEs do not themselves commercialize novel technologies, but they frequently develop and transfer these technologies. PAEs, by contrast, typically purchase patents from existing owners and seek to earn revenues by licensing (or litigating against) manufacturers that are already using the patented technology.

Proponents of PAEs argue that they foster a valuable secondary market for patents, which allows inventors to capitalize on their ideas and encourages innovation funding. Critics argue that PAEs act as a drag on innovation by diverting resources from manufacturing firms' productive R&D efforts. Critics also contend that PAEs take advantage of an imbalance in litigation costs between PAEs and defendants.

The Commission believes that it is important to understand how PAEs do business and how they affect innovation and competition. The FTC hosted a workshop with the Department

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[19] Decision and Order, Fed. Trade Comm'n, In the Matter of Motorola Mobility LLC and Google Inc., Dkt. No. C-4410 (July 24, 2013), https://www.ftc.gov/sites/default/files/documents/cases/2013/07/130724googlemotorolado.pdf.

[20] *See* ANTITRUST ENFORCEMENT AND INTELLECTUAL PROPERTY RIGHTS, *supra* note 10.

[21] *See* THE EVOLVING IP MARKETPLACE, *supra* note 11.

[22] *See, e.g.*, Fed. Trade Comm'n, Statement on the Public Interest, In the Matter of Certain Gaming and Entertainment Consoles, No. 337-TA-752 (U.S. Int'l Trade Comm'n, filed June 6, 2012), http://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-comment-united-states-international-trade-commission-concerning-certain-gaming-and-entertaining/1206ftcgamingconsole.pdf; Press Release, Fed. Trade Comm'n, FTC Testifies Before Congress on Standard Essential Patents and How Patent "Hold-Up" Affects Competition (July 30, 2013), http://www.ftc.gov/news-events/press-releases/2013/07/ftc-testifies-congress-standard-essential-patents-how-patent-hold.

of Justice on the subject of patent assertion entities in 2012, and received approval to use our 6(b) authority to conduct a study on PAEs. In 2014, we issued information requests to approximately 25 patent assertion entities in connection with our 6(b) study. We also sent information requests to approximately 15 non-practicing entities and manufacturing firms in the wireless chipset sector.

The Commission voted unanimously to request Office of Management and Budget (OMB) clearance to conduct the PAE study and the study design and methodology were approved by OMB. FTC staff has been hard at work collecting and synthesizing that information, and the FTC intends to publish a descriptive report on its findings in the very near future. It is our hope that will allow industry participants, policymakers, and academics to gain a better understanding of the PAE business model.

The FTC has also used its authority address the deceptive use of patent demand letters and other potentially abusive tactics by PAEs. In 2014, the FTC challenged MPHJ Technology Investments for sending tens of thousands of deceptive demand letters falsely threatening patent suits.[23] As in our reverse-payment cases, the FTC's efforts are designed to prevent the improper extension of IP protections beyond their appropriate scope.

Conclusion

The aims of competition law and intellectual property law are largely in harmony, but the intersection of these two fields can raise interesting and important issues. The FTC has made use of its many tools – including research, advocacy, and enforcement – to contribute to the understanding of a number of these issues and to help forge a path forward that promotes innovation and competition. The panels today will provide additional viewpoints on a number of hot topics related to antitrust and intellectual property.

Thank you again for inviting me. I am happy to take any questions.

[23] *See* Press Release, Fed. Trade Comm'n, FTC Settlement Bars Patent Assertion Entity from Using Deceptive Tactics (Nov. 6, 2014), http://www.ftc.gov/news-events/press-releases/2014/11/ftc-settlement-bars-patent-assertion-entity-using-deceptive.