The AIPLA Antitrust News

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Chair's Corner

Summer is a great time to enjoy a well-deserved vacation, unless you're an active member of our Antitrust Committee.

On June 9, Canada's Competition Bureau issued a request for public comment on proposed "Intellectual Property Enforcement Guidelines," addressing issues of competition and IP rights, including Standard Essential Patents ("SEPs"). On July 8, a request for public comment was issued regarding amendments to Japan's "Guidelines for the Use of Intellectual Property under the Antimonopoly Act," and likewise including issues concerning SEPs. Our committee worked to support the Standards and Open Source Committee to prepare draft comments on the Canadian Guidelines, and with both the IP Practice in Japan Committee and Standards and Open Source committee to prepare draft comments to the Japanese Guidelines. The results of those efforts have been posted on our web page (in the special topics folder), at http://www.aipla.org/committees/committee_pages/antitrust-law/. Our Committee was then asked to take the lead on preparing comments for a third international notice, this time a questionnaire issued by the Chinese NDRC concerning the intersection of antitrust and intellectual property law. The Standards and Open Source Committee and IP Practice in China Committee supported that effort, which went to committee vote earlier this month. The results of the NDRC effort should be posted shortly by AIPLA on the international tab (http://www.aipla.org/advocacy/intl/Pages/Other-International.aspx), as well as on our Committee page.

Our work over the summer sets the stage for what we expect to be a fantastic program during the AIPLA 2015 Annual Meeting. On Thursday, October 22, our Committee will hold a joint committee meeting with the Standards and Open Source Committees from 3:30-5:30 p.m.. The session will address standards and other IP-antitrust related topics such as U.S. and Chinese competition agency investigations and standardization reform, including FRAND licensing. We will have two speakers, one from government and one from industry, in order to provide a well-rounded program. Renata Hesse, a Deputy Assistant Attorney General in the U.S. Justice Department's Antitrust Division, and Dina Kallay, the Director of Intellectual Property & Competition at Ericsson, will be our two speakers. Each will present for approximately 20 minutes, followed by time for questions and answers. Please attend if you can!

SUBCOMMITTEES

The Committee has also established subcommittees to focus on three important topics at the intersection of IP and competition law – IP acquisitions, pharmaceuticals, and standards – with periodic telephone conference calls in which members of our subcommittees share important developments in their focus areas with members of the Committee as a whole.

IP Acquisitions: David Blonder, Subcommittee Chair. Among other support, the subcommittee prepared a letter to the

Federal Trade Commission in response to the FTC's invitation for comments regarding its proposed information requests in connection with its planned 6(b) study on patent assertion entities, and assisted in organizing our Spring AIPLA meeting effort.

Pharmaceuticals: Jennifer Tempesta, Subcommittee Chair. Among other support, the subcommittee has tracked how lower courts and the FTC are applying the Supreme Court's decision in *FTC v. Actavis,* and has arranged for a DOJ speaker, Daniel Walker, to join us during a Committee conference call on November 12 to address recent developments in the reverse payment settlement and product hopping areas.

Standards: Richard Stark, Subcommittee Chair. Among other support, the subcommittee has monitored the area of FRAND encumbered patents, provided important reports to the Committee membership, and participated in organizing our joint committee meeting.

Please contact David, Jennifer or Richard if you wish to get involved in any of the activities of the subcommittees; your assistance would be greatly appreciated.

NEWSLETTER

Our newsletter features three articles in this edition: The first, authored by Matthew Murphy and Fei Dang, addresses the new antimonopoly provisions relating to IP rights issued by China's State Administration for Industry and Commerce ("SAIC"). You may recall that our Committee prepared comments to SAIC's draft rulemaking last summer; read the article to gauge our influence on the SAIC Provisions! The second article, authored by Paul Ragusa and Sam Li, also addresses Chinese antitrust law, this time by way of comparing U.S. law with the developing law in China concerning standard essential patents, including the availability of injunctive relief. The third article, authored by Amy Foust, switches to pharmaceuticals and examines competing "Pay for Delay" bills that are pending before Congress. This article sets the stage nicely for our next Committee conference call, which as noted above will focus on reverse payment and product hopping issues.

The Antitrust Committee publishes this newsletter three times a year. We welcome articles from regular as well as first-time contributors on any relevant topics of interest. If you would like to contribute an article, please contact our newsletter editor David Swenson at david_swenson@baylor.edu.

We look forward to seeing you in Washington, D.C., if you are attending the Annual meeting, and to hearing from you during our next Committee call on November 12.

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Conclusion

Antitrust law in China is rapidly evolving. However, the evidence to date suggests that both Chinese antitrust enforcers and Chinese courts may impose antitrust scrutiny on SEP holder conduct in negotiating license agreements and seeking injunctive relief. SEP holders should take caution to ensure a good faith negotiation process occurs before taking enforcement action. Even going to court in another country to request an injunction against a Chinese defendant for alleged infringement outside of China may be subject to antitrust scrutiny within China, as evidenced by the *Huawei v. IDC* case. This area will remain an important one to watch in the months and years to come.

Competing "Pay for Delay" Bills in the 114th Congressional Session

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In September, two Senate bills addressing so-called "pay-for-delay" settlements in Hatch-Waxman litigation were introduced. Pay-for-delay settlement agreements, which are also referred to as "reverse-payment" settlements, have been defined by the Federal Trade Commission (FTC) as a promise from a generic drug firm to not market a product for a period of time in exchange for payments from a brand name drug manufacturer.[21] According to the FTC, the payments may be in monetary or non-monetary form.[22]

The first of the two bills, S. 2019, the Preserve Access to Affordable Generics Act, was introduced on September 9 by Senator Amy Klobuchar (D-MN), and includes significant changes from the bill of the same name that Senator Klobuchar introduced last session, S. 214.[23] On September 10, Senator Bernard Sanders (I-VT) introduced S. 2023, the Prescription Drug Affordability Act of 2015.[24] While both bills aim to eliminate pay-for-delay settlements, the approaches are dissimilar in ways that may be practically important for NDA holders and ANDA filers.

S. 2019 – The Preserve Access to Affordable Generics Act

The Preserve Access to Affordable Generics Act would treat certain agreements "resolving or settling, on a final or interim basis, a patent infringement claim, in connection with the sale of a drug product" as a violation of section 5 of the Federal Trade Commission Act (15 U.S.C. § 45).[25] A new section 27 of the FTC Act would

[21] *FTC v. Actavis, Inc.*, 570 U.S. ___, 133 S. Ct. 2223, 2227 (2013); FTC Staff Study, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 1 (2010), *available at* https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf.
[22] *Id.* at 5.
[23] Preserve Access to Affordable Generics Act, S. 2019, 114th Cong. (2015); Preserve Access to Affordable Generics Act, S. 214, 113th Cong. (2013).
[24] Prescription Drug Affordability Act of 2015, S.2023, 114th Cong. (2015).
[25] S. 2019, at § 3 (in proposed new § 27 of the FTC Act, see § 27(d)(1)).

create a presumption that an agreement is anticompetitive and a violation of the law if an ANDA filer "receives anything of value, including an exclusive license" and "agrees to limit or forego research, development, manufacturing, marketing, or sales of the ANDA product for any period of time."[26]

The strong presumption of anticompetitive effect would be overcome only by a showing of clear and convincing evidence that the compensation is for goods or services provided by the ANDA filer or the procompetitive benefits of the agreement outweigh the anticompetitive effects of the agreement.[27] Settlement agreements may also escape scrutiny if the value provided to the ANDA filer is limited to rights to market the ANDA product prior to expiration of an asserted patent or other statutory exclusivity, payment for reasonable litigation expenses not to exceed $7,500,000, and/or a covenant not to sue the ANDA filer "on any claim that the ANDA product infringes a United States patent."[28]

Judicial review of an FTC order under S. 2019 would be limited to certain U.S. Courts of Appeal, and FTC fact-finding would be reviewed only for supporting evidence.[29] Each party to a prohibited agreement could be fined up to "3 times the value received by the party that is reasonably attributable to the violation of this section."[30] If the NDA holder receives no express compensation under the agreement, the NDA holder could be fined based on the impermissible value received by the ANDA filer.[31] The bill further clarifies that the proposed new section 27 of the FTC Act is in addition to—not in lieu or limitation of—any other antitrust laws, and, in particular, proposed section 27 does not limit the right of the ANDA filer to "assert claims or counterclaims against any person, under the antitrust laws or other laws relating to unfair competition."[32]

Evolution of S. 2019 – The Preserve Access to Affordable Generics Act

Compared with S. 214 from the 113th session, S. 2019 clarifies that an exclusive license is something of value for the purpose of bringing a settlement agreement within the scope of proposed section 27[33]; adds the exception for settlement payment to the ANDA filer in exchange for goods and services[34]; and specifies the standard for judicial review of FTC fact-finding.[35] Notably, S. 2019 does not include sections of S. 214 that provided for FTC rule-making, particularly around exemptions for agreements the FTC considers procompetitive,[36] and factors to be weighed in considering whether the parties to a

[26] *Id.* (in proposed new § 27 of the FTC Act, see § 27(a)(2)(A)).
[27] *Id.* (in proposed new § 27 of the FTC Act, see § 27 (a)(2)(B)).
[28] *Id.* (in proposed new § 27 of the FTC Act, see § 27(c)).
[29] *Id.* (in proposed new § 27 of the FTC Act, see § 27(d)(2)).
[30] *Id.* (in proposed new § 27 of the FTC Act, see § 27(f)(1)).
[31] *Id.*
[32] *Id.* (in proposed new § 27 of the FTC Act, see § 27(e)).
[33] *Id.* (in proposed new § 27 of the FTC Act, see § 27(a)(2)(A)(i)).
[34] *Id.* (in proposed new § 27 of the FTC Act, see § 27(a)(2)(B)(i)).
[35] *Id.* (in proposed new § 27 of the FTC Act, see § 27(d)(2)(B)).
[36] S. 214, at § 3 (in proposed new § 28 of the FTC Act, see § 28(e)(1)).

suspect agreement have proven that the agreement is procompetitive.[37]

S. 2023—The Prescription Drug Affordability Act

Senator Sanders' Prescription Drug Affordability Act of 2015 presumes anticompetitive effects from settlement payments from an NDA holder to an ANDA filer, but does not include the express exceptions and limitations in S. 2019.[38] A presumption of anticompetitive effect implies that it should be possible to overcome the presumption with a showing of procompetitive benefits. However, S. 2023 does not provide a burden of proof for showing procompetitive benefits, whereas S. 2019 would require clear and convincing evidence.[39] In comparison to S. 2019, the Prescription Drug Affordability Act also eliminates the restriction on which Courts of Appeal can hear reviews of FTC orders, and the "supported by evidence" standard for upholding FTC fact-finding in an order related to proposed section 27.[40]

Like S. 2019, S. 2023 would allow for the resolution of a patent infringement claim with a license, payment of reasonable litigation expenses, and/or a covenant not to sue for patent infringement.[41] However, under S. 2023, these terms would provide the only "safe harbor" for settlement agreements related to a patent infringement claim arising from an ANDA filing. Both S. 2019 and S. 2023 would define a "patent infringement claim" to include "any allegation made to an ANDA filer, whether or not included in a complaint filed with a court of law."[42]

Other Provisions in the Prescription Drug Affordability Act

The Preserve Access to Affordable Generics Act, S. 2019, includes findings and declarations related to the magnitude of national health care spending on prescription drugs, and the proposed section 27 is the substantive heart of the bill.[43] The Prescription Drug Affordability Act, S. 2023, while proposing a similar new section 27 of the FTC Act, would also require the Secretary of Health and Human Services to negotiate drug prices charged to certain private insurance plans for part D eligible individuals[44] and to promulgate regulations for the importation of prescription medications and devices from countries other than Canada.[45] The Prescription Drug Affordability Act would further close the Part D "donut hole" in 2017 rather than 2020,[46] urge the US Trade Representative to avoid trade agreements that would raise the price of prescription drugs in the US or extend periods of market exclusivity for prescription drugs,[47] require drug manufacturers to provide rebates for drugs dispensed to part D-eligible individuals,[48] apply the Medicaid additional rebate

[37] *Id.* (in proposed new § 28 of the FTC Act, see § 28(b)).
[38] *See generally*, S. 2023, at § 401 (in proposed new § 27 of the FTC Act, see § 27(a)(1)).
[39] *See*, S. 2019, at § 3 (in proposed new § 27 of the FTC Act, see § 27(a)(2)(B)).
[40] *Id.* (in proposed new § 27 of the FTC Act, see § 27(d)(2)).
[41] S. 2023, at § 401 (in proposed new § 27 of the FTC Act, see § 27(b)).
[42] S. 2019, at § 3 (in proposed new § 27 of the FTC Act, see § 27(g)(11)); S. 2023, at § 401 (in proposed new § 27 of the FTC Act, see § 27(c)(11)).
[43] S. 2019, at § 2.
[44] S. 2023, at § 101.
[45] *Id.* at § 201.
[46] *Id.* at § 102.
[47] *Id.* at § 202.
[48] *Id.* at § 301.

requirement to generic drugs,[49] and expand the bases for termination of exclusive marketing rights.[50]

Drug manufacturers should take note of the reporting requirements of S. 2023, which would require public, annual disclosure of detailed financial information relating to R&D and operating expenditures, receipt of federal benefits such as tax credits and grants, and profits from foreign sales in each foreign country in which the drug is sold.[51] This public disclosure requirement is perhaps the most striking embodiment of the distinction between the stated fair market competition concerns of S. 2019 and the price-reduction goals of S. 2023.

Presumably, neither NDA holders nor ANDA filers welcome further restrictions on their ability to settle litigation on terms the parties consider reasonable, or at least preferable to continued litigation and uncertainty. As between the two bills, potential parties to reverse settlement agreements may favor the "safe harbor" type exceptions enumerated in S. 2019, which leave open at least a theoretical possibility of crafting a reverse settlement payment that the FTC might find procompetitive. While the restrictions in S. 2019 on forum selection for review of FTC orders and the strong deference provided to FTC fact-finding would generally be disfavored by potential regulatory targets, NDA holders may prefer the strictures of S. 2019 to the financial disclosure and rebate requirements included in other sections of S. 2023.

[49] *Id.* at § 302.
[50] *Id.* at § 501.
[51] *Id.* at § 601.

Possible Effects of Legislation on FTC Regulatory Activity

Even without these laws, the FTC has been successfully prosecuting allegedly anticompetitive behavior in the form of reverse payment settlements.[52] The U.S. Supreme Court decision in *FTC v. Actavis* held that reverse payment settlements are subject to antitrust scrutiny.[53] Just in May of this year, the FTC announced a $1.2 Billion settlement with Teva Pharmaceutical Industries, Ltd. (as the successor-in-interest to Cephalon, Inc.).[54] The FTC settlement resulted from a 2008 lawsuit alleging that Cephalon made anticompetitive payments to four generic drug makers in 2005 and 2006 to delay the entry of generic versions of sleep-disorder drug Provigil for 6 years.[55] Cephalon argued that the payments it made were for the supply of active pharmaceutical ingredients and intellectual property rights. However, the FTC asserted that the purpose of the agreements was to extend Cepahlon's market exclusivity.[56] Teva also submitted to a permanent injunction prohibiting certain

[52] *See generally*, FTC Staff Study, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS (2010), *available at* https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf.

[53] *FTC v. Actavis*, 133 S. Ct. at 2227.
[54] Press Release, Federal Trade Commission Bureau of Competition, FTC Settlement of Cephalon Pay for Delay Case Ensures $1.2 Billion in Ill-Gotten Gains Relinquished; Refunds Will Go To Purchasers Affected by Anticompetitive Tactics (May 28, 2015), *available at* https://www.ftc.gov/news-events/press-releases/2015/05/ftc-settlement-cephalon-pay-delay-case-ensures-12-billion-ill.
[55] *Id.*
[56] *Id.*

types of reverse settlement agreements across all of its US businesses.[57]

To the case law and exemplary consent decree, the pending bills would essentially add a presumption that a reverse settlement payment is anticompetitive.[58] However, as the Teva settlement demonstrates, the FTC has been able to prosecute unfair competition allegations even under circumstances where the companies involved asserted legitimate business reasons for the transaction. It seems that the proposed statutory presumption of anticompetitive effect would mostly serve to reduce the cost and scope of FTC investigations into reverse settlement payments. The pending legislation would not change the scope of the business transactions the FTC has indicated are potentially problematic, or the FTC's ability to challenge proffered legitimate business interests that the FTC finds lacking in "economic sense".[59]

The Preserve Access to Affordable Generics Act, S. 2019, is cosponsored by Senator Chuck Grassley (R-IA). Hearings on the bill were held by the Committee on the Judiciary Subcommittee on Antitrust, Competition Policy and Consumer rights on September 22, 2015. No Committee Report has been posted as of October 15, 2015. There is no corresponding legislation pending in the House of Representatives.

The Prescription Drug Affordability Act of 2015, S.2023, is cosponsored by Senator Al Franken (D-MN). It has been read twice and referred to the Committee on Finance. A bill identical to S.2023 has been introduced in the House of Representatives as H.R. 3513, sponsored by Representative Elijah Cummings (D-MD) and cosponsored by Representatives Keith Ellison (D-MN), Eleanor Holmes Norton (D-DC), John P. Sarbanes (D-MD), Janice D. Schakowsky (D-IL) and Matt Cartwright (D-PA). The House bill has been referred to the Committee on Energy and Commerce, the Committee on Ways and Means, and the Committee on the Judiciary.

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[57] *Id.*

[58] The U.S. Supreme Court considered and declined to adopt a presumption that reverse settlement payments are anticompetitive. *FTC v. Actavis*, 133 S. Ct. at 2237.

[59] Press Release, Federal Trade Commission Bureau of Competition, FTC Settlement of Cephalon Pay for Delay Case Ensures $1.2 Billion in Ill-Gotten Gains Relinquished; Refunds Will Go To Purchasers Affected by Anticompetitive Tactics (May 28, 2015), *available at* https://www.ftc.gov/news-events/press-releases/2015/05/ftc-settlement-cephalon-pay-delay-case-ensures-12-billion-ill.