The AIPLA Antitrust News

A Publication of the AIPLA Committee on Antitrust Law **October 2015**

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.

AIPLA Antitrust Committee

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China Releases New Anti-Monopoly Provisions Relating to IP Rights

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The State Administration for Industry and Commerce ("SAIC") issued the finalized *Provisions on Prohibiting the Abuse of Intellectual Property Rights to Preclude or Restrict Competition* ("the Provisions") on April 7, 2015, a year since the draft was released for public opinion. The Provisions will be effective as of August 1, 2015.

The final promulgation of the Provisions marks a significant point for the SAIC in terms of regulating over the intellectual property field. While the Provisions were first an attempt to address concerns the Anti-Monopoly Law ("AML") was used to favour Chinese licensees of intellectual property rights over foreign licensors, the Provisions have also covered many complex issues with respect to monopolistic conduct in the IP field through its recognition of the importance of encouraging competition and innovation.

Main Contents

Although the Provisions were not altered significantly in comparison with the draft, its few adjustments consists of adopting several suggestions received during its consultation period, and adjusting and/or deleting some controversial articles. Its main contents are as follows:

(1) *Objective and definition*

The objective and the basis of the Provisions are to protect market fair competition, encourage innovation, and to prevent the abuse by operators attempting to preclude or restrict competition when exercising their intellectual property rights. Meanwhile, it also gives necessary interpretations of certain concepts, such as the meaning of 'abuse of intellectual property rights to preclude or restrict competition', the meaning of 'relevant market', and so on. It is also worthy to note that not only do the Provisions specify it shares the same objectives with the anti-monopoly and the protection of intellectual property rights, it also draws the line between exercising and abusing intellectual property rights. (*Article 1 - 3*)

(2) *Reaching monopolistic agreement and exceptions*

The Provisions prohibit operators from reaching monopolistic agreement during their exercise of intellectual property rights as well as introducing the principle of safe harbour which means that, under certain circumstances, certain kinds of conduct would not be considered as monopolistic and therefore can be exempted from penalties. The circumstances are as follows:

a. the aggregate market share of operators with competing relations in the relevant market does not exceed 20%, or, there are at least four other independently controlled substitutable technologies available at reasonable costs;

b. neither the operator nor the transaction counterparty has a market share exceeding 30% in the relevant market, or, there are at least two other independently controlled substitutable technologies available at reasonable costs. (*Article 4 - 5*)

However, the safe harbour principle may introduce further uncertainty, as it will not apply where there is evidence of the agreement precluding or restricting competition, therefore parties will first have to determine any anticompetitive effects of their agreements. This may be complicated in practical application as it will be difficult to calculate specific market shares, the range of substitutable technologies available and its reasonable costs, especially with certain emerging fields such as the Internet or the age of digital products serving to blur the boundaries and ultimately making it difficult to determine the relevant market.

(3) Abusing dominant position

The Provisions prohibit operators exercising intellectual property rights from abusing their dominant position in the market to eliminate and restrict competition, including refusing, without due justification, to deal with rivals that need those essential facilities to compete. Furthermore, the Provisions provide considerations for evaluating a refusal to licence to include factors such as whether the intellectual property rights may be reasonably substituted and/or is necessary for other undertakings to compete in the relevant market; if the refusal to licence will cause a negative impact on competition or innovation, leading to the harming of the public's interests; and if the license will cause unreasonable harm to the operator. However, these conditions impose a low standard for imposing liability on an unwilling operator, therefore they raise significant controversy as the article may suppress the motivation to research and innovate because of the violation to the IP holder's core rights of exclusivity to the IP.

The Provisions also set forth abusive conducts which are prohibited to include exclusive grant back of improvements to the technology by the licensee, prohibiting the licensee from questioning the efficiency of the intellectual property rights, restricting the licensee from making use of a competing technology after expiration of the license agreement, and attaching any unreasonable restrictions and differential treatment on the licensee. (*Article 6 - 11*)

(4) Patent pool and standard

The Provisions provide for specific situations that may constitute a monopoly with respect to patent pool and the standard exercise of intellectual property rights. This includes restricting the pool participants from licensing as an independent licensor outside the patent pool, preventing the participants from developing competing technologies, forcing the licensee to grant back improved technology to the operator exclusively, and treating participants in the same relevant market discriminatorily.

Furthermore, the Provisions prohibit stipulating or implementing standards that seek to preclude or restrict competition. It specifically defines SEPs and such obligations that are borne out of SEP holders, and also stipulates the FRAND principle (fair, reasonable and non-discriminatory terms) in patent licensing which is a well-known principle, having been adopted in previous enforcement practices. While the Draft outlined the pre-requisites as 'licensor knowing their patents may be incorporated into relevant standards', the final version has amended it to state instead 'during the standard setting process', therefore signifying the importance of an objective process, which have further implications such as simplifying the process for enforcement agencies when conducting investigations and collecting evidence in specific cases. (*Articles 12-13)*

(5) *Steps and factors adopted by the AIC in anti-monopoly enforcement*

The Provisions clarifies the analysis principle and framework of anti-monopoly enforcement in the field of intellectual property rights by the SAIC organs. The Provisions sets forth five steps to be adopted when analyzing for abuse of intellectual property rights, such as determining the nature and form used when exercising intellectual property rights, the nature of the relationship between the operators, the relevant market involving the exercise of intellectual property rights, the operator's market position, and the effect of the exercise of intellectual property rights on the market. It also provides factors to be taken into consideration when analyzing the effect on competition when exercising intellectual property rights, e.g. the operator's market position and the trading counterparty, the market concentration of the relevant market, and so on. (*Article 14 - 16*)

(6) Penalty

The Provisions stipulate that the punishment for the abuse of intellectual property rights by entering into a monopolistic agreement to preclude or restrict competition is in accordance with the Anti-monopoly Law; which is the imposition of a fine amounting to more than 1% but less than 10% of last year's sales accompanied by an order to cease violation and for SAIC to seize illegal gains. Even if such a monopolistic agreement has not been implemented, a fine amounting to 500,000 Yuan at most may be imposed. (*Article 17*)

Comment

Prior to the Provisions, Article 55 of the Anti-Monopoly Law stated "this Law shall not apply to an *undertaking's exercise of intellectual property rights in accordance with the administrative regulations and laws related to intellectual property rights; but this Law shall apply to an undertaking's abuse of intellectual property rights in its attempt to eliminate or restrict competition*". However, this was a mere principle and lacked operability and effectiveness.

The Provisions are a significant step forward as it fills the legislative gap between intellectual property rights and the Anti-Monopoly Law in China, although a bit lacking as its main focus are on patents, and it does not involve trademark and copyright.

Furthermore, the Provisions not only enhance and complement relevant currently existing laws, it also provides better protection for properly exercised intellectual property rights as well as providing a better environment for competition and innovation.

The Provisions, as an SAIC regulation, apply only to anti-monopoly cases within SAIC's jurisdiction. Therefore, the Provisions will not apply to price-monopoly cases charged by the National Development and Reform Committee (NDRC) or concentration cases charged by the Ministry of Commerce (MOC). However, the principles set forth in the Provisions might become a reference for those dealing with similar issues in the NDRC, MOC or courts handling IP monopoly cases.

In the past few years, China has reinforced its anti-monopoly enforcement in both the field of price monopoly and the field of administrative monopoly. The issuance of the Provisions can be seen as a signal that regulating the abuse of intellectual property rights is becoming a focus in the anti-monopoly enforcement. In fact, according to a news report issued this March, it is the general view that monopolies concerning intellectual property rights are common in industries such as medicine, auto after-sales market and agricultural machinery, therefore stronger anti-monopoly enforcement should be carried out to provide for those industries.

SAIC's aim is to facilitate innovation and technology advancement by reducing the abuse of intellectual property which seeks to restrict or eliminate fair competition in the market. Therefore, the Provisions are a way forward into this challenging area where IP law and the AML overlap by introducing concepts such as the safe harbour principle, adopting advice and suggestions from various types of sources and re-evaluating its articles to produce the final version of the Provisions.

Antitrust Scrutiny in China of FRAND-Committed Standard Essential Patents[1]

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Introduction

Technical standards can enable multiple companies and other organizations in a competitive field to collaboratively develop platforms for new products using contributions from multiple innovators. Standard setting organizations (SSOs) often foster such collaboration by enacting rules requiring participants to identify patent rights likely essential to the standard during the standard setting process, and to commit to license standard essential patents ("SEPs") on fair, reasonable, and non-

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discriminatory (FRAND) terms.[2] Standard setting is generally regarded as pro-competitive, as standards can reduce costs, promote competition and follow-on innovation, expand output, and ultimately increase consumer welfare.[3] However, SEPs can also invite attention from antitrust regulators, both in the United States and abroad. This article examines recent developments that have occurred in one important country, China.

Background

FRAND commitments can and do vary from one SSO to another, but some patterns have emerged. "Fair" licensing can be understood to mean that the patent holder should generally license on terms that are not anticompetitive and would not constitute an antitrust violation or patent misuse.[4] "Reasonable" licensing can be understood to require that the royalty paid on a particular patent should generally be proportionate to the value of that patent to the standard and that the total royalties paid by a licensee to all SEP holders are not unreasonable in aggregate.[5] "Non-discriminatory" licensing can be understood to generally mean that the SEP holder will treat all potential similarly situated licensees similarly and refrain from withholding licenses from new market entrants.[6]

Does a FRAND commitment change the rules of patent enforcement? On one hand, the right of a patent holder to bring suit for injunctive relief against an alleged infringer is a basic patent right. On the other hand, arguments have been made that a FRAND commitment should be construed as a promise by the patent holder to license the patent, which runs contrary to the right to enjoin others from practicing it.

Some SEP holders have brought infringement suits against prospective licensees and, in certain cases, have sought injunctive relief. Some antitrust regulators have indicated that a FRAND commitment may prevent the patent holder from seeking injunctive relief, at least under some circumstances, and have gone so far as to charge SEP holders with violations for requesting injunctive relief on a FRAND-encumbered patent.[7]

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[2] Some standard-setting organizations use the term "reasonable and non-discriminatory" ("RAND") for the licensing obligations that attach to SEPs, rather than "FRAND". "RAND" and "FRAND" are generally synonymous, and for simplicity we use the term "FRAND" throughout.

[3] *See*, for example, Deborah Platt Majoras, Chairman, Fed. Trade Comm'n, *Remarks Prepared for Standardization and the Law: Developing the Golden Mean for Global Trade, Recognizing the Procompetitive Potential of Royalty Discussions in Standard Setting 2* (Sept. 23, 2005), available at http://www.ftc.gov/sites/default/files/documents/public_statements/recognizing-procompetitive-potential-royalty-discussions-standard-setting/050923stanford.pdf/.

[4] *See* David N. Makous & Mina I. Hamilton, *Compulsory IP Licensing and Standards-Setting, Standard-Essential Patents and F/RAND,* Aspatore (2014), 2014 WL 1234517; *see also* Am. Bar. Ass'n Comm. on Tech. Standardization Section of Sci. & Tech. Law, Standards Development Patent Policy Manual 22 (Jorge L. Contreras ed., 2007).

[5] See *Microsoft Corp. v. Motorola, Inc.*, C10-1823JLR, 2013 WL 2111217 (W.D. Wash. Apr. 25, 2013) ("From an economic perspective, a [F]RAND commitment should be interpreted to limit a patent holder to a reasonable royalty on the economic value of its patented technology itself, apart from the value associated with incorporation of the patented technology into the standard.")

[6] Makous & Hamilton, *supra*.

[7] *See, e.g.,* Kenneth M. Frankel, *International Antitrust Investigations of Injunctions Sought for Infringement of Standard-Essential Patents with FRAND Commitments*, AIPLA Antitrust News, May

Compared to the U.S., China has a relatively short history of antitrust law. Most antitrust enforcement in China is conducted pursuant to the 2008 Anti-Monopoly Law, and reported decisions are sparse. Thus, Chinese antitrust law remains in flux and continues to evolve. However, early indications suggest that China's competition authorities and courts are inclined to scrutinize injunction seeking on FRAND-encumbered patents for potential antitrust violations.

Chinese Courts May Not Recognize a Right to Seek Injunctions for Infringement of SEPs

In 2008, the Supreme People's Court of China, the nation's highest court, published an advisory opinion on SEPs, which provides insight into the court's position on injunction seeking on patents subject to FRAND commitments.[8] The case involved a construction engineering standard promulgated by the Ministry of Construction, where the patent owner had participated in the standard setting effort. The court's opinion, published as *Min San Ta Zi No. 4*, stated that because of the FRAND commitment, third party exploitation of technology covered by SEPs "does not constitute patent infringement" and that SEPs must be licensed at a rate "significantly lower than the normal license fee."[9] However, Dr. Zhipei Jiang, the former chief IP judge of the Supreme People's Court at the time when the advisory opinion was issued, later opined that the opinion is limited to the specific case, is not a judicial interpretation and has no generally application.[10]

More recent indications from the Supreme People's Court suggest that practicing SEPs without authorization constitutes infringement but injunctive relief may not apply:

> Regarding patents included in non-mandatory national, industrial or local standards, where an accused infringer contends non-infringement because implementing standards needs no authorization from the patentee, the people's court generally should not support such a position. But, where a patentee violates the FRAND principle, and negotiates in bad faith the licensing terms for exploiting patent included in the standards, and henceforth if the accused infringer contends that it should be stopped from exploiting the patent, the people's court should generally support such a position.

2014; Geoffrey D. Oliver, Johannes Zöttl & Christian Fulda, *Fast-Forward for FRAND Disputes in Europe*, AIPLA Antitrust News, May 2013; Paul Ragusa & Brian Boerman, *Acquisition of Standard Essential Patents: Issues to Consider Before Making the Deal*, AIPLA Antitrust News, January 2013.

[8] *See* Koren W. Wong-Ervin, *Standard-Essential Patents: The International Landscape*, ABA Intellectual Property Committee Newsletter, Spring 2014, available at http://www.ftc.gov/system/files/attachments/key-speeches-presentations/standard-essential_patents_the_intl_landscape.pdf, *citing* SPC Min San Ta Zi No. 4 (2008), "Letter re whether Chaoyang Xingnuo Corporation's exploitation of a patent an industrial standard context constitutes patent infringement," available in Chinese at http://www.chinaiprlaw.cn/show_News.asp?id=13651&key=%B1%EA%D7%BC.

[9] *Id.*

[10] Dr. Zhipei Jiang on the Reply of the Supreme People's Court regarding Standard Patent: http://www.dgips.cn/qyzs_detail.asp?nid=430.

> The licensing terms for standards-related patents should be negotiated between the patentee and the accused infringer. If an agreement cannot be reached after ample negotiation, they may request the people's court to make a determination. The people's court should determine the licensing terms in accordance with the FRAND principle and in consideration of the extent of inventiveness of the patent, its role in the standards, the technical field to which the standards belong, the nature of the standards, the scope for the implementation for the standards, relevant licensing terms and other factors.
>
> If other laws or administrative regulations have provisions on the patent of the implemented standards, those provisions should be observed.[11]

The State Administration of Industry and Commerce ("SAIC"), one of the antitrust enforcement agencies responsible for non-price enforcement, issued rules concerning IPR and antitrust earlier this year. One such rule provides that "[w]ithout justifiable reasons, operators with dominant market position shall not eliminate or restrict competition by refusing to license other operators to use their intellectual property on reasonable terms if such intellectual property constitutes an essential facility for business operation." [12] It remains to be seen how this rule will be used in future enforcement efforts.

Chinese Antitrust Authorities and Courts Have Prohibited Injunction Seeking on SEPs

There is some early indication that Chinese antitrust authorities are considering action to prevent SEP holders from seeking injunctive relief. On two recent occasions, the Chinese Ministry of Commerce (MOFCOM) has conditioned approval of high tech acquisitions on promises to refrain from seeking injunctions. In 2014, MOFCOM conditioned approval of Microsoft's acquisition of Nokia's Devices and Services business on a proviso that Microsoft would honor all existing FRAND terms on Nokia's SEPs and "refrain from seeking injunctions over such SEPs against smartphones produced by Chinese producers."[13] In 2012, MOFCOM conditioned approval of Google's acquisition of Motorola Mobility on a promise that "Google shall continue to fulfill the FRAND (fair, reasonable, and non-discriminatory terms) obligations of Motorola Mobility regarding the latter's patents."[14] A plausible interpretation of

[11] Interpretations of the Supreme People's Court on Certain Issues Concerning the Application of Law for the Trial of Patent Infringement Dispute Cases (II) (Draft for public comments), Article 27 (2014)

[12] Provisions on the Prohibition of the Abuse of Intellectual Property Rights to Exclude or Restrict Competition (SAIC Order 74, 2015), Article 7(1).

[13] *See* Becky Koblitz, *Microsoft-Nokia: China's MOFCOM Quietly Slips Into the Debate about Injunctive Relief for FRAND-Encumbered SEPs*, Antitrust Law Blog, Apr. 23, 2014, available at http://www.antitrustlawblog.com/2014/04/articles/articles/microsoft-nokia-chinas-mofcom-quietly-slips-into-the-debate-about-injunctive-relief-for-frand-encumbered-seps/.

[14] Announcement No. 25, 2012 of the Chinese Ministry of Commerce – Announcement of Approval with Additional Restrictive Conditions of the Acquisition of Motorola Mobility by Google,

these orders is that injunctive relief for an SPE is in fact permissible under Chinese law, and thus the orders are spelling out, as part of a merger decision, a commitment to give up that remedy.

Moreover, in the recent *Huawei v. IDC* case, a Chinese court found that a SEP owner had abused its patent rights and thereby violated Chinese antitrust law by seeking an injunction in a U.S. court against an alleged infringer. In 2011 InterDigital (IDC), an American patent licensing company, brought suit against Huawei, a Chinese smartphone manufacturer, in the District of Delaware as well as the U.S. International Trade Commission (ITC).[15] In both fora, IDC requested injunctions against Huawei for alleged infringement of seven SEPs owned by IDC.[16]

Huawei subsequently sued IDC in China, alleging an antitrust violation, and the Chinese trial court in Shenzhen found for Huawei, holding that IDC's injunction seeking in the United States was an abuse of dominance and a misuse of IDC's patents.[17] The trial court ordered IDC to resume licensing negotiations, placed a cap on the royalty rate IDC could receive from Huawei, and awarded Huawei ¥20M CNY in damages (approximately $3.2M USD).[18] IDC appealed, and in October 2013 the trial court's decision was affirmed by the Guangdong Higher People's Court.[19] The court characterized IDC's attempt to seek an injunction as a patentee negotiation tactic:

> Given that IDC breached its FRAND duties; IDC filed actions against Huawei in Delaware court and ITC to seek injunction remedy for its SEPs while the two parties were still in negotiating stage, requesting Huawei to stop using its SEPs; Huawei was in good faith during the whole negotiation process, while the goal for IDC to file these actions was to force Huawei to accept the unreasonably high royalty rates; SEP holders may not force a good faith negotiating party to accept terms for using SEPs; IDC's conduct therefore constitutes abusing its dominant market position.[20]

available at http://english.mofcom.gov.cn/article/policyrelease/domesticpolicy/201206/20120608199125.shtml.

15 Florian Mueller, *InterDigital Sues Huawei, ZTE and Nokia Over 3G Patents*, Foss Patents, Jul. 26, 2011, available at http://www.fosspatents.com/2011/07/interdigital-sues-huawei-zte-and-nokia.html.

16 *Id.*

17 Michael Han & Kexin Li, *Huawei v. InterDigital: China at the Crossroads of Antitrust and Intellectual Property, Competition and Innovation*, Competition Policy International Asia Column, Nov. 28, 2013, available at https://www.competitionpolicyinternational.com/huawei-v-interdigital-china-at-the-crossroads-of-antitrust-and-intellectual-property-competition-and-innovation/.

18 *Id.*

19 *Id.*; for the text of appellate court's decision (in Chinese), *see* http://www.gdcourts.gov.cn/gdcourt/front/front!content.action?lmdm=LM43&gjid=20140417030902158689.

20 *Huawei Technology Ltd. v. InterDigital Technology Corporation*, Yue Gao Fa Min San Zhong Zi 306, (Guangdong Higher People's Court, 2013), p. 57, para 1.

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

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[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]

<u>Evolution of S. 2019 – The Preserve Access to Affordable Generics Act</u>

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.