

Antitrust Issues in Licensing

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Antitrust risks arise in common intellectual property transactions. This article reviews the general principles in the antitrust analysis of transactions involving the licensing of intellectual property rights, and applies those principles in the context of practical counseling.

I. Overview

Historically, the view was that there is an inherent conflict between intellectual property rights laws that grant “monopolies” and the antitrust laws that prohibit monopoly. An intellectual property right (IPR) was assumed to confer upon the holder some monopoly.

The IPR laws and the antitrust laws are now commonly viewed as complementary. Both value innovation, competition and consumer welfare.¹ The view is that the IPR laws do not necessarily confer monopolies, but confer only the right to exclude others from the areas covered by the IPR. In actuality, most patents are either never put into practice, or, if practiced, do not convey any market power at all. Intellectual property rights are considered to be a form of personal property rights.² Where the holder of an IPR tries to extend its market power beyond the scope of the IPR, antitrust laws apply.

Antitrust analysis of transactions involving IPR is highly fact-specific and each scenario should be analyzed for antitrust risk. This is true even if no risks are immediately apparent, or if a

¹ See, *e.g.*, Antitrust Division of the Department of Justice and the Federal Trade Commission Joint 1995 Antitrust Guidelines for the Licensing of Intellectual Property (“IP Guidelines”) §1.0 <http://www.usdoj.gov/atr/public/guidelines/ipguide.htm>; *Atari Games Corp. v. Nintendo of North America, Inc.*, 897 F.2d 1572, 1576 (Fed. Cir. 1990).

² See, *e.g.*, 35 U.S.C. §261 (“[P]atents shall have the attributes of personal property.”).

current transaction seems very similar to a past deal that had little risk.

A. General Principles

Licenses of intellectual property rights are generally considered pro-competitive. They often enable the licensor to exploit technology that the licensor may not have the ability to develop or market, and provide the licensee with access to technology that it could bring to market with its financing, manufacturing and marketing capabilities. The Antitrust Division of the Department of Justice and the Federal Trade Commission recognized in their 1995 Antitrust Guidelines for the Licensing of Intellectual Property (“IP Guidelines”) that licenses might afford efficient exploitation of IPR and enable complements to come together to the benefit of consumers by lowering costs and speeding the introduction of new products and services. The key factor is whether the license “harms competition among entities that would have been actual or likely potential competitors...in the absence” of the relationship.³ Therefore, the basic antitrust test for licenses is the rule of reason.

However, the enforcement agencies have also cautioned that the licenses must involve substantial IPR. The issue is whether the IPR that is being licensed is sufficiently substantial to be licensed and subject to any related or ancillary restraints contained in the license. The IPR that is the subject of the license must not be a pretext for an agreement that is in substance a restraint of trade. Thus, for example, in *United States v. Pilkington plc*,⁴ the Antitrust Division obtained a consent decree settling allegations that the licenses there related to expired patents and trade secrets for the manufacture of flat glass and were but pretexts for allocating the worldwide market among competitors, preventing the use of competing technology and consolidating control of new technology through the use of grant back obligations.

³ IP Guidelines §3.1.

⁴ 1994-2 Trade Cas. (CCH) ¶70,842 (D. Ariz. 1994).

Licenses among competitors should be closely scrutinized, to ensure that they do not enable competitors to allocate the market or limit output. Such “horizontal” market agreements are *per se* illegal. For example, in *United States v. The MathWorks, Inc.*,⁵ MathWorks, Inc. and Wind River Systems, Inc. competed in the development and sale of software used by aerospace and automotive manufacturers to design and test dynamic control systems. They entered into agreements that gave MathWorks the exclusive worldwide right to price and sell Wind River’s MATRIXx product for two years, transferred the customer support of MATRIXx to MathWorks, required Wind River to stop developing MATRIXx, and gave MathWorks the option to acquire MATRIXx in two years. The Department of Justice alleged that these agreements were *per se* illegal in that they allocated markets and fixed prices in violation of Section 1 of the Sherman Act. The agreements also allegedly unreasonably reduced competition by eliminating Wind River from the market. The government obtained the divestiture of MATRIXx to restore competition.⁶

Particular types of licenses may require more scrutiny than others, specific types of licensor-licensee combinations may need more review, and the relationships of the IPR involved could require careful consideration if more than one IPR is involved. Certain types of license restrictions also need extra care. One court has seemingly endorsed the position that a patent holder can impose onerous license conditions, such as mandatory cross-licenses and resolution of outstanding litigation, without antitrust exposure, because a patent holder can after all refuse to license at

⁵ *United States v. The MathWorks, Inc.*, No. 02-888-A (June 21, 2002) (complaint), www.usdoj/atr/cases/f11300/11369.htm.

⁶ *United States v. The MathWorks, Inc.*, No. 02-888-A (E.D. Va. March 17, 2003) (final judgment), <http://www.usdoj.gov/atr/cases/f200800/200890.htm>. This case is also an example of conduct that may have been inoffensive if undertaken by a single entity, but was suspect when engaged in by ostensibly independent entities. The result may have been different if MathWorks had simply acquired Wind River or the MATRIXx product line.

all on any terms to begin with.⁷ However, another court views the position that license restrictions can all be justified by the simple existence of the IPR being licensed, as being “no more correct than the proposition that use of one’s personal property, such as a baseball bat, cannot give rise to tort liability.”⁸ The more prudent approach in counseling is to assume that IPR holders’ rights are not unlimited. “Intellectual property rights do not confer a privilege to violate the antitrust law.”⁹

Trademark licenses less frequently raise the types of issues often seen with patent and copyright licenses. However, in one case, the Federal Trade Commission alleged that the parties to a trademark license agreement used the license as part of an agreement to allocate the world market in microcrystalline cellulose, and obtained a consent order.¹⁰ Antitrust issues must be considered when groups of competitors join to develop a common trademark.¹¹

Beyond licenses, other transactions involving IPR may also have antitrust risk, such as acquisitions, settlement agreements or standards development activities, many of which involve IPR licenses. As in most antitrust analysis, the evaluation of the antitrust implications of such transactions are fact-specific and the transactions are generally reviewed under the standard of reasonableness.

⁷ *Townshend v. Rockwell International Corp.*, 2000-1 Trade Cas. (CCH) ¶72,890 (N.D. Cal. 2000).

⁸ *United States v. Microsoft Corp.*, 253 F.2d 34, 63 (D.C. Cir.), *cert. denied*, 534 U.S. 952 (2001).

⁹ *In re Independent Service Organizations Antitrust Litigation*, 203 F.3d 1322, 1325 (Fed. Cir. 2000), *cert. denied*, 531 U.S. 1143 (2001).

¹⁰ Complaint and Consent Order, FMC Corp. and Asahi Chemical Industry Co., Ltd., File No. 981-0237 (Dec. 21, 2000).

¹¹ *United States v. Sealy, Inc.*, 388 U.S. 350 (1967); *United States v. Topco Associates*, 405 U.S. 596 (1972).

B. Guidelines

The Antitrust Division of the Department of Justice and the Federal Trade Commission in 1995 issued the IP Guidelines which are consistent with the current view of IPR and antitrust, and in 2007 issued a joint report reaffirming their basic rule of reason analysis of IPR licenses.¹² These, and other guidelines issued by the federal antitrust enforcement agencies, provide good road maps to counseling.

The IP Guidelines apply to patent, copyright and trade secrets licenses, not to trademark licenses, which often have different competition implications. They outline the approach of the federal antitrust agencies in this area, and apply to patent, copyright and trade secrets licenses the same antitrust principles used to analyze conduct relating to any other type of personal property.

In their guidelines, the agencies define not only traditional products and services markets that may be relevant in antitrust analyses,¹³ but also technology and innovation markets. “Technology markets” are markets in which companies compete in the licensing of intellectual property. They

consist of the intellectual property that is licensed (the “licensed technology”) and its close substitutes -- that is, the technologies or goods that are close enough substitutes significantly to constrain the exercise of market power with respect to the intellectual property that is licensed.

¹² U.S. Department of Justice & Federal Trade Commission, Antitrust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition at 102 (2007) (“DOJ/FTC 2007 IP Report”).

¹³ The 1992 Horizontal Merger Guidelines provide general guidance regarding how the agencies determine relevant product and service markets in their antitrust analyses. <http://www.usdoj.gov/atr/public/guidelines/hmg.htm>.

When rights to intellectual property are marketed separately from the products in which they are used, the Agencies may rely on technology markets to analyze . . . competitive effects. . . .

IP Guidelines ¶ 3.2.2. “Innovation markets,” sometimes called research and development or R&D markets, are defined by the agencies as markets in which firms compete in research and development. They explain in the IP Guidelines:

A licensing arrangement may have competitive effects on innovation that cannot be adequately addressed through the analysis of goods or technology markets. For example, the arrangement may affect the development of goods that do not yet exist. Alternatively the arrangement may affect the development of new or improved goods or processes in geographic markets where there is no actual or likely potential competition in the relevant goods.

IP Guidelines ¶ 3.2.3.

With respect to restrictive terms in licenses, the IP Guidelines provide a safety zone. A restriction will not be challenged by the federal antitrust authorities if it is not one that is “facially anticompetitive” and therefore *per se* violative of the antitrust laws, such as price fixing, and either (a) the parties collectively hold less than 20% of each of the markets that are affected by the restriction, or (b) where no meaningful market share data can be obtained, there are at least 4 other independent competitors in the technology or innovation markets involved.

The 2000 Antitrust Guidelines for Collaborations among Competitors¹⁴ cover collaborations generally, including those based on IPR and R&D. These guidelines provide a safe harbor where the innovation market involved has at least 3 independent competitors with the specialized assets or characteristics, and the

¹⁴ <http://www.ftc.gov/os/2000/04/ftcdojguidelines.pdf>.

incentives, to engage in R&D that are alternatives to the R&D of the collaboration.

The guidelines are only indicators of the position of the federal enforcement agencies.¹⁵ They are also only persuasive on the courts. There are other sources of antitrust challenges, such as private parties and states attorneys generals, who may disagree with the approach of the guidelines. While the guidelines are generally consistent with the judicial precedents, there are some areas in which the guidelines take a different view of licenses than the precedents might justify. Nonetheless, the various guidelines provide a good basis for analysis and counseling.

C. Key Questions

As in most antitrust counseling, a fact-specific analysis is required. The substance of the transaction, not the form or the parties' labeling, is key. Therefore, in counseling clients regarding

¹⁵ In addition, beginning in 2002, the Federal Trade Commission and the Department of Justice held joint hearings on "Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy." The hearings examined the role of patents in certain industries and fostering innovation, the scope of patents, the role of the Court of Appeals for the Federal Circuit, refusals to license, common intellectual property licensing practices, patent pools, standards development, settlements of patent disputes, the impact of many of these activities on consumer welfare, and comparative international approaches to these issues. Following these hearings, the FTC issued a report in October 2003, "To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy." <http://www.ftc.gov/opp/intellect/index.htm>. This report focused on the patent system and the role of the Patent Office, and made several recommendations for improvements in the patent system. The DOJ/FTC 2007 IP Report summarizes much of the hearings and the literature in the area, and sets forth the agencies' analysis of unilateral refusals to license patents, IPR "hold ups" in standards development, and various IPR licensing practices. Hearings jointly sponsored by the FTC, DOJ and the U.S. Patent & Trademark Office continued through 2010, and on March 7, 2011 the FTC released a report entitled "The Evolving IP Marketplace: Aligning Patent Notice and Remedies with Competition" which offers recommendations on improvements in the patent system, particularly as to notice and remedies. <http://www.ftc.gov/os/2011/03/110307patentreport.pdf>

the antitrust pitfalls in IPR transactions, there are several key factual questions. The application of antitrust principles to the answers to these questions will determine the appropriate antitrust advice.

The first area to review is the business context of the transaction and the business reasons for the deal. What is the current relationship of the parties? Are they actual or potential competitors in the area of the license, or do they hold competing technology? If the parties are actual or potential competitors, then the prospective licensee may already have technology that competes with or substitutes for the technology that is being licensed. A license between firms with competing technology, of some of that technology, would be considered “horizontal”. A license that is considered a “horizontal” arrangement requires closer scrutiny than a “vertical” arrangement between parties on different levels of a distribution chain, and the agreement would be scrutinized to determine whether there is an impermissible restraint between competitors.

If the licensee lacks the capability that the license will provide, then the license is considered a “vertical” license between “supplier” and “buyer” that will generally be subject to more lenient examination, even if the parties will be competing in the area of the license. There is much less concern about anticompetitive effects resulting from transactions that do not interfere with competition that would probably have taken place absent the arrangement. Vertical licenses generally would not affect any competition that would have existed absent the license. In vertical licenses, the concerns generally are that the license may foreclose access to a necessary input or a distribution channel, raise rivals’ costs or may facilitate coordination among competitors.

Where the parties have technologies that are “blocking”, so that one party cannot exploit its technology without infringing on the rights of the other party, the situation has both “horizontal” and “vertical” features. In those cases, the technologies are often competing. On the other hand, each of the technologies may provide a capability that the other lacks. A key factor would be whether the license is necessary to resolve a technology impasse

and has only the scope needed for that resolution, or whether it is a pretext for market allocation between competitors.

Another approach is to consider whether a licensee would need all the IPR involved in order to be technically, economically and/or legally viable. Package licenses of basic and improvement patents held by different entities may be needed to ensure that a state-of-the-art product is enabled. Access to only one of several blocking or complementary patents will not enable the holder to exploit the technology. Where there is such a clear business need for the license, there is less likelihood of antitrust issues arising from the grant of the license. On the other hand, if the business reason for the license is to avoid “ruinous competition” or “stabilize” the market, antitrust questions are more likely.

Therefore, what is the arrangement that the parties are contemplating? What are the business goals that they are seeking to achieve by this arrangement, and how will the arrangement help them achieve those goals? How do the parties contemplate the relationship actually working? The nature of the IPR involved, and the relationships among the IPRs, if more than one IPR is involved, are important, along with the business reasons for including the particular IPRs in the license. In answering these questions, the record should also be reviewed. For example, what do the memoranda, PowerPoint presentations, and emails of the business persons involved in the transaction indicate?

Once these aspects are determined, there is a context in which to analyze the situation. The business needs for the arrangement and its terms may help demonstrate the reasonableness of the transaction.

The bottom line is the competitive impact of the proposed transaction. Who are the competitors that may be affected by the deal? Are the parties actual or potential competitors without the license relationship? Would the deal result in the elimination of an actual or potential competitor as an independent market participant, or would any market participant be excluded or handicapped as a result? What might be the impact on prices and outputs in the markets involved in the transaction? What might be the impact on incentives to innovate? What might happen to the

next generation of products? Who are developing the next generation of products, and what might be the impact of the license on their ability or motivation to continue development of the next generation? What might be the impact on the parties' market positions? Might the license help entrench an already dominant market player? Would the relationship create opportunities for collusion?

In answering these questions, it is useful to identify the markets that may be affected by the transaction. What products, services, geographic areas may be involved? Are we looking at technology or innovation markets? The market positions of the parties in these markets need to be considered. The existence of competing or substitute technologies or of potentially competing or substitute technologies to the technology that is being licensed should be determined; their presence may mitigate any restrictive impact of the transaction on competition. What are the barriers to entry into any of the affected markets? If it is fairly easy to enter into the markets, then any anticompetitive impact of the transaction may be easily nullified. Does the arrangement fall within any of the safe harbors of the guidelines? If any safe harbor applies, then there is generally little cause for concern, so long as the situation is monitored, particularly when a license is renewed, to ensure that the pre-requisites for the safe harbor continue to be satisfied.

If it appears that the proposed license may have the potential to reduce competition significantly in some way, such as by excluding or greatly handicapping competitors or potential competitors, or cutting output or raising prices, then additional factors needed to be considered. What efficiencies might the license accomplish that cannot be achieved another way? If there are such efficiencies that are substantial, then it may offset the potential anticompetitive impact of the arrangement. An important practical question is, who might complain about the transaction, and what might they do about their complaints?

If the analysis indicates that there are significant antitrust risks to what the parties are contemplating, then it is important to explore alternatives. In most cases, a viable alternative arrangement can be developed that could achieve the parties'

business goals, or a close approximation thereof, without or with fewer antitrust concerns, upon a closer examination of the business goals and how the parties expected the original proposed arrangement to accomplish those goals.

II. Refusals to License, Tie-ins and Package Licenses

In some instances, the very refusal to license may raise antitrust issues. This refusal may arise in the context of a request for a license that is rejected, or may arise in the context of a licensor taking the position that a particular IPR will not be licensed unless the licensee also accepts other IPRs, goods or services or cross licenses to the licensor.

The patent law provides specifically that:

No patent owner otherwise entitled to relief...shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having...(4) refused to license or use any rights to the patent; or (5) conditioned the license of any rights to the patent or the sale of the patented product on the acquisition of a license to rights in another patent or purchase of a separate product, unless, in view of the circumstances, the patent owner has market power in the relevant market for the patent or patented product on which the license or sale is conditioned.

35 U.S.C. §271(d). It should be noted that §271(d)(4) differs from the law in some other jurisdictions, such as some parts of Europe, which effectively requires the patent holder to use or lose the patent. Compulsory licenses are more readily accepted in some jurisdictions as remedies for a refusal to license.¹⁶

The antitrust laws provide that “[e]very person who shall

¹⁶ See, e.g., *IMS Health Inc. v. NDC Health Corporation*, Case C-418/01, 2004 E.C.R. I-05039 (April 29, 2004); China’s Patent Law Article 48.

monopolize, or attempt to monopolize...shall be deemed guilty of a felony...” Sherman Act §2, 15 U.S.C. §2. It also prohibits “every contract, combination...or conspiracy, in restraint of trade...” which in rule of reason situations generally requires a showing of impact on the market that is often inferred from the existence of market power. Sherman Act §1, 15 U.S.C. §1. The federal antitrust agencies view unilateral unconditional refusals to license as generally inoffensive while conditional refusals to license that have competitive impact will be scrutinized, especially where the prospective licensee has market power in the area of the IPR to be licensed.¹⁷ Therefore, in this area, the patent law might generally reach a result that is consistent with that under the antitrust laws.

A. Refusals to license

The general rule is that “[a] patent owner is not in the position of a quasi-trustee for the public or under any obligation to see that the public acquires the free right to use the invention. He has no obligation either to use it or to grant its use to others.”¹⁸ Therefore, even a monopolist may refuse to license a patent.¹⁹ It

¹⁷ DOJ/FTC 2007 IP Report at 32.

¹⁸ *Hartford-Empire Co. v. United States*, 323 U.S. 386 (1945).

¹⁹ However, the FTC obtained a consent agreement from Intel settling charges that Intel violated the antitrust laws by refusing to disclose some microprocessor trade secrets to customers who were accusing Intel of patent infringement, unless the licensees licensed their patents to Intel. *Intel Corp.*, 128 F.T.C. 213 (1999). The court found a genuine issue of material fact in *In re Microsoft Corp. Antitrust Litigation*, 699 F. Supp. 2d 730 (D. Md. 2010), *rev'd and remanded on other grounds sub nom. Novell, Inc. v. Microsoft Corp.*, 2011 U.S. App. LEXIS 9062, 2011-1 Trade Cas. (CCH) ¶77,434 (4th Cir. 2011), where Microsoft allegedly, among other conduct, refused to license its logo to plaintiff, a competitor in word-processing and spreadsheet applications, while licensing the logo to others who did not pose a similar competitive threat. Nonetheless, a patentholder is not required to continue to license its technology when it is promoting newer technology. *See, e.g., IBM v. Platform Solutions, Inc.*, 2009 U.S. Dist. LEXIS 91089 (S.D.N.Y. 2009).

would seem unlikely that the essential facilities doctrine²⁰ can be successfully invoked in such a situation. Moreover, the status of the essential facilities doctrine is in flux following the Supreme Court's *Trinko* decision, in which the Court expressly refused to endorse or repudiate the doctrine but commented that requiring owners of an essential facility to "share their advantage" with rivals "may lessen the incentive for the monopolist, rival, or both to invest in those economically beneficial facilities," compels the courts to "act as central planners," and compels "negotiation between competitors [that] may facilitate ... collusion."²¹

However, a concerted refusal to license is suspect; it can be considered a group boycott. For example, a cross-license that requires joint approval of the parties before any of the IPR involved is licensed to a third party may be questionable. In the copyright area, the Second Circuit has concluded that there may be an antitrust claim if copyright holders agree to limit licenses to third parties. In *PrimeTime 24 Joint Venture v. NBC*,²² a retransmitter alleged that major broadcast television networks, local affiliates and the National Association of Broadcasters not only brought baseless infringement suits against it, but also agreed

²⁰ The essential facilities doctrine comes into play when an entity (1) with monopoly power in one market which is an input for another market, (2) is also a competitor in that second market, and (3) uses that monopoly power against competitors in the second market by denying access to the input. The competitor in the second market seeking access must show that (a) the IPR owner controls that essential facility, (b) the competitor cannot practically duplicate that "facility", and (c) it would have been feasible for the IPR owner to provide access to the IPR. See, e.g., *United States v. Terminal R.R. Ass'n*, 224 U.S. 383 (1912); *MCI Communications Corp. v. AT&T*, 708 F.2d 1081, 1132 (7th Cir.), cert. denied, 464 U.S. 891 (1983); *Montgomery Co. Ass'n of Realtors, Inc. v. Realty Photo Master Corp.*, 878 F. Supp. 804, 817 (D. Md. 1995), *aff'd*, 91 F.3d 132 (4th Cir. 1996).

²¹ *Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 408 (2004).

²² 219 F.3d 92 (2d Cir. 2000).

not to license future re-transmission rights to it.²³

A refusal to license in order to exclude potential competitors from the market place may be an antitrust violation, if that exclusion extends beyond simply excluding others from use of the IPR. In *Data General Corp. v. Grumman Systems Support Corp.*,²⁴ the court held that copyright confers no automatic antitrust immunity for a unilateral refusal to license. However, that court also indicated that an intent merely to exclude others only from using the copyright is a presumptively valid business justification for a refusal to license, so that no violation of the Sherman Act would be found.

In *Image Technical Services, Inc. v. Eastman Kodak Co.*,²⁵ Kodak changed an existing policy and stopped selling patented and unpatented parts to independent service organizations that repaired Kodak copier equipment in competition with Kodak's service business. The U.S. Supreme Court had held earlier that the plaintiffs can go to trial on their claim that Kodak tied its patented parts to its unpatented parts, and that Kodak may have market power over its installed base of customers in the aftermarket parts area because those customers may not be able to switch from Kodak equipment without significant costs.²⁶ On remand, the jury found that Kodak had used its market power in the supply of patented parts to its installed base of customers to obtain market position in the supply of service and unpatented parts to those

²³ Conversely, joint action by potential licensees refusing to negotiate with a patent holder or seeking common license terms may be a group boycott in violation of the antitrust laws. See, e.g., *Jones Knitting Corp. v. Morgan*, 361 F.2d 451 (3d Cir. 1966); *OLA, LLC v. Builder Homesite*, 661 F. Supp. 2d 668 (E.D. Tex. 2009); *Sony Electronics Corp. v. Soundview Technologies, Inc.*, 157 F. Supp. 2d 180 (D. Conn. 2001).

²⁴ 36 F.3d 1147 (1st Cir. 1994).

²⁵ 125 F.3d 1195 (9th Cir. 1997), *cert. denied*, 523 U.S. 1094 (1998).

²⁶ *Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451 (1992).

customers. The Ninth Circuit found that the patentee's statutory right to exclude others from the area covered by the patent creates a rebuttable presumption of a valid business justification for a unilateral refusal to license or sell under the patent. However, the use of that right to exclude, to extend the market power of the patent to a market beyond the scope of the patent, may be monopoly-leveraging offensive to the antitrust laws.²⁷ The Court of Appeals concluded that the presumption of valid business justification was rebutted by a showing that Kodak refused also to sell or license its unpatented and uncopyrighted parts, while its patented or copyrighted parts accounted for only a small percentage of replacement parts for its equipment.

In comparison, in *In re Independent Service Organizations Antitrust Litigation*,²⁸ the Federal Circuit found that Xerox did not violate the antitrust laws by its refusal to sell patented replacement parts to independent service organizations that service and repair Xerox copiers in competition with Xerox. CSU, an ISO, claimed that Xerox monopolized the market of the service and repair of Xerox copiers. The Federal Circuit concluded that Xerox had no obligation to sell or license its patented parts. That court found that Xerox's motivation for its unilateral refusal to sell or license its patented parts is irrelevant. It reasoned that there should be antitrust liability only if there was illegal tying, fraud on the Patent & Trademark Office in connection with the patent, or sham litigation to enforce the patent. CSU didn't claim that Xerox tied

²⁷ On the other hand, the continuing vitality of the monopoly-leveraging theory is in doubt with the Supreme Court's decision in *Trinko*, 540 U.S. at 415 n. 4 ("to the extent the court of appeals [in considering monopoly-leveraging] dispensed with a requirement that there be a 'dangerous probability of success' in monopolizing a second market, it erred"), citing *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 459 (1993). See also *In re Independent Serv. Orgs. Antitrust Litig.*, 114 F. Supp. 2d 1070, 1088-89 (D. Kan.), *aff'd*, 203 F.3d 1322 (Fed. Cir. 2000), *cert. denied*, 531 U.S. 1143 (2001) ("A patentee may unilaterally exclude others...even if such conduct allows the patentee to obtain monopolies in multiple markets.").

²⁸ 203 F.3d 1322 (Fed. Cir. 2000), *cert. denied*, 531 U.S. 1143 (2001).

its patented parts to its unpatented parts, or allege that there was fraud on the PTO or sham litigation by Xerox. The court stated that, since *Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc.*,²⁹ protects litigation to enforce IP rights in such situations, that precedent also protects refusals to license in such situations. It found that there could be no antitrust liability if the competitive impact of the refusal to deal was in a market within the scope of the patent. The Federal Circuit also applied the logic of *Data General* to copyrighted software and manuals relating to the copiers, and found that Xerox's motivation was irrelevant where there was no evidence that the copyrights were improperly obtained or used to gain monopoly power beyond the scope of the copyright.

1. The Non-Use of Acquired Patents May Create Antitrust Risk

The analysis may differ where the refusal to deal is accompanied by non-use of the IPR by the IPR holder, so that the IPR is not being used at all. The IPR is being withheld from the marketplace entirely. In that case, there may be a differentiation between "suppressed" IPR that was developed by the IPR holder and "suppressed" IPR that was acquired by the IPR holder from others. The standard may be stricter for conduct relating to acquired technology than that for internally developed technology.

Where the IPR holder developed the technology, the inventor is entitled to a patent if the technology was patentable, even if there was an intent not to use or license the patent.³⁰ A monopoly that might result from such non-use of a patent is not an antitrust violation. It is unlikely that an essential facilities theory would prevail, since the technology is not being used at all.

On the other hand, if the technology that is being "warehoused" was acquired, a different analysis might apply. The

²⁹ 508 U.S. 49 (1993).

³⁰ *Hartford-Empire Co. v. United States*, 323 U.S. 386, clarified 324 U.S. 570 (1945).

acquisition of technology is subject to Clayton Act §7 and Sherman Act §2, although the mere accumulation of patents in a single field, no matter how many, is not an antitrust violation.³¹ Problems may arise, however, based on the intent of the acquirer and how the acquisition of the patents affected competition. For example, in *Kobe, Inc. v. Dempsey Pump Co.*,³² the court found that there was acquisition, non-use and vigorous enforcement of “every important patent” in the field with the intent to exclude competition. The patent holder also obtained covenants not to compete from the sellers of the patents that were acquired, and widely publicized its infringement suits enforcing its patent portfolio. The court there found that the result was a “complete monopoly of the business relating to hydraulic pumps for oil wells.”

Nonetheless, even if there is suspect suppression of acquired technology by the patent holder, the inventor of the technology who sold it may not have antitrust standing to challenge the subsequent suppression of the technology.³³ Moreover, even though the case did not involve IPR but regulated telecommunications services, the reasoning of the Supreme Court in *Trinko* would appear to apply to refusals to license and raise significant doubts as to when, if ever, such a refusal may rise to the level of an antitrust violation, especially in the context of 35 U.S.C. §271(d)(4).

B. Tie-ins

If a client wants to grant a license, but only if another patent is licensed or another good or service is purchased by the

³¹ *Automatic Radio Mfg. Co. v. Hazeltine Research, Inc.*, 339 U.S. 827, 834 (1950).

³² 198 F.2d 416 (10th Cir.), *cert. denied*, 344 U.S. 837 (1952).

³³ *See, e.g., McDonald v. Johnson & Johnson*, 722 F.2d 1370 (8th Cir. 1983), *cert. denied*, 469 U.S. 870 (1984); *Alling v. Universal Manufacturing Corp.*, 5 Cal. App. 4th 1412, 7 Cal. Rptr. 2d 718 (Ca. App. 1992).

licensee, use caution. The bundling of a license with another license, good or service can create significant antitrust exposure.

For a tie involving a patent to be *per se* offensive to the antitrust laws, the following need to be demonstrated: (1) the patent used as the tying item has market power; (2) in order to obtain a license on the patent, the licensee is required to take something else from the patent holder, an entity related to the patent holder, or an entity that will give the patent holder an economic interest in the transaction involving the tied item; and (3) a substantial volume of the tied item is involved.³⁴ If these three attributes are not all present, a tie would not be *per se* offensive to the antitrust laws, but might still be found to be an unreasonable restraint of trade, which is much more difficult to demonstrate if the attributes are absent. The federal antitrust agencies have indicated that they would balance the anticompetitive effects and procompetitive efficiencies of a tie involving IPR.³⁵

The early common presumption that an IPR conveyed market power was eventually abandoned in the IP Guidelines, the patent law, and most modern lower court case law.³⁶ The Supreme Court eliminated any doubt by ruling in *Independent Ink, Inc. v. Illinois Tool Works, Inc.*³⁷ that there is no presumption that a patent conveys market power. After reviewing its precedents on tie-ins, particularly where patents were involved, and the 1988 amendment to section 271(d)(5) of the Patent Act expressly renouncing any presumption of market power in a patent, the Supreme Court concluded there was no basis for any such presumption surviving in the antitrust context. Therefore, tying

³⁴ See, e.g., *Eastman Kodak Co. v. Image Technical Services*, 504 U.S. 451 (1992); *Northern Pac. Ry. v. United States*, 356 U.S. 1, 5-6 (1958).

³⁵ DOJ/FTC 2007 IP Report at 114.

³⁶ See, e.g., 35 U.S.C. §271(d)(5); *Orion Electric Co. v. Funai Electric Co.*, 2002 WL 377541 (S.D.N.Y. Mar. 11, 2002).

³⁷ 547 U.S. 28, 126 S. Ct. 1281, 1293 (2006).

arrangements involving patents are unlawful only if there is proof of market power in the tying patent.

A tie can be found not only by express agreement, but also by conduct. For example, in *C.R. Bard, Inc. v. M3 Systems, Inc.*,³⁸ the court found that modifying a patented biopsy gun so that only the patent holder's needles can be used with the gun effectively imposed a tie.

For intellectual property, a finding of a tie may have repercussions beyond antitrust. If a tie in violation of the antitrust laws is found, then it is also a misuse of the patent, in which case the patent holder cannot enforce the patent against any infringer at all, until the misuse has been purged.

The existence of an impermissible tie may arise in the context of patent pools and package licenses. In the copyright area, the block booking of movies is still a source of tying claims. In those cases, a film distributor requires movie theatres to book less desirable films in order to be permitted to exhibit a potential blockbuster. Trademark licenses, especially in the context of franchises, often raise issues of improper tie-ins.³⁹

The initial question in evaluating a tie is the business reason for the tie. If separate IPRs are involved, are they blocking or complementary IPRs, so that it is as a practical matter not feasible to use only one of the IPRs without also using the other? If the IPRs are complementary or blocking, then there is a substantial business reason for the tie.

If the IPR is being tied to something that is distinct and not

³⁸ 120 F. Supp. 2d 1145 (N.D. Ill. 2000).

³⁹ See, e.g., *Susser v. Carvel Corp.*, 332 F.2d 505 (2d Cir. 1964), cert. dismissed, 381 U.S. 15 (1965); *Siegel v. Chicken Delight, Inc.*, 448 F.2d 43 (9th Cir. 1971); *Redd v. Shell Oil Co.*, 524 F.2d 1054 (10th Cir. 1975); *Principe v. McDonald's Corp.*, 631 F.2d 303 (4th Cir. 1980); *Krehl v. Baskin-Robbins Ice Cream Co.*, 664 F.2d 1348 (9th Cir. 1982); *Packaging Supplies, Inc. v. Harley-Davidson, Inc.*, 2009 U.S. Dist. LEXIS 25732 (N.D. Ill. 2009).

needed to practice the IPR being licensed (or, if needed, obtainable elsewhere), then the market power commanded by the IPR needs to be examined. The market position of the tying technology may be insignificant, or there may be several competing technologies, in which case the tie is not a *per se* violation of the antitrust laws and also unlikely to be found to be an unreasonable restraint on trade. This may be the case especially with new and untried technology, which the holder might package with other items to increase its attractiveness to potential licensees. However, if the tying technology is the dominant technology, then there may be market power that is being abused by the tie. In the context of patents particularly, the situation must be monitored over time. A patent that may not have any market power when a license was first issued, may have substantial market power when the license is up for renewal.

The impact of a tie involving IPR with substantial market power must be examined. The extent of the exclusion of other suppliers of the tied item from potential customers is an important factor; these competing suppliers may be denied significant access to the marketplace, if their likely customers are buying the tied item from the IPR holder and not from them because of the customers' need for the tying IPR.

C. Package Licenses

A package license might be characterized as a tie in which both the tying item and the tied item are IPR.⁴⁰ The licensor bundles several patents and/or technologies into one license. The reasoning of *LePage's Inc. v. Minnesota Mining and Manufacturing Co.*,⁴¹ regarding the antitrust analysis of loyalty rebates and discounts, might indicate that certain royalty structures

⁴⁰ Cf., *U.S. Philips Corp. v. International Trade Commission*, 424 F.3d 1179 (Fed. Cir. 2005), *cert. denied*, 126 S. Ct. 2899 (2006) (in context of patent misuse, a package license does not require the licensee to use all the IPR licensed).

⁴¹ 324 F.3d 141 (3d Cir. 2003), *cert. denied sub nom. 3M Co. v. LePage's Inc.*, 542 U.S. 953 (2004).

can be construed to create package licenses.

The key question is the need for such a package license. What are the relationships among the technologies that are bundled in the package? Are they complementary technologies that must be used together to make a complete product or service? Are they basic and improvement technologies that should be used together to produce state-of-the-art results?

If there is no need to have the technologies in one package, then the question is what is the business need for the package. A more appropriate arrangement may be separate licenses for each of the patents or technologies in the proposed package. The arrangement might otherwise be susceptible to challenge as a tie-in arrangement offensive to the antitrust laws, particularly if the tying technology has market power.

III. Patent Pools

Patent pools may be viewed as packages of technologies from more than one source.⁴² Two or more technology owners may license their technologies to each other, with the right to sublicense to others, or they may license their technology to a third party that will sublicense the pooled technology to others.

Participating in pools is not uncommon, especially in the high tech and standard setting contexts.⁴³ Pools are often pro-competitive and expedite the exploitation of technology. They may facilitate the integration of complementary technologies,

⁴² Blanket licenses in the copyright context might be analogous to patent pools. *Broadcast Music Inc. v. CBS Inc.*, 441 U.S. 1 (1979). The Department of Justice found unobjectionable a non-exclusive web-based joint news registry that the Associate Press organized, into which content owners place material that may be licensed individually or otherwise by methods the owners select. Business Review Letter of Antitrust Division, Department of Justice, dated March 31, 2010, relating to AP news registry.

⁴³ See, e.g., *Matsushita Electrical Industrial Co. Ltd. v. Cinram International, Inc.*, 299 F. Supp. 2d 370 (2004).

reduce transaction costs, clear blocking positions, and avoid costly infringement litigation. Yet, the creation and administration of a patent pool can pose serious antitrust risk as pools may restrict competition among the contributors of IPR to the pool and in markets downstream from the pool, and may also dampen innovation.⁴⁴ Package licenses from the pool may raise tying issues.⁴⁵ Key elements of the pool, such as purpose, scope, administration, and control of the flow of competitive data among pool members, must be carefully considered.⁴⁶

The first key question is the purpose of the pool. Often that explains the need to have all the technologies in a pool to provide common access to licensees. If the separately owned technologies placed in the pool are blocking or complementary technologies, then a pool may be the only practical way to exploit these technologies and the federal agencies view such pools as typically procompetitive.⁴⁷ Otherwise, a license of only one of the technologies involved may have little value, since the licensee would not have assurance of access to the other technologies that are needed along with the licensed technology.

Even if some of the technologies being pooled should be packaged, each of the technologies being pooled should be reviewed to determine whether that technology needs to be pooled with the others to fulfill the purpose of the pool and provide potential licensees with a package of technologies from different

⁴⁴ See, e.g., Nancy Gallini, Private Agreements for Coordinating Patent Rights: The Case of Patent Pools, IEL Paper in Comparative Analysis of Institutions, Economics and Law No. 5 (June 2011) <http://polis.unipmn.it/pubbl/RePEc/uca/ucaiel/iel005.pdf>

⁴⁵ Cf., *U.S. Philips Corp. v. International Trade Commission*.

⁴⁶ Similar issues have arisen in the trademark context, where teams in sports leagues designated common agents to handle licensing of their intellectual property, their trademarks and logos. *American Needle Inc. v. National Football League*, 130 S. Ct. 2201 (2010); *MLB Properties v. Salvino, Inc.*, 542 F.3d 290 (2d Cir. 2008).

⁴⁷ DOJ/FTC 2007 IP Report at 84-85.

sources that will enable the licensees to produce a good or service. If the pool has only the technologies needed to fulfill the purpose of the pool, then the pool is probably pro-competitive; it enables a stronger offering to potential licensees and access to the market for the owners of the technologies. In that case, even if the pool will be the only source of such a package of technologies, its creation is unlikely to be challenged as anti-competitive.

If the technologies that are being pooled are not blocking, complementary, or a basic technology and its improvements, then the business reasons for creating the pool should be determined. Concerns that may be raised by these considerations are amplified if the parties are actual or potential competitors outside the pool, in the area that is covered by the pool, especially if they hold significant market positions.

If in fact the technologies being pooled are substitutes for each other, so that they are really competing technologies and practicing one of them will not infringe on any of the others, the better approach may be for the technologies not to be pooled but for the technology owners to compete for licensees and license their technologies independently. The pool may include more technology than is warranted. However, if the “duplicative” technologies cannot be fully utilized on a “standalone” basis, but must be combined with other technologies that are available only in the pool, that may justify including those “duplicative” technologies in the pool.⁴⁸ One approach may be to have all technologies be contributed to the pool on a non-exclusive basis and to remove the “duplicative” technologies from the pool, so that the “duplicative” technologies can be licensed in competition with the pool, perhaps in a competing pool together with complementary technology that was contributed to the pool on a non-exclusive basis.

The federal antitrust agencies have favored the use of third party technical experts to determine which technologies should be included in the pool, and some major patent pools have been

⁴⁸ Cf., *Broadcast Music Inc. v. CBS Inc.*, 441 U.S. 1 (1979) (blanket music licenses considered under the rule of reason).

organized with such a system.⁴⁹

Beyond the antitrust pitfalls of over-inclusion in patent pools and package licenses from such pools, the case of *U.S. Philips Corp. v. International Trade Commission*,⁵⁰ is a reminder that package licenses are also subject to attack as patent misuse rendering all the patents in the license unenforceable.⁵¹

⁴⁹ See, e.g., Business Review Letter of Antitrust Division, Department of Justice, dated October 21, 2008, relating to RFID standard patent pool; Business Review Letter of Antitrust Division, Department of Justice, dated November 12, 2002, relating to 3G wireless patent pool; Business Review Letters dated December 16, 1998, June 10, 1999, relating to DVD patent pools; Business Review Letter, dated June 26, 1997, relating to MPEG-2 compression technology pool. The Antitrust Division considers the following factors as indicating little likelihood of anticompetitive impact from a patent pool: (1) pool limited to IPR essential to industry standard, as determined by independent expert; (2) royalties allocated to IPR holders based in part on number of patents each contributed to pool; (3) IPR licensed non-exclusively to pool; (4) pool provided method for removing IPR found to be invalid, unenforceable, or no longer essential; (5) licenses offer to any interested party on non-discriminatory basis; and (6) engagement of independent licensing administrator. See, e.g., Business Review Letter of Antitrust Division, Department of Justice, dated October 21, 2008.

⁵⁰ 424 F.3d 1179 (Fed. Cir. 2005), *cert. denied*, 126 S. Ct. 2899 (2006). In analyzing whether patent misuse occurred, the Federal Circuit found that a package license was not a tie since there is no requirement that the licensee use any of the licensed IP; a patent license is merely an agreement by the licensor not to sue the licensee for infringement if the licensee should practice the patent. It concluded that, to constitute patent misuse, the package licenses there must be found to have extended the scope of “essential” patents in the package to anticompetitive effect. See also, *Princo Corp. v. International Trade Commission*, 563 F.3d 1301 (Fed. Cir. 2009), *en banc*, 616 F.3d 1318 (Fed. Cir. 2010), *cert. denied*, 131 S. Ct. 2480, 2011 U.S. LEXIS 3703 (2011) (further proceedings in dispute between Philips and Princo before the ITC).

⁵¹ See also, *U.S. Philips Corp. v. Princo Corp.*, 173 Fed. Appx. 832, 2006 U.S. App. Lexis 7631 (Fed. Cir. 2006) (reaffirming *U.S. Philips v. ITC* that 35 U.S.C. §271(d)(5) provides safe harbor from patent misuse claims and does not define patent misuse). Cf., *Globespanvirata*,

Restrictions on the contributors to the pool should be reviewed for their potential impact. The central issue with restraints relating to a pool is whether they are reasonably ancillary to the pool's legitimate purpose. Are the licenses of technology to the pool exclusive, so that the technology owners may not license the technology directly to others? Are the technology owners free to develop improvements without being required to contribute those improvements to the pool? If improvements must be licensed to the pool, what terms will be required? Any collateral agreements relating to the pool should be reviewed. There should be a clear business reason for agreements that relate to the functioning of the pool.

The administration of the pool also needs to be carefully arranged. The better approach may be to have a third party administer the pool, negotiate with licensees and establish terms and royalties. The policy of the pool should be to make licenses generally available to all financially qualified applicants, and to charge royalties that are related to the particular package of technologies licensed. Antitrust exposure may be lessened if the royalties charged by the pool are small relative to the value of the downstream products incorporating the pool's IPR. Tie-in implications should be considered. Grantback requirements should be carefully limited. Firewalls among pool participants and the pool may be appropriate, to ensure that data flows and activity coordination are limited to that needed for the functioning of the pool.

Finally, the pool's impact on future innovation should be considered.⁵² What might be the impact of the pool, as structured, on the incentives to continue to develop new technology in the

Inc. v. Texas Instrument, Inc., 2006-1 Trade Cas. (CCH) ¶75,229 (D.N.J. 2006) (granting motion to dismiss allegation of an illegal patent pool because plaintiff had not proved the pool to be a *per se* tying arrangement, citing *Philips*).

⁵² See, e.g., *United States v. Automobile Manufacturers Ass'n*, 307 F. Supp. 617 (C.D. Ca. 1969), *appeal dismissed*, 397 U.S. 248 (1970); IP Guidelines §5.5.

area?

IV. Cross Licenses

Unlike the other situations discussed in this article, there is a two-way technology flow in a cross-licensing situation. The parties in a cross-license are licensing their respective technologies to each other.⁵³

As in other situations where more than one IPR are involved, a key issue is the need for the cross-license. Does each of the parties need the technology of the other in order to fully utilize its own technology? Are the parties' technologies complementary, so that neither can bring a product or service to market without having access to the other's technology? Or are the parties' technologies blocking each other, so that each cannot use its own technology without infringing upon the other's rights? Is one party's technology an improvement upon the other's, so that the first can't use its technology without infringing on the other's rights, but the other cannot provide a competitive product or service without the first's improvement? In these types of situations, a cross-license may be the only practical way of enabling the parties to fully exploit their technologies.

On the other hand, if the parties do not need both sets of technologies in order to fully exploit their own technology, then the question must be asked why there is the linkage of the technologies in a cross-license. Separate and independent licenses of the parties' technologies might be more appropriate.

V. License Restrictions Generally, Particularly in Networks of Licenses

Just as licenses are generally beneficial to the exploitation of IPR and to consumer welfare, restrictions in licenses are often recognized to be pro-competitive, by enabling the efficient and effective exploitation of IPR, and preventing free riding.

⁵³ See, e.g., *Texas Instruments, Inc., v. Hyundai Electronics*, 49 F. Supp. 2d 893 (E.D. Tex. 1999).

Therefore, most license restrictions are tested under the reasonableness standard. For example, field of use restrictions, limiting the licensee's right to practice the licensed IPR to a particular industry, customer group or product type, are common and generally inoffensive to the antitrust laws. In many situations, such as an agreement by the licensee not to challenge the validity of the licensed patent⁵⁴ or restrictions on resale of a patented product,⁵⁵ patent concerns may be greater than antitrust concerns.

For most license restrictions, key questions are whether the restriction enables the licensor to exert control beyond the scope of the patent and whether the restriction is reasonable and ancillary to a "commercially supportable" license that is not a sham for anticompetitive purposes.⁵⁶ Therefore, the restriction should be reasonably related to the licensed IPR. If there are questions about the competitive impact of the restriction, who may complain about the restrictions and what are possible alternatives should be considered. Where the licensor holds substantial market power, even restrictions that generally raise little controversy may come under antitrust attack. The FTC reached a settlement with Intel regarding its practices that allegedly limited access to computer Central Processing Unit and Graphics Processing Unit markets, which required modifications to the change of control terms in licenses with 3 of its competitors, to decrease the potential of those terms to limit the ability of the competitors to enter into mergers or joint ventures or to raise capital.⁵⁷

⁵⁴ *Lear, Inc. v. Adkins*, 395 U.S. 653, 671 (1969).

⁵⁵ *See, e.g., United States v. Univis Lens Co.*, 316 U.S. 241 (1942); *Ethyl Gasoline Corp. v. United States*, 309 U.S. 436 (1940).

⁵⁶ *A&E Plastik Pak Co. v. Monsanto Co.*, 396 F.2d 710, 715 (9th Cir. 1968). *See also, e.g., Princo Corp. v. International Trade Commission*, 616 F.3d 1318 (Fed. Cir. 2010) (*en banc*), *cert. denied*, 131 S. Ct. 2480, 2011 U.S. LEXIS 3703 (2011) (agreement not to license competing pool technology for non-standard purposes considered reasonably ancillary without actual adverse impact on competition).

⁵⁷ Decision and Order, *In re Intel Corp.*, No. 9341, Section III.B (FTC Aug. 4, 2010) <http://ftc.gov/os/adjpro/d9341/100804inteldo.pdf>

Some license restrictions are considered *per se* violations. As a matter of counseling, clients should be advised against attempting to dictate the terms, particularly prices, at which licensees sell products produced under license.⁵⁸ Less often, the parties may attempt to restrict the terms at which the licensor will license to others. That should also be avoided.

A network of licenses with licensees who compete with each other should also be reviewed to ensure that it does not actually effectuate a cartel among the licensees, using the licensor as a hub and conduit. Exclusive territories and output limitations that are unilaterally imposed by a licensor on its licensees may be reasonable as a method to exploit its IPR efficiently and effectively. However, if such terms are included in other licenses granted by the licensor at the behest of licensees, they are suspect.⁵⁹

The business reasons for the terms should be explored. It is not uncommon that the business goals can be achieved, or approximated, by alternative license terms that are less suspect under the antitrust laws. For example, if the concern is that the licensee may sell the licensed product at such a low price that a percentage royalty will yield little revenue for the licensor, then the royalty might be set at the greater of a minimum dollar amount per unit and a percentage of the licensee's revenues.

VI. Exclusivity

Although exclusivity is common in licenses, it can lead to antitrust concerns. Whether a license is exclusive is determined by its substance, and how it is actually implemented, not by how the parties label it. An exclusive license is tested under the rule of

⁵⁸ See Section VIII, below, and *State Oil v. Khan*, 522 U.S. 3 (1997), and *Leegin Creative Leather Products, Inc. v. PSKS, Inc.*, 551 U.S. 877 (2007).

⁵⁹ See, e.g., *United States v. General Motors Corp.*, 384 U.S. 127 (1966).

reason. A key factor in the test is whether the parties would be actual or potential competitors absent the license.

A. Exclusive License

It is common that a licensor will agree not to license others in a specified area, be it geographic, use or customer group, and not to practice the IPR itself in that area. With this exclusivity, the licensee has the security of knowing that it is the only holder of the IPR in the area, and can devote its best efforts to exploiting the IPR without concern about free riders. Exclusive licenses are generally acceptable under the antitrust laws especially if other potential licensees can license similar technology from others, or if the exclusivity is unlikely to have significant impact on prices or output levels in the market generally even if specific competitors may be adversely affected. In many situations, exclusive licenses can be viewed as simply substituting the licensee for the licensor in the marketplace, and therefore not changing the competitive landscape. Moreover, refusals to license are generally not offensive to the U.S. antitrust laws.⁶⁰ In the rare case whether the licensor controls IPR that is an essential input for some products or services, then exclusive licenses might be attacked under the essential facilities doctrine.⁶¹

An exclusive license may also be viewed as the acquisition by the licensee from the licensor of the licensed IPR. The scope and terms of the license (such as a license of all rights under a patent for the remaining life of the patent) may have the effect of a transfer of the IPR for all practical purposes. In that case, Clayton Act §7, 15 U.S.C. §18, would apply, to determine whether the transaction is an acquisition that may tend to lessen competition or create a monopoly.⁶²

⁶⁰ See Section II.A.

⁶¹ See, however, Section II.A, and below.

⁶² Similar issues arise in the context of a merger or an acquisition in which IPR is transferred. In those situations, complete divestiture or licensing of IPR may be required to resolve antitrust concerns arising

from an aggregation of IPR. *See, e.g., In the Matter of Perrigo Co.*, FTC File No. 111-0083, 76 Fed. Reg. 45801 (August 1, 2011) (notice containing proposed consent agreement) (divestiture of assets, including IPR, relating to 6 generic drugs); *United States v. Dean Foods Co.*, Case No. 10-CV-59 (E.D. Wisc. July 29, 2011) (final judgment) (divestiture of dairy processing plant and trademark required in acquisition of consumer products division of Foremost Farms USA Cooperative); *In the Matter of Grifois, S.A.*, FTC Dkt No. C-4322 (Decision and Order, July 22, 2011) (divestiture of fractionation and plasma collection facilities and Koate pdFVII business and brand name); *United States v. Unilever N.V.*, Case No. 1:11-Cv-00858 (D.D.C. July 18, 2011) (proposed final judgment) (divestiture of value hair care brands); *In the Matter of Hikma Pharmaceuticals PLC*, FTC Dkt No. C-4320 (Decision and Order, June 7, 2011) (divestiture of IPR and assets relating to generic injectable phenytoin and promethazine); *In the Matter of Novartis AG*, FTC Dkt No. C-4296 (Decision and Order, October 1, 2010) (divestiture of assets and IPR related to Miochol-E eye care drug in acquisition of Alcon, Inc.); *In the Matter of The Dun & Bradstreet Corp.*, FTC Dkt No. 9342 (Decision and Order, September 10, 2010) (divestiture required of K-12 database, trademark and associated IPR); *In the Matter of Nufarm Ltd*, FTC Dkt No. C-4298 (Decision and Order, September 10, 2010) (divestiture of IPR and assets related to 3 herbicides in acquisition of A.H. Marks Holding Ltd); *In the Matter of The Dow Chemical Co.*, FTC Dkt No. C-4243 (Decision and Order, April 3, 2009) (divestiture of Rohm & Haas acrylics assets and related IPR); *In the Matter of Whole Foods Market, Inc.*, FTC Dkt No. 9324 (Decision and Order, March 6, 2009) (divestiture of 32 Wild Oats stores, IPR); *In re Teva Pharmaceutical Industries, Ltd*, FTC File No. 051-0214 (March 7, 2006) (Decision and Order) (divestiture of assets relating to 15 drugs to resolve investigation of merger); *In the Matter of Nestlé Holdings, Inc.*, FTC Dkt No. C-4082 (Decision and Order, November 12, 2003) (divestiture of Dreamery, Godiva, Whole Fruit brands of ice cream and sorbet); *In re Ciba-Geigy, Ltd.*, 123 F.T.C. 842 (1997) (non-exclusive license to third party of patent rights in HSV-tk gene therapy required in merger of two companies engaged in gene therapy); *The Upjohn Co.*, 121 F.T.C. 44 (1996) (divestiture required of Pharmacia's assets in research, development, manufacture and sale of topoisomerase I inhibitors or the treatment of colorectal cancer); *Glaxo PLC*, 119 F.T.C. 815 (1995) (divestiture required of Wellcome's worldwide research and development assets in research and development for oral drugs for the treatment of migraine attacks, and Glaxo required for a 10-year period to obtain FTC approval before acquiring more than 1% of any company engaged in clinical development, manufacture or sale of migraine drugs). *Compare Press*

An exclusive license may raise concern under §7 if the licensor and licensee are actual or potential competitors in the area in which the IPR is practiced, and there are few other competitors in that market. An exclusive license in that context may result in the exit from the market of one of the few competitors, leaving the market even more concentrated, and may violate §7. Similarly, an exclusive license may raise concern if the licensee is already the owner or exclusive licensee of a substantial amount of competing technology, so that the acquisition of the licensed IPR may result in the licensee holding much of the IPR in the area.

*In the Matter of Biovail Corporation*⁶³ is a case where the exclusive license of an essential input foreclosed competition from the licensee's competitors. Biovail manufactured and sold the drug Tiazac. When Andrx Pharmaceuticals, Inc. developed a generic version of this drug and certified to the FDA that it did not infringe any patents, Biovail entered into an exclusive license with DOV Pharmaceuticals, Inc. for a patent covering a unique formulation of the active ingredient in Tiazac. Biovail then attested that this patent covered the approved formulation of Tiazac, which prevented the FDA from granting final approval to Andrx's generic equivalent, and forced Andrx to defend its product. Thus, Biovail's exclusive license raised substantial barriers to entry into the market and gave it the power to exclude competition. Biovail entered into a consent decree with the FTC which required it to return part of the rights to the DOV Pharmaceuticals patent and prohibited it from taking any action

Release, Federal Trade Commission, Federal Trade Commission Closes Its Investigation of Genzyme Corporation's 2001 Acquisition of Novazyme Pharmaceuticals, Inc., File No. 021-0049 (Jan. 13, 2004), <http://www.ftc.gov/opa/2004/01/genzyme.htm> (FTC closed investigation of merger of only two companies engaged in research and development of enzyme-replacement treatment for Pompe disease, on basis that treatment primarily used for other ailments for which there are competitive therapies that would likely counter any effort to exercise market power in treating Pompe disease with enzyme-replacement therapy).

⁶³ FTC Docket No. C-4060 (April 23, 2002) (complaint), <http://www.ftc.gov/os/caselist/c4060.htm>.

that would trigger additional statutory stays on final FDA approval of a generic form of Tiazac.⁶⁴ Similar issues have arisen in the trademark context where a licensee has obtained exclusive licenses from sports leagues and associations.⁶⁵

In many collaborations, particularly in the biotechnology area, where exclusive IPR licenses are often coupled with an investment by the licensee in the licensor, the premerger notification requirement under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, 15 U.S.C. §18a, may also be triggered, because of the sizes of the parties and of the transaction.

B. Exclusive Dealing

Exclusive dealing is involved where the licensee is restricted from licensing similar or competing technology from others, or from developing its own IPR in the area. It provides incentive to the licensee to focus on the licensed IPR, and comfort to the licensor that knowledge transferred to the licensee might not be used to benefit the licensor's competitors.

⁶⁴ *In the Matter of Biovail Corporation*, Docket No. C-4060 (October 4, 2002) (final decision and order) <http://www.ftc.gov/os/2002/10/biovaildo.pdf>. See also, *Andrx Pharmaceuticals v. Biovail Corporation*, 256 F. Supp. 2d 799 (D.C. Cir. 2001). Similarly, exclusive supply agreements that denied essential input to competitors have been challenged. See, e.g., *Geneva Pharmaceuticals Technology Corp. v. Barr Laboratories*, 386 F.3d 485 (2d Cir. 2004) (Barr obtained exclusive supply of essential ingredient, thus allegedly delaying competitor's entry into market and allowing Barr a monopoly); *FTC v. Mylan Laboratories*, 62 F. Supp. 2d 25 (D.D.C.), *modified*, 99 F. Supp. 2d 1 (D.D.C. 1999) (Mylan obtained exclusive supply of essential ingredients from sole suppliers, so that competitors lacked key ingredients and Mylan raised prices by 2,000-3,000%, sharing profits with its suppliers).

⁶⁵ See, e.g., *American Needle Inc. v. National Football League*, 130 S. Ct. 2201 (2010); *MLB Properties v. Salvino, Inc.*, 542 F.3d 290 (2d Cir. 2008); *Pecover v. Electronic Arts*, 633 F. Supp. 2d 976 (N.D. Cal. 2009).

A factor that should be considered is whether the access of other IPR holders to the market would be substantially restricted by the unavailability of the licensee. If the licensor has a network of exclusive dealing licenses, so that many licensees are restricted from dealing with similar or competing IPR, then there might be such a restrictive effect on the market place. This was the situation in the first *Microsoft* case, where the per unit license fee charged by Microsoft to computer manufacturers, regardless of whether the Windows operating system was actually installed on a particular computer, effectively foreclosed other operating systems from being installed on computers produced by those manufacturers and therefore from the market.⁶⁶ The government's position turned on the substance of the arrangement, not the form, focusing on the impact of the fee structure and not the characterization of the relationship by the parties. Similarly, in *United States v. Dentsply International, Inc.*,⁶⁷ the U.S. challenged a manufacturer's dealer restrictions as effectively prohibiting its network of dealers from representing competing makers of prefabricated artificial teeth, and excluding competing makers from the majority of available distribution channels. The Third Circuit reversed the judgment after trial for Dentsply, commenting that "the firm that ties up the key dealers rules the market,"⁶⁸ and remanded with instructions for injunctive relief against Dentsply.

If there will be foreclosure of competitors of either the licensor or the licensee from the marketplace as a result of the exclusivity, then there should be consideration of the complaints that may be made and how, and of the practical alternatives to the proposed arrangement.

⁶⁶ *United States v. Microsoft Corp.*, 1995-2 Trade Cas. ¶¶ 71,027, 71,096 (D.D.C. 1995) (consent decrees).

⁶⁷ 399 F.3d 181 (3d Cir. 2005), *cert. denied*, 546 U.S. 1089 (2006). *Cf. LePage's Inc. v. Minnesota Mining and Manufacturing Co.*, 324 F.3d 141 (3d Cir. 2003), *cert. denied*, 542 U.S. 953 (2004) (loyalty rebates and discounts in distribution of Scotch brand tape and other 3M products may be form of impermissible exclusive dealing).

⁶⁸ 399 F.3d at 190.

C. Co-Exclusive Licenses

A “co-exclusive” license is midway between an exclusive and a non-exclusive license, in the sense that the licensee is sharing rights only with one other entity. In many cases, this occurs when the licensor reserves the right to compete with the licensee but agrees not to license any other licensees. In other cases, the licensor licenses two licensees with the same rights.

One case highlights a pitfall in drafting co-licenses with two licensees. In *Cook Incorporated v. Boston Scientific Corp.*,⁶⁹ Angiotech granted co-exclusive licenses to Cook Incorporated and Boston Scientific Corporation to produce and market stents that are coated using Angiotech’s patented technology with medication for the treatment of arteriosclerosis. These licenses were embodied in a single document and granted Cook and Boston Scientific worldwide co-exclusive rights under Angiotech’s technology. None of the parties could assign its rights or obligations under the agreement without the prior consent of the others.

Cook contracted with a third party to handle obtaining regulatory approval for its stents and to sell its stents. Boston Scientific notified Cook that it considered Cook’s arrangement with Guidant a breach of the license agreement, and issued a press release to that effect. Cook filed an action seeking a declaratory judgment that it was not in breach of the Angiotech license, and alleging that Boston Scientific had violated the Lanham and Sherman Acts by sending the notice letter and issuing the press release. Cook alleged that Boston Scientific’s interpretation of the license renders it a horizontal restraint of trade by giving Boston Scientific a veto over the arrangement that Cook, Boston Scientific’s competitor, had with Guidant to produce stents.

On a motion to dismiss, with respect to Cook’s Sherman Act claim, the Northern District of Illinois, Eastern Division, ruled that the Angiotech license agreement might be concerted action that violates the antitrust laws, if Boston Scientific’s interpretation

⁶⁹ 208 F. Supp. 2d 874 (N.D. Ill. 2002).

of it is correct. The court ruled that Cook stated a claim, even though Cook would have invalidated the license it received from Angiotech if it prevails.

The case was ultimately resolved on unrelated grounds. However, the fact that Cook's complaint withstood a motion to dismiss demonstrates that there are significant antitrust risks in following Angiotech's approach in licensing its IPR.

Some lessons might be learned from this case. First, it may be wiser not to embody multiple licenses to different licensees in one document executed by all the licensees. It is entirely possible that Angiotech's intent was that it, and only it, would have the right to approve the actions of its licensees, and not that the licensees would have the right to review each other's activities. The consent clause in question might have been drafted without taking full account of the fact that both licensees were signatories.

Second, it is wiser not to permit licensees to have a veto on the activities of other licensees. This is the prudent approach for all licenses. Such a veto arrangement creates a situation where competitors can restrict each other's activities. In any event, the licensor can retain a right of approval over the licensee's sublicense arrangements.

Finally, this type of situation can arise in the context of licenses involving know-how, copyrights or trademarks, and so care should be taken in those contexts too. All types of licensees may feel that they have an interest in the activities of other licensees and want to have some powers over those activities. With the possible exception of franchise licenses, where specific state statutes may have an impact, it is wiser not to permit a licensee to have review rights over the activities of other licensees.

VII. Territorial, Use, Customer Restrictions

It is common to include in licenses restrictions on the geographic areas within which the licensee may use the technology granted, the uses to which the technology may be put, and the customers to whom products or services using the technology may be provided.

The general rule is that such restrictions are tested under the standard of reasonableness.⁷⁰ In particular, 35 U.S.C. §261 provides that a patent holder may “grant and convey an exclusive right...to the whole or any specified part of the United States.”

However, where the licensor and licensee are competitors, care must be taken that the restrictions are not a horizontal allocation of markets in the guise of a license *à la Pilkington*.⁷¹ Similarly, if a licensor has a network of licenses containing such restrictions, with licensees who are competitors of each other, care must be taken that the restrictions are unilaterally imposed by the licensor, in its sole judgment as to how its technology should be exploited. The licensor should not be reacting to requests from licensees for restrictions on fellow licensees or otherwise acting in ways that may facilitate a horizontal market allocation among its licensees.⁷²

One factor that should be reviewed is whether the restrictions extend beyond the scope of the IPR licensed. For example, in *Pilkington*, the license restrictions prohibited the licensees from using any competing technologies outside of the licensed territories.

VIII. Resale Price and Output Restrictions

Under *State Oil v. Khan*⁷³ and *Leegin Creative Leather Products v. PSKS, Inc.*⁷⁴, resale price setting is judged under the rule of reason. Therefore, it is generally permissible under federal

⁷⁰ *Continental T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36 (1977).

⁷¹ *E.g.*, *United States v. Topco Associates*, 405 U.S. 596 (1972); *United States v. Sealy, Inc.*, 388 U.S. 350 (1967); *Timken Roller Bearing Co. v. United States*, 341 U.S. 593 (1951); *Hartford-Empire Co. v. United States*, 323 U.S. 386, 400, *clarified*, 324 U.S. 570 (1945).

⁷² *E.g.*, *United States v. Sealy, Inc.*, 388 U.S. 350 (1967).

⁷³ 522 U.S. 3 (1997).

⁷⁴ 551 U.S. 877 (2007).

antitrust law for a licensor to set the prices at which a licensee may sell products under license, unless anticompetitive impact is found.⁷⁵ Nonetheless, the prudent course with respect to resale prices, particularly minimum resale prices, may still be to do no more than to suggest them. Many states have specifically retained a *per se* prohibition against resale price setting.

Minimum output requirements are generally inoffensive under the antitrust laws, since they tend to increase output and decrease price, both ordinarily pro-competitive outcomes. However, maximum output restrictions should be very carefully reviewed. While the courts have generally reviewed maximum output restrictions under the rule of reason standard,⁷⁶ the IP Guidelines (§3.4) include them within the category of potentially *per se* unlawful license provisions where the parties are actual or potential competitors. While the courts have generally reasoned that the licensor could have prevented any output at all by refusing to grant the license, the impact of the restriction is effectively the same as resale price maintenance, so that there is a similar basis for finding these restrictions questionable.

Moreover, to the extent there is a network of licenses containing price and/output restrictions, there is the potential of an agreement among competitors to set prices or output that violate the antitrust laws. Cross-licenses or pools of competing licenses containing such terms may be vulnerable to such attack. Licenses from a single licensor containing such terms that are monitored vigorously by licensees might be found to be improper horizontal collusion among the licensees.

IX. Grant backs

It is also common to include in licenses grant backs from

⁷⁵ Similarly, restrictions on the terms under which licensees may sublicense are subject to the rule of reason. *See, e.g., USM Corp. v. SPS Technologies, Inc.*, 694 F.2d 505, 513-14 (7th Cir. 1982), *cert. denied*, 462 U.S. 1107 (1983).

⁷⁶ *See, e.g., NCAA v. Board of Regents*, 486 U.S. 85 (1984).

the licensee to the licensor of improvements that the licensee makes in the licensed IPR. There are usually good business needs for including such grant backs. For example, without the grant back, the licensor may have put the licensee in business and enabled the improvement, but put its own IPR at risk of obsolescence without sharing in the benefits of the improvements. Grant backs encourage licensors to offer IPR to licensees who could improve the technology, without fear that the licensee will make the IPR obsolete.

Grant backs that are non-exclusive generally raise no questions under the antitrust laws. More questions are raised and antitrust exposure becomes a concern when the grant backs are exclusive and the licensee is restricted from licensing the improvements to others or to use it. Such exclusivity is especially suspect if the licensor has a network of licenses with an exclusive grant back requirement. Market conditions need to be reviewed to analyze the impact of the network.

The scope of the grant back requirement should be carefully considered. Are all improvements on the licensed IPR to be granted back to the licensor? Or are only improvements in a particular area of use or particular uses of improvements to be granted back? What use may the licensor make of the granted-back IPR? What are the duration and scope of the grant back? What sublicensing rights, royalties are involved?

The impact of the grant back requirement on incentives to innovate should also be considered. If the grant back is too onerous on the licensee, it may have little incentive to improve the licensed IPR since it may not get much of the fruits of its labors.

X. Royalties

Royalties terms more often raise misuse than antitrust issues.⁷⁷ Such issues may arise particularly in the context of hybrid licenses involving more than one type of IPR or where multiple patents are involved.

⁷⁷ See, Section XI.A, below.

From the patent misuse perspective, the key is to ensure that royalties are not attributable to patents past their expiration. Post-expiration royalties are patent misuse, while they are unlikely to be considered an antitrust violation.⁷⁸ In fact, such arrangements may be pro-competitive,⁷⁹ in permitting a lower or no royalty in the early years of a license, when the licensee may have little cash flow, and may be still be just learning the technology, beginning to apply it and introduce it into the marketplace, and in enabling the licensor to recoup the delay in return on the license by collecting royalties for a longer period than the patent term. For example, in the biotech area, the IPR licensed may not be incorporated into products, but may be used to develop products, so that there may be a lag of many years before any income is generated from the use of the IPR that is licensed. One possible approach to such a situation is to establish the royalty amount, and then to schedule deferred payments of that royalty.

Similarly where multiple patents are involved, there is no necessity under the antitrust laws to have royalties that diminish as the patents under the license expire; the earlier to expire patents may be of substantially less value than the later to expire, so that maintaining the same royalty rate throughout the term of the license may merely be reflecting the true value of the license. Nonetheless, the conservative approach is to have royalties decrease as the licensed patents expire.⁸⁰

⁷⁸ See, *Brulotte v. Thys Co.*, 379 U.S. 29 (1964); *Scheiber v. Dolby Labs, Inc.*, 293 F.3d 1014 (7th Cir. 2002), *cert. denied*, 537 U.S. 1109 (2003); *Bayer AG v. Housey Pharmaceuticals, Inc.*, 228 F. Supp. 2d 467 (D. Del. 2002). In contrast, trade secret licenses providing for royalties indefinitely are enforceable even after the secret has become public knowledge. See, e.g., *Warner-Lambert Pharmaceuticals Co. v. John J. Reynolds, Inc.*, 178 F. Supp. 655, 663-67 (S.D.N.Y. 1959), *aff'd*, 280 F.2d 197 (2d Cir. 1960); *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 266 (1979).

⁷⁹ DOJ/FTC 2007 IP Report at 122.

⁸⁰ In the copyright area, adjustable-fee blanket licenses have been approved, to account for situations where the licensee has already licensed directly from the copyright holder some of the copyrights in the

Differentiated royalties, where different licensees pay different royalties, generally don't raise antitrust issues unless competition is affected by the handicapping of licensees.⁸¹ Total sales royalties, where the royalty payable is based on the licensee's total sales of a product, whether or not the particular item used the licensed IPR, may raise antitrust issues.⁸² The more prudent course may be to have royalties clearly related to the use of the licensed IPR.

XI. Settlements of Disputes Involving IPR

It is not uncommon that infringement lawsuits are settled by licenses between the parties. While it might be argued that an agreement that was approved by the court in settlement of a lawsuit should be acceptable under the antitrust laws,⁸³ the federal enforcement agencies, and some courts, are clearly not of that view.⁸⁴

blanket license. *In re Application of THP Capstar Acquisition Corp.*, 756 F. Supp. 2d 516 (S.D.N.Y. 2010); *Broadcast Music, Inc. v. DMX, Inc.*, 726 F. Supp. 2d 355 (S.D.N.Y. 2010).

⁸¹ *E.g., USM Corp. v. SPS Tech.*, 694 F.2d 505, 512 (7th Cir. 1982).

⁸² *See, e.g., United States v. Microsoft Corp.*, 1995-2 Trade Cas. ¶¶ 71,027, 71,096 (D.D.C. 1995) (consent decrees); Section VI.B above. Royalties based on worldwide sales, regardless of whether there is worldwide patent coverage, are considered under the rule of reason. *See, e.g., Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100 (1969); *Automatic Radio Manufacturing Co. v. Hazeltine Research*, 339 U.S. 827 (1950).

⁸³ *See, e.g., Valley Drug Co. v. Geneva Pharmaceutical, Inc.*, 344 F.3d 1294 (11th Cir. 2003), *cert. denied*, 543 U.S. 939 (2004); *In re Tamoxifen Citrate Antitrust Litigation*, 277 F. Supp. 2d 121 (E.D.N.Y. 2003), *aff'd*, 429 F.3d 370 (2d Cir. 2005), *amended*, 466 F.3d 187 (2d Cir. 2006), *cert. denied sub nom. Joblove v. Barr Labs, Inc.*, 551 U.S. 1144 (2007); *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 261 F. Supp. 2d 188, 231-57 (E.D.N.Y. 2003).

⁸⁴ *See, e.g., Louisiana Wholesale Drug Co. v. Hoechst Marion Roussel, Inc.*, 332 F.3d 896 (6th Cir. 2003), *cert. denied sub nom. Andrx*

Therefore, transactions entered into as part of the settlement of a lawsuit involving IPR, must be analyzed in the same manner as any other IPR transaction for antitrust issues. In particular, the principal purpose of the transaction must be considered. An arrangement may be found to have been created principally to exclude competition, and not merely to settle priority between the parties as to certain IPR.⁸⁵ In some cases, a settlement may be rejected at least in part as a result of competitive impact concerns even if there is no allegation of anticompetitive intent.⁸⁶

A. IPR Settlements under Hatch-Waxman

In the past decade, in the pharmaceutical patent arena, some types of patent settlements have been found anticompetitive under the antitrust laws. These settlements were driven by the distinctive incentives of the Hatch-Waxman Act,⁸⁷ that was intended to encourage the introduction of generic alternatives to brand name products. The Hatch-Waxman Act allows generic drug makers to avoid the strict requirements of a new drug application (NDA) through an abbreviated new drug application

Pharms., Inc. v. Kroger, Co., 543 U.S. 939 (2004); *In re Abbott Laboratories*, FTC, Dkt. No. 9273, C-3945, 2000 WL 681848 (Decision & Order 2002); *In re Hoechst Marion Roussel, Inc.*, FTC, Dkt. No. 9293, 2001 WL 502087 (Decision & Order 2001); *In the matter of Schering-Plough Corp.*, FTC, Dkt. No. 9297, 2003 WL 22981651 (Final Order Dec. 18, 2003), *rev'd*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006); IP Guidelines ¶5.5.

⁸⁵ See, e.g., *United States v. Singer Mfg. Co.*, 374 U.S. 174 (1963); *Hartford Empire Co. v. United States*, 323 U.S. 386, *clarified*, 324 U.S. 570 (1945); *Duplan Corp. v. Deering Milliken, Inc.*, 444 F. Supp. 648 (D.S.C. 1977), *aff'd in part & rev'd in part*, 594 F.2d 979 (4th Cir. 1979), *cert. denied*, 444 U.S. 1015 (1980).

⁸⁶ See, e.g., *The Authors Guild v. Google Inc.*, 2011 U.S. Dist LEXIS 29126 (S.D.N.Y. 2011).

⁸⁷ Also known as the Drug Price Competition and Patent Term Restoration Act of 1984. Pub. L. 98-417, 98 Stat. 1585 (1984), 21 U.S.C. § 355.

(ANDA). In an ANDA, the generic applicant relies on the safety and efficacy information that supported the NDA for the brand name drug. The ANDA must also include a “Paragraph IV” certification, that either the generic drug applicant is not infringing any patent covering the branded drug that is listed in the FDA’s “Orange Book” or the branded drug’s patent is invalid. The branded drug maker can challenge that certification by suing for patent infringement within 45 days. Once this suit is filed, the generic applicant may not sell its drug until the earlier of 30 months or the final resolution of the lawsuit. In addition, when approved by the FDA, the first generic drug applicant has an 180-day exclusivity against all other generics that made the same certification. Under the Hatch-Waxman Act as originally enacted, if the generic applicant never markets its generic version of the drug, and thus never triggers the 180-day period, all other generic applicants are blocked.

Thus, under Hatch-Waxman, the branded drug maker has every incentive to sue the first successful generic drug applicant for infringement because while the suit is pending, or up to 30 months, no generic made by any manufacturer can be marketed. This has led to a decade-long effort by the FTC, now joined by the DOJ, to prevent anti-competitive conduct in this context. A review of its first three major prosecutions in the area reflects the complex issues at the intersection of IPR law and antitrust law, and the split in the Circuits, in such cases.

The first patent settlement in the Hatch-Waxman context that the FTC challenged was in *In re Abbott Laboratories*.⁸⁸ Abbott makes Hytrin, a hypertension and prostate drug with about \$540 million in U.S. sales annually. In January 1993, Geneva Pharmaceuticals filed an ANDA for the tablet form of a generic alternative to Hytrin. In December 1995, Geneva filed an ANDA for the capsule form of a generic alternative. In April 1996, Geneva filed its certification that Abbott’s patents were not valid

⁸⁸ Docket No. 9293 (March 16, 2000) (complaint), CCH Trade Reg. Rep. [1997-2001 Transfer Binder] ¶24,715, <http://www.ftc.gov/os/2000/03/abbottcmp.htm>; (May 26, 2000) (decision and order), <http://www.ftc.gov/os/2000/05/c3945.do.htm>

and that Geneva's alternatives did not infringe Abbott's patents. In June 1996, Abbott filed suit alleging that Geneva's tablet product infringed its patents, omitting Geneva's capsule formulation. Therefore, the 30-month Hatch-Waxman stay that would end in December 1998 applied only to Geneva's ANDA for its tablet formulation. In April 1998, the ANDA for Geneva's capsule formulation was approved, and Geneva informed Abbott that it would launch that product. Abbott estimated that it would lose about \$185 million, or 70 percent of its sales of Hytrin, in the first six months of such a launch.

At that time, the parties reached a confidential agreement that was not disclosed to the court, under which Geneva agreed: (1) not to market its generic alternatives until the earlier of the final resolution of the patent infringement lawsuit or the entry into the market of another generic version of Hytrin; and (2) not to forfeit or transfer its 180-day exclusivity, assuming it had the ability to do so. In return, Abbott agreed: (a) to pay Geneva \$4.5 million monthly until the federal district court decided the case; and (b) if Geneva prevailed before the district court, to place \$4.5 million monthly in escrow pending the final disposition of the case, after which the prevailing party would receive the escrowed sums. There was some indication that Abbott's payments were estimated to exceed Geneva's likely profits from sales of its generic products.

The parties continued to litigate the case, and in September 1998 Geneva won summary judgment on the claim that Abbott's patent was invalid. Geneva did not enter the market and Abbott continued to make payments, now into escrow, while the case was appealed to the Federal Circuit. The Federal Circuit affirmed the trial court decision in July 1999. The parties maintained the status quo pending U.S. Supreme Court review. Shortly thereafter, the FTC's investigation of the confidential agreement became known. Geneva terminated the agreement and entered the market in August 1999. In the meantime, at least one other generic manufacturer had filed an ANDA that was approved, but was prevented from entering the market because of Geneva's 180-day exclusivity.

The settlement that was reached with the FTC in March 2000 provided that: (i) Geneva would waive its 180-day exclusivity for the tablet formulation; (ii) the parties would not enter into such agreements in litigation without express court approval; and (iii) the parties would notify the FTC of such agreements. The FTC indicated that it might seek disgorgement in future prosecutions of similar activity.

Private litigation ensued. In *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*,⁸⁹ plaintiffs alleged that the Abbott and Geneva agreement relating to Hytrin was *per se* illegal under Section 1 of the Sherman Act. The 11th Circuit found that, because there was a patent involved, it was not a simple case of one firm making payments to potential competitors to exit or refrain from entering the market. It reasoned that by its very nature a patent grants exclusionary power, and instructed the trial court to identify the scope of the patent there and the extent to which the agreement reflects that scope. Any provisions of the agreement that extended beyond the scope of Abbott's patent would be subject to rule of reason antitrust review. On remand, the Southern District of Florida found that, at the time of the agreement to make payments, the likelihood was that the patent would be, as it ultimately was, found to be invalid. Therefore, the court concluded that the agreement exceeded the scope of the patent, and was *per se* illegal.⁹⁰

⁸⁹ 344 F.3d 1294 (11th Cir 2003), *cert. denied*, 543 U.S. 939 (2004).

⁹⁰ *In re Terazosin Hydrochloride Antitrust Litigation*, 352 F. Supp. 2d 1279 (S.D. Fla. 2005). During the appeal from this decision, the indirect purchaser plaintiffs and the states reached a settlement with Abbott and Geneva. *In re Terazosin Hydrochloride Antitrust Litigation*, 2005-2 Trade Cas. (CCH) ¶¶74,924, 74,925, 74,926 (S.D. Fla. 2005). Other plaintiffs continued to pursue their actions. *E.g.*, *Kaiser Foundation v. Abbott Laboratories*, Case No. 2:02-CV-02443, C.D. Ca. On appeal after a jury trial in the Central District of California, the Ninth Circuit affirmed the verdict of no damages under Sherman Act §1 and the trial court's finding of no sham litigation, and reversed summary judgment in the Southern District of Florida for the defendants on a Sherman Act §2 claim under *Walker Process Equipment v. Food*

A similar situation arose in connection with Cardizem. In September 1995, Andrx Corp. filed the first ANDA for a generic alternative to Cardizem CD, Hoechst's leading hypertension and angina medication with U.S. sales of over \$700 million annually. Andrx thus became eligible for the 180-day exclusivity period under Hatch-Waxman. Hoechst AG (a predecessor to Aventis SA) filed a patent infringement suit against Andrx that started the 30-month stay of FDA approval, which would end in July 1998. Hoechst apparently forecast that a generic substitute such as Andrx's product would cause it to lose about 40 percent of its Cardizem sales in the first year.

The parties reached an agreement in September 1997 that did not end the action, but provided that: (1) Andrx would not market its product after its ANDA was approved in July 1998 at the end of the 30-month Hatch-Waxman stay; (2) Andrx would not forfeit or transfer its 180-day exclusivity; and (3) Andrx would not market any non-infringing generic that it may develop. In return, Hoechst would pay Andrx: (a) \$10 million per quarter beginning from the time the ANDA was approved; and (b) an additional \$60 million annually beginning July 1998 until the lawsuit was finally decided. The agreement did not settle the case and end the Hatch-Waxman 30-month stay of FDA approval, but did provide an incentive for Hoechst to prosecute and end the case after the 30 months by more than doubling its payments to Andrx at that point.

The FTC investigated and brought an administrative proceeding against Aventis and Andrx. The settlement that became final in May 2001: (i) barred agreements that restricted relinquishing the 180-day exclusivity right or restricted entry into the market of a non-infringing product; (ii) required approval by the court and notice to the FTC of interim settlements of patent litigation involving payments to the generic manufacturer and the generic manufacturer temporarily refraining from marketing its

Machinery & Chemicals Corp., 382 U.S. 172 (1965). The Court of Appeals concluded that plaintiff had submitted sufficient evidence regarding the withholding of information to the Patent and Trademark Office that would have prevented the issuance of the relevant patent. 552 F.3d 1033, 1047-53 (9th Cir. 2009).

product; and (iii) mandated notice to the FTC of similar agreements in other contexts.

As with Hytrin, private damages litigation ensued. Plaintiffs alleged that Hoechst and Andrx violated Section 1 of the Sherman Act.⁹¹ In contrast with the 11th Circuit on Hytrin, the Sixth Circuit determined that the agreement was at its core a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the United States. The court was unpersuaded that the agreement was merely an attempt to enforce patent rights or an interim settlement of the patent litigation, and found that the agreement was designed to bolster the patent's effectiveness in inhibiting competitors by paying the only potential competitor \$40 million a year to stay out of the market and was not designed simply to take advantage of a monopoly that naturally arises from a patent.

Schering-Plough made K-Dur 20, a prescription potassium chloride supplement used to treat low potassium levels, with annual sales of over \$220 million. Upsher-Smith Laboratories filed an ANDA for a generic version of K-Dur 20 in August 1995 and submitted the requisite certification. Schering sued Upsher-Smith in December 1995 for patent infringement, triggering the 30-month Hatch-Waxman stay that would end in May 1998. In June 1997, Schering and Upsher-Smith settled the litigation, and Upsher-Smith agreed: (1) not to enter the market until September 2001 with any version of K-Dur 20, infringing or non-infringing; and (2) to license Schering to market five Upsher-Smith products. In return, Schering agreed to pay Upsher-Smith \$60 million.

Following the settlement, Schering never sold four of the five products licensed from Upsher-Smith and sold only minimal amounts of the fifth, without expectations of making further sales. Upsher-Smith's ANDA was approved in November 1998, but Upsher-Smith did not begin marketing its products, so that its 180-

⁹¹ *Louisiana Wholesale Drug Co. v. Hoechst Marion Roussel, Inc.*, 332 F.3d 896 (6th Cir. 2003), *cert. denied sub nom. Andrx Pharms., Inc. v. Kroger, Co.*, 543 U.S. 939 (2004).

day exclusivity did not begin to run, and no other generic could enter the market.

In December 1995, the ESI Lederle, Incorporated division of American Home Products Corporation filed an ANDA for its generic alternative to K-Dur 20 along with a Paragraph IV certification. Schering sued ESI in February 1996 for patent infringement, triggering the 30-month stay that would end in August 1998. In January 1998, Schering, American Home Products and ESI reached an agreement under which AHP and ESI agreed: (1) not to market their versions of K-Dur 20, infringing or non-infringing, until January 2004; (2) not to market more than one generic version between January 2004 and September 2006; (3) not to support any study of the bioequivalence to K-Dur 20 of any product until September 2006 when the K-Dur 20 patent expires; and (4) to license to Schering two generic products that ESI was developing. In return, Schering was to pay ESI up to \$30 million in lump sums and in installments over seven years.

Following the agreement, Schering made no sales of the products it licensed from ESI. ESI received tentative approval of its ANDA in May 1999, but was not eligible for final approval until Upsher-Smith's 180-day exclusivity expired. In the meantime, Andrx filed an ANDA for its generic alternative.

The FTC filed an administrative complaint against Schering, Upsher-Smith and American Home Products in April 2001, alleging that the companies had violated Section 5 of the FTC Act by entering into unlawful agreements to delay the entry of low-cost generic competition to K-Dur 20.⁹² The complaint also alleged that Schering had monopoly power in the manufacture and sale of potassium chloride products and that Schering conspired separately with Upsher-Smith and American Home

⁹² *In the Matter of Schering-Plough*, Docket No. 9297 (April 2, 2001) (complaint), <http://www.ftc.gov/os/2001/04/scheringpart3cmp.pdf>.

Products to monopolize the manufacture and sale of potassium chloride products.⁹³

After trial the Administrative Law Judge dismissed all charges.⁹⁴ His Initial Decision stated that the FTC had not met its burden of proving the relevant product market or that Schering-Plough maintained an illegal monopoly in that market. Moreover, the Initial Decision stated that the theories advanced by the FTC required an presumption that the patent at issue was invalid or that the patent was not infringed, and that there was no basis in law or fact for the presumption.

On appeal, the Commission reversed the ALJ, and issued an order against Schering-Plough.⁹⁵ The Commission noted that plaintiff may satisfy the burden of demonstrating actual or likely market effects by reference to facts specific to the case, without a full-blown market analysis but through direct evidence of the competitive restraint, in this case the agreement that deferred entry of a potential competitor. The defendants asserted that the agreements and payments were ancillary to the settlement of the patent litigation, but the Commission found that the defendants had not met their burden of showing that the payments were reasonably necessary elements of a procompetitive settlement, or offering any other procompetitive factors.

With respect to the patents, the Commission pointed out that a presumptively legal patent does not confer the presumptive

⁹³ American Home Products reached a settlement with the FTC on April 2, 2002, before the Administrative Law Judge issued the Initial Decision.

⁹⁴ *In the Matter of Schering-Plough*, Docket No. 9297 (June 27, 2002) (Initial Decision), <http://www.ftc.gov/os/adjpro/d9297/020627id.pdf>.

⁹⁵ *In the Matter of Schering-Plough*, Docket No. 9297 (December 18, 2003) (Final Decision), <http://www.ftc.gov/os/adjpro/d9297/031218commissionopinion.pdf>; *In the Matter of Schering-Plough*, Docket No. 9297 (December 18, 2003) (order), <http://www.ftc.gov/os/adjpro/d9297/031218finalorder.pdf>.

right to preclude generic entry. It reasoned that the validity of the patent was not a factor in the analysis because, even if the patent was valid, if the payment by the patentholder to the alleged infringer in the settlement resulted in entry by the infringer that was later than if the settlement did not include a payment, then there was anticompetitive impact. The Commission concluded that such a delayed entry had an anticompetitive impact because the evidence demonstrated that generic entry had a dramatic impact on market prices and provided a benefit to consumers, so that delayed generic entry would harm consumers by depriving them of earlier access to a low-cost generic alternative. It found that Schering's payments resulted in a greater delay in generic entry than would have otherwise occurred and that the payments were nothing more than a mechanism to delay entry of the generic.

While the Commission stated that these agreements are not *per se* illegal (although a streamlined analysis may be more appropriate in a future case), that it was ruling only on the existence of a violation and that there may be no damages resulting from any illegality in this type of conduct, it is difficult to see how the standard enunciated in *Schering-Plough* could lead to any finding other than liability and what type of practical guidance it provides to businesses.

In contrast, in setting aside the FTC's decision and vacating the cease and desist order against Schering-Plough Corporation relating to its K-Dur 20 drug, the 11th Circuit placed great importance on the existence of the patent.⁹⁶ However, it did so in the context of a statement that "neither the rule of reason nor the *per se* rule analysis is appropriate in this context,"⁹⁷ which leaves one at a loss as to the appropriate standard. Yet, by its insistence on considering all the facts, including the patent, and focusing on the need to make a fact-specific inquiry and therefore give deference to the ALJ's fact finding, particularly in the context

⁹⁶ *Schering-Plough Corporation v. FTC*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006).

⁹⁷ 402 F.3d at 1065.

of review of a reversal of the ALJ by the Commission,⁹⁸ the 11th Circuit seems to be quintessentially applying the rule of reason. For example, the 11th Circuit noted that “complaint counsel acknowledged that it could not prove that Upsher and ESI could have entered the market on their own prior to the ’743 patent’s expiration... This reinforces the validity and strength of the patent... the proper analysis now turns to whether there is substantial evidence to support the Commission’s conclusion that the challenged agreements restrict competition beyond the exclusionary effects of the ’743 patent.”⁹⁹ This appears to be an appropriate formulation of what should be included in any test of such agreements, a consideration of whether the agreement limited competition that would have existed without the agreement and in the presence of the patent.¹⁰⁰

The Supreme Court has thus far denied certiorari in the reverse payment litigations,¹⁰¹ leaving open the question of whether such agreements involving payments by the patentholder to the alleged infringer are *per se* illegal or subject to the rule of reason. Legislation has been introduced to prohibit reverse payments.¹⁰² In the meantime, agreements which may have the

⁹⁸ *Id.* at 1062-63.

⁹⁹ *Id.* at 1068.

¹⁰⁰ Private plaintiffs have also been unsuccessful in challenging the K-Dur settlements. *In re K-Dur Antitrust Litigation*, 2009 U.S. Dist. LEXIS 126249; 2010-1 Trade Cas. (CCH) ¶76,949 (D.N.J. 2009), *adopted by*, 2010 U.S. Dist. LEXIS 28918, 2010-1 Trade Cas. (CCH) ¶76,949 (D.N.J. 2010).

¹⁰¹ *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, 543 U.S. 939 (2004); *Andrx Pharms., Inc. v. Kroger, Co.*, 543 U.S. 939 (2004); *Federal Trade Commission v. Schering-Plough Corp.*, 126 S. Ct. 2929 (2006); *Joblove v. Barr Labs, Inc.*, 551 U.S. 1144 (2007); *Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, 129 S. Ct. 2828 (2009); *Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, 131 S. Ct. 1606 (2011).

¹⁰² *E.g.*, Rush Amendment to H.R. 3200, 111th Cong. (2009); Protecting Consumer Access to Generic Drugs Act of 2009, H.R. 1706,

effect of delaying entry by an alleged patent infringer, continue to provide fodder for government enforcement and private litigation.¹⁰³

111th Cong. (2009); Preserve Access to Affordable Generics Act, S.369, 111th Cong. (2009).

¹⁰³ While the anxiety drug buspirone hydrochloride also generated an FTC consent decree and private litigation, the matters were settled without any legal adjudication on the merits. *In the Matter of Bristol-Myers Squibb Company*, Docket No. C-4076 (April 18, 2003) (Decision and Order) <http://www.ftc.gov/os/2003/04/bristolmyerssquibbdo.pdf>; *In re Buspirone Patent Litigation*, 210 F.R.D. 43 (S.D.N.Y. 2002); <http://www.busparsettlement.com>. The FTC has also taken advantage of merger investigations to obtain prophylactic terms against reverse payment arrangements. *E.g.*, *In the Matter of Perrigo Co.*, FTC File No. 111-0083, 76 Fed. Reg. 45801 (August 1, 2011) (notice containing proposed consent agreement) (in connection with acquisition by Perrigo of Paddock Laboratories, prohibitions against accepting certain payments from Abbott Laboratories, maker of AndroGel, or entering any pay for delay arrangements with Abbott relating to generic AndroGel). A number of other cases have been brought by private plaintiffs alleging improper reverse payments arrangements or other settlements between brand name and generic drug makers. *E.g.*, *Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98, *reh'g en banc denied*, 625 F.3d 779 (2d Cir. 2010), *cert. denied*, 131 S. Ct. 1606 (2011) (applying *In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187 (2d Cir. 2006), *cert. denied sub nom. Joblove v. Barr Labs, Inc.*, 551 U.S. 1144 (2007), to affirm summary judgment for Bayer and Barr because the reverse payment settlement related to a patent that was not procured by fraud, the underlying patent litigation was not objectively baseless, and the settlement did not bar the generic maker from selling non-infringing products and thus remained within the patent-in-suit); *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 544 F.3d 1323 (Fed. Cir. 2008) (affirming summary judgment for defendants since the test for determining the validity of the reverse, exclusion or exit payment is whether the settlement agreement constrained competition beyond the scope of the patent claims), *cert. denied sub nom. Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, 129 S. Ct. 2828 (2009); *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 261 F. Supp. 2d 188, 231-57 (E.D.N.Y. 2003) (motion for partial summary judgment for plaintiffs denied since settlement agreement was not *per se* illegal because it did not prevent generic entry, perpetuate litigation, or

manipulate the 180-day exclusivity provision, and because rule of reason treatment was more appropriate to a case involving the exclusivity of a patent); *In re Tamoxifen Citrate Antitrust Litigation*, 277 F. Supp. 2d 121 (E.D.N.Y. 2003) (settlement agreement was not *per se* illegal and was subject to the rule of reason because it was not made in bad faith – it resolved the pending patent litigation and did not leverage the 180-day exclusivity period and there was no pattern of settlements or continuing behavior to show bad faith), *aff'd*, 429 F.3d 370 (2d Cir. 2005), *amended*, 466 F.3d 187 (2d Cir. 2006), *cert. denied sub nom. Joblove v. Barr Labs, Inc.*, 551 U.S. 1144 (2007) (settlements not antitrust violations if they are within the scope of the patents, *i.e.*, no restriction on marketing non-infringing products, a generic would necessarily infringe the branded drug’s patent, and no bar on patent challenges by other generic makers); *Andrx Pharmaceuticals, Inc., v. Elan Corporation, Plc.*, 421 F.3d 1227 (11th Cir. 2005) (reversing dismissal of Andrx’s complaint that Elan, which held a patent on controlled-release naproxen, and SkyePharma, Inc. entered into a settlement agreement that violated Sections 1 and 2 of the Sherman Act by barring any generic naproxen competitors and that exceeded the scope of exclusion intended by the patent, while noting that summary judgment may still be appropriate and that Elan’s patent infringement suits against SkyePharma were protected from antitrust liability under *Noerr-Pennington*); *FTC v. Watson Pharmaceuticals*, 611 F. Supp. 2d 1081 (C.D. Cal. 2009) (Solvay allegedly settled infringement actions against generic AndroGel makers by paying them under business promotion agreements and licensing them to enter the market in 2015, 5 years before the patents expire); *In re AndroGel Antitrust Litigation (No. II)*, 687 F. Supp. 2d 1371, *clarified*, 2010 U.S. Dist. LEXIS 113593 (N.D. Ga. 2010); *FTC v. Cephalon, Inc.*, 551 F. Supp. 2d 21 (D.D.C. 2008) (Cephalon allegedly sued 4 generic Provigil manufacturers for infringement, settling with each on the basis of generic entry delayed until 3 years before the expiration of the patent and \$200 million in licenses to Cephalon, along with supply co-development agreements); *King Drug Co. of Florence v. Cephalon, Inc.*, 702 F. Supp. 2d 514 (E.D. Pa. 2010); *FTC v. Warner Chilcott Holdings Company III, Ltd.*, 2007 U.S. Dist. LEXIS 4240 (D.D.C. 2007) (complaint) (Barr licensed exclusively to Warner Chilcott for \$20 million its generic version of Warner Chilcott’s oral contraceptive Ovcon); *Meijer, Inc. v. Warner Chilcott Holdings Co.*, 565 F. Supp. 2d 49 (D.D.C. 2008); *Meijer, Inc. v. Warner Chilcott Holdings Co.*, 572 F. Supp. 2d 38 (D.D.C. 2008); *Walgreen Co. v. Warner Chilcott Holdings Company Ltd*, No. 06-00494 (D.D.C. March 16, 2006) (complaint); *The Kroger Co. v. Sanofi-Aventis*, No. 06-163 (S.D. Ohio March 23, 2006) (complaint) (Sanofi-Aventis and Bristol-Myers Squibb, which jointly marketed Plavix, allegedly entered

Amendments in 2003 to the Hatch-Waxman Act attempted to realign the incentives of parties.¹⁰⁴ As originally enacted, whenever an additional patent related to a drug was added to the FDA's Orange Book, the generic applicant would need to make a new Paragraph IV certification. This allowed a branded drug maker to file another patent infringement suit, resulting in another 30-month stay. Under the amendments, generic applicants need certify only to patents listed in the Orange Book at the time their ANDA applications are submitted.

Under the original provisions of the Hatch-Waxman Act, the 180-day marketing exclusivity to the first generic application approved ran from the earlier of the first marketing of the generic drug or the date of the first court decision holding that the patent under the Paragraph IV certification was invalid or not infringed. Under the amendments, the 180-day exclusivity period begins with the marketing of the product, without regard to any judicial determination regarding any patent, if tentative FDA approval is

into an agreement with Apotex where Apotex refrained from introducing its generic version of Plavix); *Asahi Glass Co. v. Pentech Pharmaceuticals, Inc.*, 289 F. Supp. 2d 986 (N.D. Ill. 2003) (Posner, J. sitting by designation) (dismissing plaintiff's complaint asserting that an agreement to settle Hatch-Waxman patent litigation violated Section 1 of the Sherman Act, because the agreement was a legitimate settlement of a patent infringement suit); *Eon Labs Manufacturing v. Watson Pharmaceuticals*, 164 F. Supp. 2d 350 (S.D.N.Y. 2001); *Bristol-Myers Squibb Co. v. Copley Pharmaceuticals*, 144 F. Supp. 2d 21 (D. Mass. 2000). Cf., *MedImmune v. Genentech*, 427 F.3d 958 (Fed. Cir. 2005) (*Noerr-Pennington* protection for patent infringement suits that led to challenged settlement agreements), *rev'd on other grounds*, 549 U.S. 118 (2007).

¹⁰⁴ Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 21 U.S.C. 355(j)(2) and (5). See also U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Draft Guidance for Industry, Listed Drugs, 30-Month Stays, and Approval of ANDAs and 505(b)(2) Applications Under Hatch-Waxman as Amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Questions and Answers, October 2004; <http://www.fda.gov/cder/guidance/6174dft.pdf>.

granted within 30 months of the filing of the ANDA. This 180-day period can be forfeited if the generic applicant fails to market the drug in a timely manner. The period can also be forfeited if the generic drug is withdrawn or deemed withdrawn by the FDA, the first applicant amends or withdraws its Paragraph IV certification, the Orange Book listed patents expire, or the generic applicant is found to have entered into an agreement that violates the antitrust laws.

Moreover, under the amendments, if more than one applicant files a substantially complete ANDA on the same day for a previously unchallenged drug, each will be entitled to share the 180-day period, but there will only be one such period, and it begins on the first day of marketing by any of the first generic applicants. The first ANDA with a Paragraph IV certification that is approved will not have to share the 180-day exclusivity with any later applicant which files a Paragraph IV certification covering the drug. Agreements among ANDA applicants and NDA drug makers regarding the exclusivity period, or the manufacturing, marketing, or sale of the brand-name or generic drug, must be filed with the FTC and DOJ within 10 days of execution.¹⁰⁵

XII. Standards Development Activities

Another area in which IPR is often important and where antitrust implications may arise is standards development.

Standards often increase consumer welfare and efficiency by establishing uniform approaches that enables interoperability

¹⁰⁵ Other amendments specify that a generic applicant must give notice of its application to the branded maker within 20 days of the filing of the ANDA application with the FDA. This notice triggers the 45-day window to bring an infringement suit. If the branded maker does not take action within that 45 day period, the generic applicant may bring a declaratory judgment action after offering confidential access to its application so that the branded maker may determine whether to bring an infringement suit. The amendments allow a generic applicant to bring a counterclaim seeking the deletion of the branded maker's patent from the Orange Book, although this is not an independent cause of action, and does not provide for monetary damages.

and scale. For example, the adoption of the standard for an electrical outlet enabled the development of a wide range of appliances without the need for a multitude of adaptors. Nonetheless, the standards development process, and standards themselves, may be abused and create anticompetitive effects. For instance, in *Allied Tube & Conduit Corp. v. Indian Head, Inc.*,¹⁰⁶ the Supreme Court affirmed the Section 1 liability of a member of a fire safety association for influencing the association to adopt a biased safety code to benefit its product and disfavor competing products. In *American Society of Mechanical Engineers v. Hydrolevel Corp.*,¹⁰⁷ the Supreme Court held an association liable for the anticompetitive acts of its agents, where the agents were members of a subcommittee that drafted an industry standard to benefit their employer's competitive interests.

Standards, and the standards development process, are generally tested under the rule of reason.¹⁰⁸ Some of the factors that may be considered are whether there is economic detriment to an excluded or non-qualifying firm,¹⁰⁹ the scope of the restrictions in the standard,¹¹⁰ how the standards are applied,¹¹¹ and whether a boycott or price fixing is involved.¹¹²

¹⁰⁶ 486 U.S. 492 (1988).

¹⁰⁷ 456 U.S. 556 (1982).

¹⁰⁸ See, e.g., *Addamax Corp. v. Open Software Found.*, 888 F. Supp. 274 (D. Mass. 1995).

¹⁰⁹ See, e.g., *Associated Press v. United States*, 326 U.S. 1 (1945).

¹¹⁰ See, e.g., *Thompson v. Metropolitan Multi-List, Inc.*, 934 F.2d 1566 (11th Cir. 1991), *cert. denied*, 506 U.S. 903 (1992).

¹¹¹ See, e.g., *Cooney v. American Horse Shows Ass'n*, 495 F. Supp. 424 (S.D.N.Y. 1980).

¹¹² *Fashion Originators' Guild of Am., Inc. v. FTC*, 312 U.S. 457 (1941); *National Macaroni Mfrs. Assoc. v. FTC*, 345 F.2d 421 (7th Cir. 1965).

Standards often incorporate IPR and require licenses of IPR. The activities of holders of IPR essential to the implementation of a standard may be subject to antitrust scrutiny, both during the development of the standard, and after the standard has been adopted. At the development stage, standards development organizations commonly require all participants to disclose any IPR that may be essential to a standard being developed, and to agree to license the essential IPR on reasonable and non-discriminatory terms to enable compliance with the standard. The federal antitrust agencies consider negotiations during the standards development process by the SDO with the IPR holder on the precise terms of such licenses possibly to be procompetitive and therefore unlikely to be *per se* unlawful.¹¹³ There may be antitrust and other implications of a possible failure to disclose IPR essential to a standard, and of the royalty structure and other terms that the holder of essential IPR demands in licenses to enable compliance with the standard.¹¹⁴

In *In re Dell Computer Corp.*,¹¹⁵ the FTC alleged that Dell had violated Section 5 of the FTC Act through its participation in the Video Electronics Standards Association (VESA). While a member of VESA, Dell supported a design standard for a computer bus design, the VL-bus. Dell certified to VESA that the

¹¹³ DOJ/FTC 2007 IP Report at 55-56.

¹¹⁴ A standard may be set unilaterally, and the licensing of IPR covering such a standard is also subject to antitrust scrutiny. In *Intel Corp. v. VIA Technologies, Inc.*, 319 F.3d 1357 (Fed. Cir. 2003), Intel established a standard for certain computer chip specifications, and provided a reciprocal royalty-free license available on its website for the technology needed to implement the standard. Via manufactured products that complied with the standard, after accepting Intel's license. Intel sued for infringement, claiming that the license did not cover technology needed to implement optional portions of the standard. The Federal Circuit found that, while the parties' differing interpretations of the scope of the license each had merit, the District Court did not err in resolving the ambiguity against the drafter, Intel, and affirmed the District Court's summary judgment of non-infringement.

¹¹⁵ 121 F.T.C. 616 (1996).

standard did not infringe on any Dell patents. In fact, a year earlier, Dell had received a patent covering the mechanical slot configuration used on the computer motherboard to receive the VL-bus card. Not only did Dell apparently fail to disclose this patent, but, once the standard was implemented, Dell informed VESA members who were manufacturing computers using the new design standard that they were infringing Dell's patents. The FTC alleged that Dell harmed competition by hindering, preventing, and raising the costs associated with the acceptance of the VL-bus standard. In addition, the FTC alleged that Dell's actions had chilled willingness to participate in industry standard setting efforts. Dell entered into a consent decree which required it to cease all efforts to enforce the patent.

In *Unocal*,¹¹⁶ the FTC alleged that Unocal had violated Section 5 of the FTC Act in its dealings with the California Air Resources Board (CARB), by subverting California's regulatory standard-setting process relating to low-emissions gasoline. Unocal participated in CARB rule-making proceedings to develop regulations and standards governing the composition of low-emissions gasoline. During the rulemaking, Unocal also worked with the industry groups that provided information to CARB. Although Unocal knew that the United States Patent and Trademark Office had allowed most of the pending patent claims based on its emissions research, Unocal concealed this information from CARB and other participants in the CARB proceedings. The FTC alleged that, until the announcement of its patent rights, Unocal continued to perpetuate the false and misleading impression that it did not possess, or would not enforce, any proprietary interests relating to reformulated gasoline (RFG). By the time Unocal announced its patent rights, the low-emissions gasoline standard was about to go into effect and the refining industry had spent billions to implement the standard.

The complaint alleged that Unocal's misrepresentations harmed competition and led directly to the acquisition of

¹¹⁶ *In the Matter of Union Oil Co. of California*, Docket 9305, (March 4, 2003) (complaint) <http://www.ftc.gov/os/2003/03/unocalcmp.htm>

monopoly power in the technology to produce and supply low-emissions gasoline to California. Unocal's "patent ambush" also enabled it to undermine competition and harm consumers in the downstream product market for low-emissions gasoline in California. In the absence of Unocal's alleged fraud, CARB would not have adopted RFG regulations that are substantially covered by Unocal's patent, the terms on which Unocal could enforce its proprietary interests would have been substantially different, or both.

Unocal moved to dismiss the complaint on the grounds that the *Noerr-Pennington* Doctrine protected its activities and Complaint Counsel had insufficiently alleged Unocal's actual or threatened monopoly power.¹¹⁷ The Administrative Law Judge found that Unocal's interactions with CARB were protected by the *Noerr-Pennington* Doctrine,¹¹⁸ and that while the interactions between Unocal and the industry groups were not immune under *Noerr-Pennington*, the FTC did not have jurisdiction to decide the patent issues related to those interactions. He therefore dismissed the complaint. On appeal, the Commission reversed and vacated the Initial Decision, reinstated the complaint, and remanded the case.¹¹⁹

The FTC and Unocal ultimately reached a settlement in connection with Chevron Corporation's 2005 acquisition of Unocal.¹²⁰ Chevron and Unocal agreed: (1) not to enforce any of

¹¹⁷ *In the Matter of Union Oil Co. of California*, Docket 9305 (March 28, 2003) (motion to dismiss) <http://www.ftc.gov/os/adjpro/d9305/0328respmotfordismissal.pdf>

¹¹⁸ *In the Matter of Union Oil Co. of California*, Docket 9305 (November 26, 2003) (Initial Decision) <http://www.ftc.gov/os/2003/11/031126unionoil.pdf>

¹¹⁹ *In the Matter of Union Oil Co. of California*, Docket 9305 (July 7, 2004) (Commission Decision) <http://www.ftc.gov/os/adjpro/d9305/040706commissionopinion.pdf>

¹²⁰ *In the Matter of Union Oil Co. of California*, Docket 9305 (August 2, 2005) (Decision and Order) <http://www.ftc.gov/os/adjpro/d9305/050802do.pdf>.

Unocal's patents concerning low emissions gasoline; (2) not to take any new action to recover any damages or costs for alleged infringements of any of the patents; (3) not to collect any fees, royalties or other payments, in cash or in kind, for the practice of any of the patents, including but not limited to fees, royalties, or other payments, in cash or in kind, to be collected pursuant to any license agreement; (4) to disclaim or dedicate to the public the remaining term of the patents; and (5) to move to dismiss, with prejudice, all pending legal actions relating to the alleged infringement of patents.

In *Rambus Inc.*,¹²¹ the FTC alleged that Rambus had violated Section 5 of the FTC Act by participating in the work of an industry standard setting organization, JEDEC, without disclosing that it possessed a patent and several pending patent applications that covered technologies ultimately adopted in some JEDEC standards. According to the FTC, Rambus perfected its patent rights, and once the standards had become widely adopted, enforced those patents against companies manufacturing products in compliance with the standards. The Administrative Law Judge dismissed the FTC's claims, finding that Complaint Counsel did not demonstrate (1) that the challenged conduct amounted to a pattern of anticompetitive acts and practices, (2) exclusionary conduct, (3) intent, (4) causation, (5) anticompetitive effects or (6) that manufacturers needed to use Rambus's technology to comply with the standard.¹²² The Commission reversed the ALJ and found that Rambus had in fact violated Section 2 of the Sherman Act and Section 5 of the FTC Act.¹²³ The Commission found that a key

¹²¹ *In the Matter of Rambus, Inc.*, Docket No. 9302 (June 18, 2002) (complaint), <http://www.ftc.gov/os/adjpro/d9302/020618admincmp.pdf>.

¹²² *In the Matter of Rambus, Inc.*, Docket No. 9302 (February 24, 2004) (Initial Decision) <http://www.ftc.gov/os/adjpro/d9302/040223initialdecision.pdf>.

¹²³ *In the Matter of Rambus, Inc.*, Docket No. 9302 (Aug. 2, 2006), available at <http://www.ftc.gov/os/adjpro/d9302/060802commissionopinion.pdf>

factor was whether the specific standards development process created a reasonable expectation of non-deceptive conduct that Rambus's behavior failed to meet, and rejected Rambus's argument that its non-disclosure of information relating to its patent applications was necessary to protect trade secrets.¹²⁴ The D.C. Circuit reversed, finding that, even if there would have been anticompetitive impact if Rambus had engaged in deception to avoid being excluded from the standards, there would have been no anticompetitive effect if Rambus had only avoided making assurances that it would demand only reasonable and non-discriminatory (RAND) license fees.¹²⁵ It reasoned that "an otherwise lawful monopolist's use of deception simply to obtain higher prices normally has no particular tendency to exclude rivals and thus to diminish competition."¹²⁶

In an unusual action, the FTC charged Negotiated Data Solutions LLC ("N-Data") with violating §5 of the FTC Act, without alleging any violation of the Sherman Act, claiming that N-Data's repudiation of its predecessor's commitment to a SDO regarding royalties for patented technology in a standard was both

¹²⁴ The FTC later issued a final order on damages, imposing a compulsory license setting royalties declining over time. <http://www.ftc.gov/opa/2007/02/070502rambus.htm> As a result of the D.C. Circuit's reversal of the FTC's order on liability, the FTC issued an order acknowledging that Rambus may charge higher royalties. <http://www.ftc.gov/os/adjpro/d9302/081017orderrespondent.pdf> It dismissed the remainder of the case, after certiorari was denied on the D.C. Circuit's reversal. *In re Rambus, Inc.*, No. 9302 (FTC 2009), <http://www.ftc.gov/os/adjpro/d9302/090512orderdismisscomplaint.pdf>

¹²⁵ *Rambus, Inc. v. FTC*, 522 F.3d 456, 464 (D.C. Cir. 2008), *cert. denied sub nom. FTC v. Rambus, Inc.*, 129 U.S. 1318 (2009).

¹²⁶ 522 F.3d at 464. In contrast, the court in *Research in Motion v. Motorola, Inc.*, 2008 U.S. Dist. LEXIS 101241 *19 (N.D. Tex. 2008), denied a motion to dismiss antitrust claims based on alleged failure to fulfill a promise to SDO to license on fair, reasonable and non-discriminatory (FRAND) terms, finding a breach of a FRAND commitment "harmful to competition".

an unfair method of competition and an unfair practice.¹²⁷ N-Data settled the action by agreeing to honor the commitment and refrain from asserting patent claims on the license fees.¹²⁸

Private plaintiffs have also brought antitrust claims based upon alleged misconduct relating to standards development.¹²⁹ For example, in *Townshend v. Rockwell International Corp.*,¹³⁰ Townshend invented the technology underlying the 56K modem and licensed it to 3Com (then U.S. Robotics). Townshend sued Rockwell and Conexant for patent infringement. The defendants asserted counterclaims under Sections 1 and 2 of the Sherman Act alleging that Townshend and 3Com conspired to obtain invalid

¹²⁷ Complaint, *In the Matter of Negotiated Data Solutions LLC*, Dkt. No. C-4234 (FTC Sept. 22, 2008), <http://www.ftc.gov/os/caselist/0510094/080923ndscomplaint.pdf>

¹²⁸ Decision and Order, *In the Matter of Negotiated Data Solutions LLC*, Dkt. No. C-4234 (FTC Sept. 22, 2008), <http://www.ftc.gov/os/caselist/0510094/080923ndsdo.pdf> In *Vizio v. Funai Electric*, 2010 U.S. Dist. LEXIS 30850 (C.D. Cal. 2010), claims similar to those made against N-Data were upheld on the basis of *United States v. Line Materials Co.*, 333 U.S. 287, 314 (1948), that a violation of Sherman Act §1 occurred when a patentee that participated in developing a standard and made a FRAND commitment, transferred the patent to the defendant with the understanding that the assignee would repudiate the FRAND commitment and share the profits.

¹²⁹ Abuse of a standard setting process can also present risk under other laws. For instance, in *Rambus v. Infineon*, 318 F.3d 1081 (Fed. Cir. 2003), Rambus sued Infineon for patent infringement and Infineon counterclaimed for fraud under Virginia state law on the ground that Rambus had not disclosed patents and patent applications related to two technologies to JEDEC. The fraud claims were tried to a jury, which found Rambus guilty. The District Court set aside one of the fraud verdicts, but allowed the other to stand. The Federal Circuit reversed in part, finding that there was no fraud because Rambus did not breach its duty to disclose. Given the varying degrees of disclosure required by different standard setting initiatives, the possibility of a fraud claim should be kept in mind when counseling clients in this context.

¹³⁰ 2000-1 Trade Cas. (CCH) ¶72,890 (N.D. Cal. 2000).

patents relating to 56K modems, to fraudulently procure an industry standard for the operation of products involving Townshend's technology, to deny the technology to 3Com's competitors or condition the availability of the technology on reciprocal dealing with 3Com. They claimed that Townshend and 3Com had lobbied the International Telecommunications Union to adopt an industry standard based on Townshend's technology. The court ultimately dismissed the counterclaims for failure of proof.¹³¹

XIII. Some Additional Considerations

Antitrust issues may have implications beyond the

¹³¹ See also, e.g., *Apple Inc. v. Motorola Mobility, Inc.*, 2011 U.S. Dist. LEXIS 72745 (W.D. Wisc. 2011) (alleged refusal to comply with FRAND commitment to SDO); *Actividentity Corp. v. Intercede Group PLC*, No. C08-4577, Doc. #52 (N.D. Cal Sept. 11, 2009) (Actividentity allegedly failed to disclose patent after adoption of standard but before standard gained market acceptance); *Rambus Inc. v. Hynix Semiconductor Inc.*, 2008 U.S. Dist. LEXIS 60838 (N.D. Ca. 2008); *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297 (3d Cir. 2007) (Broadcom alleged that Qualcomm refused to license on FRAND terms its patents relating to chipsets in mobile phones after it had asserted to various standard setting bodies that it would do so if certain technology, to which its patents were "essential," became the standard for the industry); *Wang Laboratories, Inc. v. Mitsubishi Elecs. America, Inc.*, 103 F.3d 1571 (Fed. Cir. 1997) (Wang's claims against Mitsubishi for infringement after Wang convinced a standards body to adopt its technology for computer memory modules without disclosing its pending patent applications were invalid because an implied license existed); *Stambler v. Diebold, Inc.*, 11 U.S.P.Q.2d (BNA) 1709 (E.D.N.Y.), *aff'd*, 878 F.2d 1445 (Fed Cir. 1988) (summary judgment granted based on laches and estoppel because plaintiff waited 10 years after a standard setting body adopted a standard that infringed his patent to assert his patent rights, and 10 year silence could reasonably have been interpreted as abandonment of the patent claims); *Potter Instrument Co. v. Storage Technology Corp.*, 207 U.S.P.Q. (BNA) 763 (E.D. Va. 1980), *aff'd*, 641 F.2d 190 (4th Cir. 1981) (summary judgment granted dismissing infringement claims based on laches because plaintiff had waited longer than 6 years after a standards body adopted a standard that infringed his patent to assert his patent rights).

antitrust remedies that are available to the injured party, if the doctrine of patent misuse is invoked. And foreign law implications should be considered where cross-border situations are involved.

A. Misuse

Misuse may in some circumstances be a more important consideration than antitrust. That is because misuse may be found even when there is no antitrust violation,¹³² and because misuse results in unenforceability of the IP rights against the world, and not just liability to the other party in litigation. “[P]atent misuse is not an affirmative claim, but rather a defense that ‘results in rendering the patent unenforceable until the misuse is purged.’”¹³³

Misuse is a form of the “unclean hands” doctrine that was developed in the patent context, most often in the context of finding that the patent holder extended the scope of the patent beyond its legal scope.¹³⁴ Some courts have extended it to copyright situations.¹³⁵ With the Federal Circuit’s en banc opinion in *Princo Corp. v. Int’l Trade Comm’n*¹³⁶ clarifying the standards for patent misuse, the tests for misuse and antitrust have converged

¹³² See, Section X, above.

¹³³ *Bernhardt LLC v. Collezione Europa USA, Inc.*, 2002 WL 1602447, (M.D.N.C. July 3, 2002) (citing *B. Braun Med., Inc. v. Abbott Labs.*, 124 F.3d 1419, 1427 (Fed. Cir. 1997)); see also *Virginia Panel Corp. v. Mac Panel Co.*, 133 F.3d 860, 868 (Fed. Cir. 1997), *cert. denied*, 525 U.S. 815 (1998) (“Patent misuse is an affirmative defense to an accusation of patent infringement.”).

¹³⁴ E.g., *Morton Salt Co. v. G.S. Suppiger Co.*, 314 U.S. 488 (1942).

¹³⁵ See, e.g., *Alcatel USA, Inc. v. DGI Technologies*, 166 F.3d 772 (5th Cir. 1999); *Practice Management Information Corp. v. American Medical Ass’n*, 121 F.3d 516 (9th Cir.), *cert. denied*, 522 U.S. 933 (1997); *Lasercomb of America, Inc. v. Reynolds*, 911 F.2d 970 (4th Cir. 1970).

¹³⁶ 616 F.3d 1318 (Fed. Cir. 2010), *cert. denied*, 131 S. Ct. 2480, 2011 U.S. LEXIS 3703 (2011).

substantially. Under *Princo*, a practice is patent misuse only if it prevents competition that the patentholder could not prevent through enforcing the patent.¹³⁷

B. Foreign Law

Where there are parties from outside the U.S., foreign law may need to be considered. In some cases, the foreign law that may be relevant may take a more restrictive view than the U.S. of permissible IPR license relationships.

For example, in the European Union, the 2004 Technology Transfer Block Exemption Regulation (TTBER),¹³⁸ accompanied by Technology Transfer Guidelines, are intended to simplify the application of competition rules to the licensing of IPR, and to bring the EU regime closer to the U.S. approach.¹³⁹ Although the 2004 law contains some significant changes from the earlier TTBER, those changes do not fully align the policy of the European Community with that of the U.S.

The 2004 law contains market share thresholds for the application of the block exemption. The TTBER applies where the combined market share of parties to licenses who are competitors does not exceed 20% or the individual market share of parties who are not competitors does not exceed 30%. These thresholds apply for the duration of the agreement, although there is a grace period of two years following the year in which a threshold is first exceeded and the agreement is no longer eligible for protection under the block exemption.

¹³⁷ 616 F.3d at 1337.

¹³⁸ Commission Reg. No. 772/2004, [2004] O.J. 2004 L 123/11 http://europa.eu.int/comm/competition/antitrust/legislation/entente3_en.html#technology.

¹³⁹ However, unlike in the U.S., where patent and copyright are exclusively under federal law, the EU member states' laws govern IPR generally, with the exercise of IPR subject to EU competition law. EC Treaty, Article 295; [1966] ECR 299 at 345-46.

The law also includes a list of hardcore restrictions, which, if included in an agreement, disqualifies the agreement from the exemption. In general, agreements between competitors are more stringently regarded than those between non-competing entities, but price fixing, output restrictions, and market or customer allocations are generally prohibited regardless of the relationships of the parties to the agreement.

Agreements that fall outside the block exemption, and therefore not protected by the exemption, must be individually analyzed under the Guidelines and may be individually struck from an agreement. The TTBER also specifically excludes from the block exemption and subjects to the Guidelines: (1) any direct or indirect obligation on the licensee to grant an assignment or an exclusive license to the licensor or to a third party designated by the licensor in respect of its own severable improvements to or its own new applications of the licensed technology; and (2) any direct or indirect obligation on the licensee not to challenge the validity of IPR which the licensor holds in the EU, although the agreement may provide for termination of the agreement in the event that the licensee challenges the validity of one or more of the licensed IPR.

The TTBER exempts from the EU's competition law strictures only certain forms of bilateral licensing agreements, but not any multi-lateral agreements. Therefore, all patent pools may be found violative of Articles 101 or 102 of the European Union Treaty. The Guidelines provide some relief from that threat, by applying the principles contained in the TTBER to multi-party arrangements. Nonetheless, both the TTBER and the Guidelines are generally much more restrictive than the current state of U.S. law as to permissible terms in licensing arrangements, ranging from exclusivity to field of use, to royalties terms.¹⁴⁰ Similarly, the line of cases from *Magill*,¹⁴¹ through *Oscar Bronner*,¹⁴² to

¹⁴⁰ One notable exception is that it is permissible in the EU to have royalties attributable to patents past expiration. *Ottung v. Klee*, Case 320/87, 1989 E.C.R. 1177 (May 12, 1989).

¹⁴¹ *Radio Telefis Eireann v. EC (Magill)*, 1995 E.C.R. 743.

IMS,¹⁴³ reflect a much more skeptical approach to refusals to deal than that of U.S. courts, and much greater willingness to embrace the essential facilities doctrine and compulsory licensing. In *IMS*, IMS Health Inc. sued NDC Health Corp. for copyright infringement of IMS's "1860 brick structure" to collate pharmaceuticals sales data. The brick structure was developed in the 1970s by IMS in collaboration with drug retailers, dividing Germany into 1860 geographic areas containing drugstores. Pharmaceuticals sales data in Germany has since been generally gathered and analyzed according to the 1860 brick structure. NDC claimed that the brick structure is in fact an industry standard and that IMS had violated EU competition law by refusing to license it to NDC. Ultimately, the European Court of Justice held that if the brick structure is "indispensable" to such marketing data studies, it is a violation of EU law to refuse to license the brick structure if the prospective licensee intends to use the brick structure to offer:

new products or services not offered by the copyright owner and for which there is a potential consumer demand; the refusal is not justified by objective considerations; the refusal is such as to reserve to the copyright owner the market for the supply of data on sales of pharmaceutical products in the Member State concerned by eliminating all competition on that market.¹⁴⁴

The implications of this ruling on standards, particularly *de facto* standards, that incorporate IPR, may be severe, since it raises the prospect of compulsory licenses.

¹⁴² *Oscar Bronner GmbH & Co. KB v. Mediaprint Zeitungs und Zeitschriftenverlag GmbH & Co. KG*, 1998 E.C.R. I-7791.

¹⁴³ *IMS Health Inc. v. NDC Health Corporation*, Case C-418/01, 2004 E.C.R. I-05039 (April 29, 2004).

¹⁴⁴ *Id.*, *slip op.* at I-12 – I-13. In the meantime, the German national court had held on the copyright infringement claim that IMS did have a valid copyright on the 1860 brick structure, but that the copyright was not infringed if NDS had used similar numbers but differently shaped segments in its data gathering.

In 2010, the European Commission replaced earlier statements by adopting revised guidelines on horizontal cooperation agreements,¹⁴⁵ and issuing two block exemption regulations relating to some types of research and development¹⁴⁶ and specialization agreements¹⁴⁷. The new guidelines are more detailed than the 2001 guidelines and provide revised guidance on standard setting. They recognize both the benefits of standardization and the risks of collusion or the creation of entry barriers in standards setting, emphasizing that standards setting may not be a pretext for agreements to restrict competition. The guidelines also recognize the market power that may be created by the inclusion of IPR in standards and the effective exclusion of alternative technologies, and indicated that the freedom of SDO members to develop alternative standards or technologies will be important in the EC's review of SDO activities. The guidelines list 4 factors that must be present before standard setting activities are outside the reach of Article 101 of the EU Treaty: (1) participation in the SDO is unrestricted and open to all relevant parties; (2) the SDO procedures are transparent; (3) the standardization agreement includes no obligation to comply with the standard; and (4) access

¹⁴⁵ Guidelines on the Applicability of Art. 101 of the Treaty on the Functioning of the European Union to Horizontal Cooperation Agreements, 2011/C 11/01, O.J. C11, 14.1.2011, p.1; C33, 2.2.2011, p. 20. <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2011:011:0001:0072:EN:PDF>

¹⁴⁶ Commission Regulation (EC) No. 1217/2010 of 14 December 2010 on the application of Art. 101(3) of the Treaty on the Functioning of the European Union to certain categories of research and development agreements, O.J. L335, 18.12.2010, p. 36; O.J. L152, p. 34. <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:335:0036:0042:EN:PDF>

¹⁴⁷ Commission Regulation No. 1218/2010 of 14 December 2010 on the application of Art. 101(3) of the Treaty on the Functioning of the European Union to certain categories of specialisation agreements, O.J. L335, 18.12.2010, p.43; O.J. L151, p. 15. <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:335:0036:0042:EN:PDF>

to the standard is on fair, reasonable and non-discriminatory (FRAND) terms. A FRAND commitment is considered an essential preventive to entry barriers or abusive practices by holders of IPR included in the standard.

Other jurisdictions, from South Africa¹⁴⁸ and Japan¹⁴⁹ to China,¹⁵⁰ also take a harsher view than the U.S. courts generally of refusals to deal, including refusals to license IPR, in the context of what are deemed to be essential facilities. They appear to be inclined to define essential facilities much more broadly than U.S. courts have.¹⁵¹

XIV. Conclusion

The types of transactions involving IPR are as varied as the rights themselves being licensed. It is crucial to examine each transaction involving an IPR in sufficient detail to determine the substance of the arrangement. Within the fact-specific analysis, however, there are some constants. What is the business reason for and business context of the deal? What exactly is the arrangement the parties are contemplating? What is the

¹⁴⁸ The South African Competition Act of 1998 provides that it is an offense for a dominant firm to “refuse to give a competitor access to an essential facility when it is economically feasible to do so.” The law has been used to challenge refusals to license patents for anti-AIDS drugs.

¹⁴⁹ The Japan Fair Trade Commission had proposed amendments to Japan’s antitrust law, to define essential facilities as those essential to produce goods or services in an “important market” and “almost impossible” for competitors to duplicate, and to authorize prosecution of refusals to provide access to such essential facilities. The proposals were tabled in the face of substantial opposition.

¹⁵⁰ China’s Anti-Monopoly Law provides in Article 17 that a business in a dominant market position may not, “without valid reasons,” refuse to deal. Article 48 of the Patent Law also provides for compulsory licensing if a patentholder has monopolistically used its patent.

¹⁵¹ See, *Verizon Communications v. Trinko*, 540 U.S. at 411.

competitive impact of the transaction? Posing these questions and carefully weighing the answers will generally lead to sound antitrust counsel.