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THE SEDONA CONFERENCE® COMMENTARY ON THE INTERSECTION OF THE PATENT & ANTITRUST LAWS

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The Sedona Conference® Commentary on the Intersection of the Patent & Antitrust Laws

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Author:
The Sedona Conference®

Editors:
David A. Balto
Thomas Greene (Sections I & II only)
Kevin D. McDonald
Will Shieber
Daniel R. Shulman
Stephen W. Smith

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Preface

Welcome to the 2010 version of The Sedona Conference® Commentary on the Intersection of the Patent and Antitrust Laws. The mission of The Sedona Conference® Working Group on the Intersection of the Patent and Antitrust Laws (WG4) is to create guidelines to help courts resolve disputes on certain issues that arrive at the intersection of the patent and antitrust laws. Sections I & II were originally published in 2007 on our website and in 8 Sedona Conference Journal at 57 (2007), Section III was completed in the Fall of 2010 and Section IV was completed in the Spring of 2010 and are now being published for the time.

While all Working Group members played a role in the revisions and enhancements to this commentary, I would like to especially thank Thomas Greene for his work on Sections I & II (along with Cheryl Johnson and James Langenfeld), and David A. Balto, Kevin D. McDonald, Daniel R, Shulman, and Stephen W. Smith for their work on Sections III & IV.

Finally, we welcome public comment on this and other publications of The Sedona Conference.® Please reach out to us at our website at www.thesedonaconference.org or email us at info@sedonaconference.org.

Richard G. Braman
Executive Director
The Sedona Conference®
December 2010

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I. Introduction: The History of American Patent & Antitrust Laws

Patents represent strategic assets in the 21st century. But despite the importance of patents—or perhaps because of it—patent policy is increasingly unsettled. On the one hand, legal protection of new and novel ideas is the lifeblood of a modern economy. On the other, the modular nature of much innovation means that an old patent can hamper or block development of the next generation of technology. And overlapping thickets of patents must be navigated to make virtually any complex product. Ultimately, too much protection risks future advances while too little protection jeopardizes today's innovations.

Finding a path of grace between these two extremes is not a new challenge. Judges and legislatures have been wrestling with the appropriate mix of robust competition and state-sanctioned monopoly to advance new technology since at least the 16th century. In today's courtrooms, the boundaries of these two very different legal regimes are most often delineated at the points of intersection between patent law and antitrust law.

Working Group 4 of The Sedona Conference® has been studying the intersection of patent and antitrust law. This article sketches the background for the Working Group's evaluation of this intersection. It reviews the common law roots of both antitrust and patent law, and highlights the potential for tensions developing between antitrust and intellectual property law.

A. Common Law Roots

The English common law was skeptical, if not hostile, to any form of monopoly. Sir Thomas More, for example, in his book *Utopia*, written in 1516, opined that "Suffer not thies ryche men to bye up all, to ingross and forstalle, and with theyr monopolye to kepe the market alone as please them."[1] The royal family, however, could issue letters patent[2] to give individuals monopolies over particular lines of commerce.[3] This was relatively rare until the time of Elizabeth I who issued letters patent on a wide range of ordinary consumer goods including salt, iron, playing cards, beer and various kinds of cloth.[4] In response to the "odium which arose from abuse" of royal grants,[5] Parliament enacted the Statute of Monopolies in 1623.[6] The Act prohibited "all monopolies" with one exception. That exception was for letters patent for a period not to exceed 14 years for the "sole working or making of any new manufactures within the realm" to be granted to the "true and first inventor" but only if "not contrary to the law nor mischievous to the state by raising prices of commodities at home, or hurt of trade or generally inconvenient."[7]

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[1] H. FOX, MONOPOLIES AND PATENTS 24 (1947).
[2] Letters patent were public documents as opposed to letters close which were sealed.
[3] See *Darcy v. Allein*, 11 Co. Rep. 84b, 77 Eng. Rep. 1260 (K.B. 1602) (Darcy was allowed to monopolize the sale of playing cards pursuant to a royal grant even though such monopolies were contrary to the common law.).
[4] Miller, *The Case of the Monopolies-Some of Its Results and Suggestions*, 6 MICH. L. REV. 1, 2 (1907).
[5] 4 W. HOLDSWORTH, A HISTORY OF ENGLISH LAW 348 (2nd ed. 1937).
[6] An Act concerning Monopolies and Dispensations with Penal Laws and the Forfeitures thereof, 21 Jac. 1, c. 3 (4 Statutes at Large) 734 (1811).
[7] *Id.* at section 6.

Sir Edward Coke's commentaries on the common law of England became the standard reference works for law students like Jefferson and Adams in the American colonies. His report on the Case of Monopolies concluded that a grant of an exclusive license to sell playing cards "was utterly void" as "against the common law."[8] He noted that among the "inseparable incidents" of every monopoly were that (1) "the price of the same commodity will be raised, for he who has the sole selling of any commodity, may and will make the price as he pleases"; (2) "after the commodity [is] granted, the commodity is not so good as it was before"; and (3) monopoly "tends to the impoverishment of divers artificers" who are precluded from making the monopolized product.[9]

When the U.S. Constitution was drafted, four states suggested amendments that would have paralleled the English Statute of Monopolies. Although advocated by Jefferson, this proposal was not adopted.[10] Rather, the new Constitution authorized Congress to enact laws to "promote science and the useful arts by securing for limited times to authors and inventors the exclusive right to their respective writing and discoveries."[11] According to Madison in Federalist No. 43, this was included to "protect a right of common law."[12] And in this instance, he argued, the "public good fully coincides…with the claims of individuals."[13]

The first patent law under the new Constitution was enacted in 1890 as "An Act to Promote the Progress of Useful Arts". This was succeeded in 1893 with a statute substantially attributed to Jefferson,[14] the language of which is virtually identical to parts of today's law.[15] Patentable subjects included "any new and useful art, machine, manufacture or composition of matter or any new and useful improvement on any art, machine, manufacture or composition of matter."[16] An applicant had to provide a "written description of his invention, and of the manner of using, or process of compounding the same, in such full, clear and exact terms to distinguish the same from all other things before known and to enable any person skilled in the art or science of which it is a part, or with which it is most nearly connected, to make, compound and use the same."[17] An inventor was required to "fully explain the principle, and the several modes in which he has contemplated the application of" his invention.[18] Only the "true inventor" could seek to obtain a patent and only if the invention had not been "known or used before the application."[19] Like the 1623 Statute of Monopolies, letters patent guaranteed a state-protected monopoly for 14 years.

The 19th century saw a dramatic increase in the number of patents. Doctrinally, the most important legal development was the mid-century decision in *Hotchkiss v. Greenwood,*[20] that clarified that a patentable invention had to be not only new, but not obvious. This was enforced by a new examination system that is credited by economic historians with reducing the number of patent

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[8] *Darcy v. Allein* (The Case of Monopolies) 11 Co. Rep. 84b, 77 Eng.Rep. 1260 (K.B. 1603).
[9] *Id.*
[10] Letter, Jefferson to Madison, (Aug. 28, 1789, in *The Republic of Letters* 1 (James Morton Smith, ed., 1995).
[11] U.S. CONST., art. 1, section 8, clause 8.
[12] The Federalist No. 43 (Madison).
[13] *Id.*
[14] *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 147 (1989).
[15] Compare Patent Act of 1793, 1 Stat. 318-323 (Feb. 21, 1793), section 1 with 35 U.S.C. §101.
[16] Patent Act of 1793, section 1, 1 Stat. 318-323 (Feb. 21, 1793).
[17] Patent Act of 1793, section 3, 1 Stat. 318-323 (Feb. 21, 1793).
[18] *Id.*
[19] Patent Act of 1793, sections 3 and 1, 1 Stat. 318-323 (Feb. 21, 1793).
[20] 52 U.S. 248 (1850).

lawsuits and spurring innovation.[21] In 1887, the United States joined the Paris Convention for the Protection of Industrial Property to become a formal part of international efforts to protect patented inventions.

In 1890, the Sherman Act became law.[22] The new statute prohibited both combinations in restraint of trade and monopolization. Senator Sherman stated that the new Act was designed to "supplement the enforcement of established rules of the common and statute law by the courts of the several States".[23] With enactment of the Sherman Act, the competing elements of the Statute on Monopolies became part of U.S. statutory law. The general prohibitions against restraints of trade and monopoly were now explicit in the Sherman Act while its limited exception to encourage new inventions was captured in the Patent Act.

B. The PTO and its "Customers"

The Patent and Trademark Office issued 165,485 patents in federal fiscal year 2005. This is over twice the number issued in 1985 and approximately 30% more than in 1995.[24] Despite political rhetoric suggesting that patents uniquely advance U.S. interests, 80,247 of these patents, or approximately half, were issued to residents of foreign nations.[25] Japan led with 34,079 patents with Germany second with 10,502. Emerging technology centers like China and India were well behind with 583 and 405 patents, respectively.

The PTO has declared its mission to be "helping our customers get patents."[26] Examiners spend an estimated 18 hours on an individual application, reviewing the application, testing it against prior art contained in various databases and writing up their analyses.[27] The process is secret and much of the burden of providing prior art, particularly in the most innovative industries, is on patentees' legal representatives.[28] Incentives in the PTO are generally understood to favor grants over denials,[29] and 95-97% of all applications ultimately result in a patent.[30] Despite this approval rate, it takes an average of 31 months to process a patent application, a backlog the agency expects

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[21] ZORINA B. KHAN, THE DEMOCRATIZATION OF INVENTION: PATENTS AND COPYRIGHTS IN AMERICAN ECONOMIC DEVELOPMENT, 1790-1920 (2004).
[22] 26 Stats. 209 (July 2, 1890).
[23] 21 Cong. Rec. 2547 (1890).
[24] U.S. Patent and Trade Office*, Performance and Accountability Report Fiscal Year 2005*, Table 6: Patents Issued, available at http://www.uspto.gov/web/offices/com/annual/2005/060406_table6.html.
[25] *Id.* at Table 10: Patents Issued by United States to Residents of Foreign Countries (FY 2001-FY 2005) (Preliminary for FY 2005), available at http://www.uspto.gov/web/offices/com/annual/2005/060410_table10.html.
[26] Mark Lemley, *Rational Ignorance at the Patent Office*, 95 NW. L. REV. 1, 2 n. 3 (2001). The current formal mission statement provides that: "The USPTO's mission is to insure that the Intellectual Property system contributes to a strong global economy, encourages investment in innovation, and fosters entrepreneurial spirit. Intellectual property is an invention or creation embodied in the form of a patent, trademark, trade secret, or copyright," available at http://www.uspto.gov/web/menu/intro.html.
[27] Brenda Sandburg, *Speed Over Substance?* INTELL. PROP MAG., Mar. 1999 (estimating 18 hours on average with more time spent on more complex applications); compare *Patent Nonsense: The Knowledge Monopolies*, The Economist, Apr. 8, 2000 ("[P]atent examiners spend only eight hours on a patent, on average.").
[28] 37 C.F.R. § 1.56.
[29] Mark Lemley, *Rational Ignorance at the Patent Office*, 95 NW. L. REV. 1, 2, n. 3 (2001).
[30] Cecil D. Quillen, Jr. & Ogden H. Webster, *Continuing Patent Applications and Performance of the U.S. Patent and Trademark Office*, 11 FED. CIR. B.J. 1 (2001).

to close by hiring 1,200 new examiners in 2007.[31] These hires are in addition to a record-setting addition of 1,193 examiners in 2006.[32]

In the last 15 years, the PTO has administered a system that has become increasingly patent friendly. The United States Supreme Court concluded in 1980 that a newly developed microorganism could be the subject of a patent in *Diamond v. Chakrabarty*.[33] In the following year, it determined in *Diamond v. Diehr* that a computer program could be patented.[34]

The doctrine of equivalency was given a broad sweep in the Court's decisions in *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*[35] and *Festo v. Shoketsu Kinzoku Kogyo Kabushiki,* although the Court acknowledged that this made the scope of patents "less certain".[36] These decisions contrast with earlier cases that opined that clear definition of claims was necessary to "guard against unreasonable advantages to the patentee and disadvantages to others arising from uncertainty as to their rights."[37]

The Federal Circuit, created in 1982 to bring uniformity to patent jurisprudence, raised evidentiary standards for challenging patents in 1986.[38] The same court relaxed standards for evaluating whether an invention is "obvious" to practitioners skilled in the art.[39] It also softened the "best mode" requirement, substantially freeing applicants from having to specify the means by which their inventions will work in the real world.[40] According to an IBM attorney, this "invites the patenting of ideas that may have been visualized as desirable but have no foundation in terms of the research or development that may be required to enable their implementation."[41]

Finally, the Federal Circuit decided in *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*[42] that "business methods" are patentable. As one patent specialist noted in the *National Law Journal*, companies should "now seek U.S. patent rights for any conceivable business operation, such as methods of billing clients, hiring employees, marketing products or service…or simply obtaining funding."[43]

These developments have engendered dramatically different reactions. At one end of the spectrum, the PTO argues that the current system "has propelled our nation from a small agrarian

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[31] U.S. Patent and Trademark Office, 2007-2012 Strategic Plan 6, available at http://www.uspto.gov/web/offices/com/strat2007/stratplan2007-2012.pdf.
[32] *Id.*
[33] 447 U.S. 303 (1980).
[34] 450 U.S. 175 (1981).
[35] 520 U.S. 17 (1997).
[36] 535 U.S. 722, 732 (2002).
[37] *McClain v. Ortmayer*, 141 U.S. 419, 424 (1891), *see also General Electric Co. v. Wabash Appliance Corp.*, 304 U.S. 364, 369 (1938).
[38] *Medtronics, Inc. v. Intermedics, Inc.*, 799 F.2d 734 (Fed. Cir. 1986); *Hybridtech Inc. v. Monoclonal Antibodies Inc.,* 802 F.2d 1367 (Fed. Cir.1986).
[39] *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530 (Fed. Cir. 1983); *Simmons Fastener Corporation v. Illinois Tool Works*, 739 F.2d 1573 (1984).
[40] Dan L. Burk & Mark A. Lemley*, Is Patent Law Technology Specific?,* 17 BERKELEY TECH. L.J. 9-10 (2003).
[41] John D. Flynn, *Comments on the International Effort to Harmonize the Substantive Requirements of Patent Laws* (IBM 2001), available at http://www.uspto.gov/web/offices/dcom/olia/harmonization/TAB42.pdf.
[42] 927 F. Supp. 502, 516 (D. Mass. 1996), *rev'd*, 149 F.3d 1368 (Fed. Cir. 1998), cert. denied, 525 U.S. 1093 (1999).
[43] Barry Schindler*, In Focus: Intellectual Property, Key ruling for business methods*, NATIONAL LAW JOURNAL (Dec. 5, 2005).

society to the preeminent technological and economic superpower…and has become the basis for economic development in nations throughout the world."[44] At the other, the National Institutes of Health have stated categorically that the granting of patent rights for biological research tools, expected to be critical for the development of stem cell technologies, "can stifle the broad dissemination of new discoveries and limit future avenues of research and product development."[45]

In the middle, a 2003 report of the Federal Trade Commission concluded that while there was "much to praise" in the system, "[p]oor patent quality and legal standards and procedures that inadvertently may have anticompetitive effects can…hamper competition that otherwise would stimulate innovation."[46] To address its concerns, the FTC suggested a number of reforms including third-party involvement in challenging patents during the examination process, strengthening the obviousness requirement and reclaiming the "preponderance of the evidence" review standard.[47]

Likewise, the National Academy of Sciences concluded in a major report in 2004 that "[c]ontinuing high rates of innovation suggest that the patent system is working well and does not require fundamental changes."[48] However, the National Academy, like the FTC, suggested that a number of reforms are necessary including reinvigoration of the obviousness requirement, institution of third-party participation in the process at the PTO, shielding some research uses of patented products or processes from infringement claims and increased staffing at the agency.[49]

Both the Supreme Court and Congress have begun to react to concerns about patent quality. In *KSR International v. Teleflex, Inc.,*[50] the Court rejected Federal Circuit precedent on obviousness, scoring that court's approach as too formulaic. The Supreme Court concluded that:

> …the results of ordinary innovation [based on existing art] are not the subject of exclusive rights under the patent laws. Were it otherwise patents might stifle, rather than promote, the progress of useful arts.[51]

Other high court cases have also begun to cut back on Federal Circuit decision. In two important procedural decisions, the Court has made it easier to effectively challenge poor patents. In *eBay, Inc. v. MercExchange, L.L.C.,*[52] the Court rejected the principle that injunctions should be issued in the normal course of patent litigation. It noted that such a rule was contrary to equity jurisprudence in other areas of the law, and four justices argued that the reflexive issuance of injunctions gave "undue leverage" to patent holders for claims of "potential vagueness and suspect

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[44] Jon W. Dudas, Message from the Undersecretary of Commerce for Intellectual Property and Director of the U.S. Patent and Trademark Office 1 (Nov. 2, 2005, available at http://www.uspto.gov/web/offices/com/annual/2005/02_message_director.html.

[45] Principles and Guidelines for Recipients of NIH Grants for Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice, 64 Fed. Reg. 72,090, 72,092 (Dec. 23, 1999); *see also* Scott Iyama, *The USPTO's Proposal of a Biological Research Tool Patent Pool Doesn't Hold Water*, 57 STAN. L. REV. 1223 (2005).

[46] Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* 4-5 (Oct. 2003), available at http://www.ftc.gov/os/2003/10/innovationrpt.pdf.

[47] *Id.* at 7-18.

[48] Committee on Intellectual Property Rights, National Research Council, *A Patent System for the 21st Century* 1 (Stephen A. Merrill, Richard C. Levin & Mark B. Myers, eds.) (National Academy of Sciences, 2004).

[49] *Id.* at 5-8.

[50] 550 U.S. 398, 127 S.Ct. 1727 (2007).

[51] *Id.* at 1746.

[52] 547 U.S. 388, 126 S.Ct. 1837 (2006).

validity."[53] In *MedImmune, Inc. v. Genetech, Inc.,*[54] the Court rejected jurisprudence requiring a patent licensee to breach its licensing agreement in order to seek a judgment on the patent's validity.

Congress has begun its own overhaul of the patent system. After several years of hearings, omnibus bills to amend the patent law have been reported to the floors of both houses.[55] Although there are major differences in the two bills, both the House and Senate bills provide for a post-grant opposition procedure already used in Europe to improve patent quality.[56]

[53] *Id.* at 1842.
[54] 549 U.S. 118, 127 S.Ct. 764 (2007).
[55] H.R. 1908 (Berman et al.), reported to the House floor on July 18, 2007, S. 1145 (Leahy et al.), reported to the Senate floor on July 19, 2007; *see* Marcia Coyle, *Patent reform finds traction*, 29 NATIONAL LAW JOURNAL 1 (July 30, 2007).
[56] *Id.* at 17.

II. The Role of Innovation in a Global Economy

A. Patent Thickets, Strategic Portfolios and the Business of Innovation

Many people think that a single patent will give rise to a complete product, as Alexander Graham Bell's work gave rise to the telephone. Modern realities are far different. The DVD player and disk, for example, require the interplay of 115 patents for the players and 95 patents for the disks themselves. The patents for the practical production of these products are held by Koninklijke Philips Electronics, N.V., Sony Corporation of Japan and Pioneer Electronics of Japan.[57]

The interplay of patents can be so dense that innovators can face a "patent thicket". Such thickets have been defined academically as "an overlapping set of patent rights requiring that those seeking to commercialize new technology obtain licenses from multiple patentees."[58] Patent thickets for innovative companies are akin to walking through a dense wood without stepping on a twig.

In response to patent thickets in which multiple patents from competing companies "read on" each other, technology companies have sought collections of patents that will force other companies in the thicket to seek licenses from them. The key is the ability to threaten others who wish to make products with potential infringement claims. According to Cisco general counsel Mark Chandler, his company invests in patents "to assure that if someone wants to assert patents against us, we will have some countervailing tools."[59] Research suggests that large companies tend to seek a large number of patents while smaller companies will seek fewer, but more strategic, patents.[60]

The value of a patent portfolio is hard to measure. However, an effective portfolio should facilitate in-house innovation, side-step expensive litigation, improve the company's bargaining position with rivals and enhance efforts to attract capital.[61] A closely related set of patents can operate as a "super-patent", fencing competitors out of a lucrative area.[62]

The cost of securing a U.S. patent in 1996 ranged from $10,000 to $30,000.[63] The cost of securing the same patent in 10 European countries was typically $95,000.[64] If the patents are litigated, a survey of the American Intellectual Property Law Association in 2003 found that the median cost of discovery in actions involving less than $1 million was $290,000 while the total

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[57] DOJ Business Review Letter, Assistant Attorney General Joel I. Klein to Gerard R. Beeney, re: Proposed package licensing of essential DVD patents 2 (Dec. 16, 1998), available at http://www.usdoj.gov/atr/public/busreview/2121.htm.

[58] Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools and Standard-Setting*, 1 INNOVATION POLICY AND THE ECONOMY 1 (Adam Jaffe, Joshua Lerner and Scott Stern, eds.) (MIT Press, 2001).

[59] Michael Orley, *The Patent Epidemic: It's wasting companies' money and slowing the development of new products*, BUSINESS WEEK (Jan. 6, 2006) 60, 61.

[60] John R. Allison & Mark A. Lemley, *Who's Patenting What? An Empirical Exploration of Patent Prosecution*, 53 VAND. L. REV. 2099, 2128 (2000); *see also* F.M Scherer, *Schrumpeter and Plausible Capitalism*, 30 JOURNAL OF ECONOMIC LITERATURE 1416, 1423 (1992).

[61] Gideon Parchomovsky & R. Polk Wagner, *Patent Portfolios*, 154 U. PA. L. REV. 1, 33-44 (2005); *see also* James Bessen, *Patent Thickets: Strategic Patenting of Complex Technologies*, available at http://www.researchoninnovation.org/online.htm#thicket.

[62] *Id.* at 32-33.

[63] Wayne M. Kennard, *Obtaining and Litigating Software Patents*, 431 PLI/PAT 193, 208 (1996).

[64] Edwin F. Berrier, Jr., *Global Patent Costs Must Be Reduced*, 36 IDEA 473, 476-77 (1996).

litigation costs were $500,000.[65] For actions in which the patent was worth between $1 million and $25 million, discovery costs were $1 million and the total litigation costs were $2 million.[66] While these costs are substantial, and have certainly risen, even a spurious threat of an infringement claim can cause companies to pay significant sums. For example, hundreds of companies paid a total of $1.5 billion in royalties to the Lemelson Foundation for so-called "submarine" patents on bar code technology that were ultimately held to be unenforceable by the Federal Circuit.[67]

B. Academic Perspectives on Patents and Innovation

The role of innovation in the economy is an on-going subject of academic research and thought. Joseph Schumpeter, an early writer on innovation, famously rejected much classical economic thought, arguing that "perennial gales of creative destruction" made concepts like market power of limited relevance.[68] At the other end of the spectrum, it has been argued that patent monopolies—assuming they confer market power—must be closely circumscribed.[69] This view was reflected in the so-called "Nine No-No's", a list of licensing practices that the U.S. Department of Justice once considered presumptively unlawful.[70]

By the 1970s, it was argued that since patents can add to consumer welfare, there was no necessary tension between antitrust and patent law.[71] Ward Bowman, for example, wrote that:

Both antitrust law and patent law have a common central economic goal: to maximize wealth by producing what consumers want at the lowest cost. In serving this common goal, reconciliation between patent and antitrust law involves serious problems of assessing effects, but not conflicting purposes. [72]

While Bowman saw this as theoretically correct, he cautioned that there are "serious problems of assessing effects" of patent monopolies.

Landes and Posner commented that "if intellectual property rights are enforced too strictly, then subsequent innovators will be foreclosed and overall welfare will be reduced."[73] Likewise, a respected Berkeley economist has noted: "when there are multiple gate keepers, each of whom must

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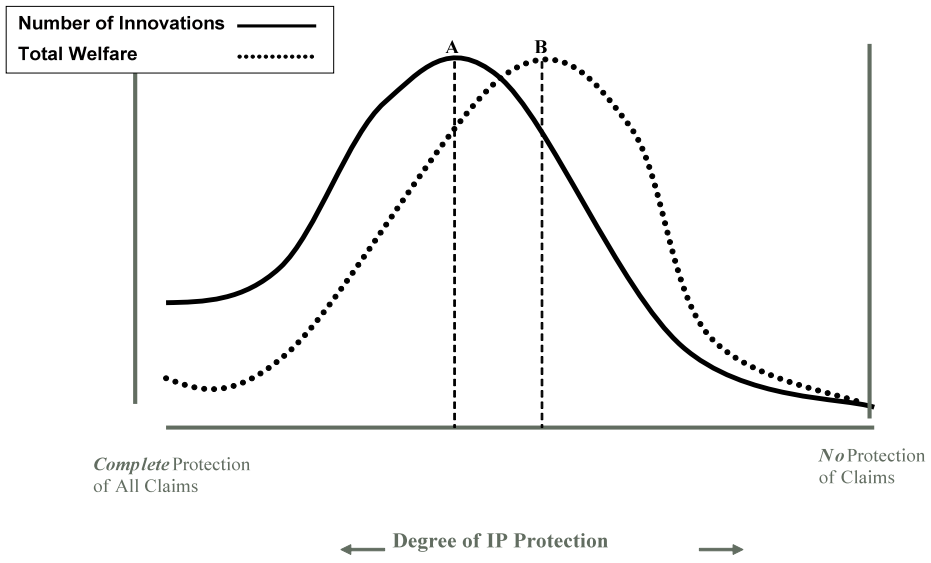
[65] Am. Intellectual Prop. Law Assoc., Report of the Economic Survey 2003, at 22 (2003), cited in James E. Besson & Michael J. Meurer, *Lessons for Patent Policy from Empirical Research on Patent Litigation*, 9 LEWIS & CLARK L. REV. 1, 2, n. 5.
[66] *Id.*
[67] Brenda Sandburg*, Lemelson patents are unenforceable*, THE RECORDER (Sept. 13, 2005); *see Symbol Technologies v. Lemelson Medical, Education & Research Foundation,* 422 F.3d 1378 (Fed. Cir. 2005).
[68] JOSEPH A. SHUMPETER, THE PROCESS OF CREATIVE DESTRUCTION (Unwin. 1942).
[69] *See, e.g., Mercoid Corp. v. Mid-Continent Inv. Co.*, 320 U.S. 661 (1944); *Carbice Corp. v. American Patents Dev. Corp.*, 283 U.S. 27 (1931).
[70] For a description of the Nine No-No's, see Willard K. Tom & Joshua A. Newberg, *Antitrust and Intellectual Property: From Separate Spheres to Unified Field*, 66 ANTITRUST L. J. 167, 178-184 (1998).
[71] Charles Rule, *The Administration's Views: Antitrust Analysis after the Nine No-No's*, 55 ANTITRUST L.J. 365 (1986); see also Richard Gilbert and Carl Shapiro, *Antitrust Issues in the Licensing of Intellectual Property: The Nine No-No's Meet the Nineties*, BROOKINGS PAPERS ON ECONOMICS: MICRONOMICS 283-336 (1997)
[72] WARD BOWMAN, JR., PATENT AND ANTITRUST LAW: A LEGAL AND ECONOMIC PORTFOLIO (1973).
[73] William Landes & Richard Posner, *An Economic Analysis of Copyright Law*, 18 J. LEGAL STUD. 325, 326 (1989).

grant permission before a resource can be used…the resource may be underutilized" and, in the case of patents, "innovation is stifled."[74]

The point made by all three of these commentators is illustrated by a chart created by James Langenfeld.[75] In Figure 1, both the number of innovations and total welfare are charted on a single graph. The horizontal axis delineates the possible levels of IP protection from complete IP protection at the far left to no protection at the far right.

Figure 1: Optimal IP Protection



Looking first at innovation, total innovation is lower with complete protection of all IP claims because subsequent inventors are foreclosed from prior art unless they pay significant rents. This is reflected by the point of intersection between the total innovation line and the vertical axis. But innovation increases to point A as innovators are allowed to more fully take advantage of prior art. After Point A, however, innovation declines because the inventors' incentives are diminished. That is, inventors cannot reap as many profits from their inventions because others can more easily copy the innovation and drive down prices.

This analysis assumes that there is a clear relationship between the scope and depth of intellectual property protection and the production of new innovations. This assumed relationship is the subject of increasing scrutiny, with some economists arguing that patents play a "surprisingly

[74] Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools and Standard-Setting*, *in* 1 INNOVATION POLICY AND THE ECONOMY (Adam Jaffe, Joshua Lerner, and Scott Stern, eds. MIT Press, 2001). Researchers have also uncovered a so-called "patent paradox", that is, increased patenting is associated with declining expenditures on research and development and reductions in real innovation. Gideon Parchomovsky & R. Polk Wagner, *Patent Portfolios*, 154 U. PA. L. REV. 1 (2005).

[75] James Langenfeld, *Intellectual Property Protection and Antitrust: Steps Toward Striking a Balance*, 53 CASE W. RES. L. REV. 91, 97 (2001).

minor role" in innovation pointing, instead, to larger economic trends like levels of education and the scope of public funding of basic research.[76] Recognizably, such research could have a profound effect on how we think about the relationship between antitrust law and the patent system.

The line for total welfare peaks at Point B, somewhat to the right of the peak of the total innovation line. According to Dr. Langenfeld:

> With complete intellectual property protection, total welfare is relatively lower than the number of innovations. Innovators gain all of the benefits from their innovations, there is no price competition or competition from the follow innovations of others, and no consumer surplus from innovations. As intellectual property protection is relaxed (moving left to right in Figure 1), total welfare increases to its peak at point B, with more development innovations by others and more competition reducing prices and increasing consumer welfare. The optimal total welfare will in general be at the point B, right of point A, indicating that total welfare is maximized with less intellectual property protection than a structure designed to maximize innovations. However, reducing intellectual property protection below point B reduces total welfare as innovators have increasingly less incentive to innovate and fewer innovations occur.[77]

Antitrust enforcers have typically focused on maximizing total or consumer welfare,[78] not maximizing the number of innovations. If patent law is interpreted to maximize the number of innovations and not weigh the benefits of price competition to consumers, then there is the clear possibility that patent and antitrust laws can come into conflict. This is an important touchstone when assessing the competing, and often contentious, claims of patent and antitrust law.

C. Conclusion

In the context of the potential tension of patent and antitrust laws, the Sedona Working Group 4 analyzed a number of specific recurring and practical issues at the intersection of antitrust and patent laws. The Working Group was composed of lawyers and economists, members of plaintiff and defense bars, intellectual property and competitive experts, and public officials. This group attempted to develop principles of decision and analysis that offer practical guides to navigating the particularly difficult points at the intersection between antitrust and patent law.

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[76] This analysis assumes that the degree of IP protection is the important driver of innovation. Various writers suggest that many other factors affect innovation. *See, e.g.,* F.M. Scherer, *The Political Economy of Patent Policy Reform in the United States,* 7 J. ON TELECOMM. & HIGH TECH. L. 167(2006), available at http://www.researchoninnovation.org/scherer/Scherer-PoliticalEconomy2009.pdf (patents play "surprisingly minor role" in decisions of companies to invest in research and development).

[77] Langenfeld, *supra,* n. 68 at 98. The precise peaks of the curves discussed above will likely be the subject of further empirical research. Economists continue to research the sources and drivers of innovation in modern economies. In particular, research continues on the relationship of innovation to levels of IP protection, levels of education, macroeconomic activity and many other factors.

[78] *See, e.g.,* Timothy J. Muris, *Robert Pitofsky Public Servant and Scholar*, 52 CASE W. RES. L. REV. 25, 37 (2001 "there is wide-spread agreement that the purpose of antitrust is to protect consumers"). Antitrust laws allow government agencies or private parties to obtain relief by eliminating practices that reduce competition in pricing or innovation, and obtaining fines or damages.

III. Standard Setting

A. Introduction

Standard setting organizations (SSOs) are critical to the efficient operation and growth of our increasingly technological society.[79] Indeed, "[i]ndustry standards are widely acknowledged to be one of the engines driving the modern economy."[80] SSOs operate in many industries and develop standards for a wide range of products, including the World Wide Web, computer operating systems, and wireless telecommunications systems. The standards promulgated by SSOs enable a wide variety of products to interoperate with each other through standardized interfaces such as the USB port, audio/video cables and electrical outlets.

At the same time, it has long been recognized that "a standard-setting organization . . . can be rife with opportunities for anticompetitive activity."[81] For example, in *Hydrolevel*, the Supreme Court upheld a finding of antitrust liability against a standard setting organization for the conduct of its agents in using the association's safety standards to benefit a group of member companies over their rival.[82] Likewise, in *Allied Tube*, the Supreme Court upheld a finding of antitrust liability against a member of a safety association that was found to have improperly stacked the voting process to induce the association to adopt a safety code that favored its product over those of its competitors.[83] 486 U.S. at 500-01. More recently, the focus has been on allegations that abuses of the standard-setting process may confer market power on patent holders.[84]

SSOs' ability to achieve their procompetitive mission often depends on the implementation and enforcement of IP disclosure and licensing policies - rules requiring SSO members to disclose any patents or patent applications they hold that relate to proposed standards, and in some circumstances to license those patents on reasonable and non-discriminatory terms. In the absence of such rules, there is the potential for "bait and switch," where a patent holder encourages adoption of a standard that requires the use of its patents by offering to license them on one set of terms and then later, once the standard is widely adopted, actually charges less favorable terms.[85] Likewise, there is "the potential for 'hold up' by the owner of patented technology after its technology has been chosen by the SSO as a standard and others have incurred sunk costs which effectively increase the relative cost of switching to an alternative standard."[86] This is because the adoption of a patented technology as a standard may, by definition, eliminate competitive substitutes for it; in this

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[79] *See* Standards Development Organization Advancement Act of 2004, Pub. L. 108-237, tit. 1, § 102, 118 Stat. 661 (June 22, 2004) (noting congressional finding of "the importance of technical standards developed by voluntary consensus bodies to our national economy"); *Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 501, 506-07 (1988) (noting the pro-competitive benefits of standard setting).

[80] U.S. Dep't of Justice & Fed. Trade Comm'n, Antitrust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition, at 33 (April 2007) ("DOJ-FTC Report").

[81] *Am. Soc'y of Mech. Eng'rs, Inc. v. Hydrolevel Corp.*, 456 U.S. 556, 571 (1982).

[82] *Id.* at 572-74.

[83] This report focuses on IP issues that arise in legitimate standard setting contexts, and therefore does not address anticompetitive abuses of standard-setting processes that may arise in contexts where standard-setting conduct is merely a sham among competitors to effectuate an unlawful agreement to raise price or limit output.

[84] *See* Robert P. Merges & Jeffrey M. Kuhn, "An Estoppel Doctrine for Patented Standards," 97 CAL. L. REV. 1 (2009) ("Merges & Kuhn").

[85] Merges & Kuhn at 1.

[86] DOJ-FTC Report at 35; *see also* Merges & Kuhn at 1 (terming this the "snake-in-the-grass" tactic).

event, the owner of the patented technology may be able charge higher royalties than it would have been able to obtain if it had disclosed its patent position at the outset of the standard-setting process when competitive substitutes were available. As discussed in this chapter, there are several cases in which antitrust agencies or private parties have alleged that patent "hold-up" violates the antitrust laws.

The Sedona Conference® urges SSOs to develop clear and enforceable rules governing the disclosure and licensing of intellectual property. Such rules can prevent or deter most opportunistic behavior, leaving antitrust to serve the role for which it is best suited – as a remedy in cases in which the IP holder's conduct has significant anticompetitive consequences.[87] The more appropriate and effective mechanism for addressing the potential competitive issues raised by the standard-setting process is the process itself, supplemented by common law and patent law.[88]

B. Key SSO Rules and Terms

SSOs have adopted a diverse set of operating rules. Although the intellectual property-related provisions of these organizations' rules vary, they generally reflect the following two elements, which together are designed to address the hold-up problem:

1. Disclosure of Intellectual Property

Many SSOs require their members to disclose whether they hold intellectual property rights that may implicate proposed standards. The nature of these requirements, however, varies widely. Some SSOs impose on their members an express obligation to disclose intellectual property, while others have rules that imply such an obligation, and still others have no obligation. Likewise, among those SSOs that have a disclosure policy, some require their members to disclose issued patents only, others require disclosure of patents and patent applications, and still others extend the obligation beyond patents to other IP rights.[89] The Federal Circuit has found that a disclosure duty may exist, even in the absence of an expressly stated duty, where the SSO's members treat the disclosure policy as imposing such a duty.[90]

SSOs' requirements for compliance with these policies also vary. SSOs generally do not require members to search their IP portfolios for IP that may implicate a proposed standard, but rather require a good faith certification regarding the members' IP rights. In addition, SSOs generally view the disclosure obligation as continuing in nature, although in some organizations this

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[87] *See*, *e.g.*, Mark A. Lemley, "Intellectual Property Rights and Standard-Setting Organizations," 90 CAL. L. REV. 1889, 1935 (2002) ("Lemley") (antitrust law "cannot substitute for a general enforcement regime for disclosure rules").

[88] *See, e.g.,* Merges & Kuhn at 14 ("[A]ntitrust law is ill-equipped to handle even straightforward disputes involving patents and standards. . . . [and] should only be a backstop to other mechanisms for preventing strategic behavior . . . ."); *Rambus v. FTC*, 522 F.3d 456, 464 (D.C. Cir. 2008), *cert. denied*, 129 S. Ct. 1318 (2009) (Where deception in the standard-setting process "raises the price secured by a seller, but does so without harming competition, it is beyond the antitrust laws' reach.") *But see Broadcom Corporation v. Qualcomm Inc.*, 501 F.3d 297, 315 (3rd Cir. 2007) (Citing FTC's subsequently overturned decision in *Rambus* and holding that a patent holder's intentionally false promise to license essential proprietary technology on FRAND terms, coupled with an SSO's reliance on that promise when including the technology in a standard, and the patent holder's subsequent breach of that promise, is actionable under the Sherman Act.)

[89] *See, e.g.*, Lemley at 1904-05.

[90] *Rambus Inc. v. Infineon Techs. AG*, 318 F.3d 1081, 1098 (Fed. Cir. 2003); *Qualcomm Inc. v. Broadcom Corp.*, 548 F.3d 1004 (Fed. Cir. 2008).

expectation is implied rather than express. The good faith certification approach is designed to balance the cost of participating in SSOs – particularly for technology companies that may participate in dozens of such organizations – with the benefits of IP disclosure.[91] The absence of a clear legal duty to search, however, has led to antitrust disputes in which a central question has been whether an IP disclosure certification was executed in good faith.[92]

2. Reasonable and Non-Discriminatory Terms

A second, often complementary, way in which SSOs attempt to address the hold-up problem is to request or require members that own IP that implicates a standard to commit to license it on certain terms, usually either "fair, reasonable and non-discriminatory" (FRAND) or "reasonable and non-discriminatory" (RAND) terms. For example, the Joint Electronics Devices Engineering Council ("JEDEC") policy states:

> **8.2 Reference to patented products in JEDEC standards and publications**
>
> JEDEC standards and non-product registrations (e.g., package outline drawings) that require the use of patented items should be considered with great care. (For the purpose of this policy, the term "patented items" includes items and processes for which a patent has been applied.) While there is no restriction against drafting a proposed standard in terms that include the use of a patented item if technical reasons justify the inclusion, committees should avoid standardization that refers to a product on which there is a known patent unless all the relevant technical information covered by the patent is known to the formulating committee, subcommittee, or task group.
>
> If the committee member indicates a reasonable belief that the proposed standard may require the use of patented items, then the committee chairperson must promptly request a written assurance from the patent owner or applicant. The written assurance must state that, in the event that the patent or patent application is required, licenses will be made available to applicants desiring to implement (e.g., including to use) the proposed standard, either with or without compensation, under reasonable terms and conditions that are demonstrably free of any unfair discrimination.
>
> * * *
>
> **8.3 Special legal disclaimer**
>
> In exceptional situations, the Board has the discretion to approve the issuance of a standard for which a patent owner or applicant has not provided written assurance that the relevant patent or patent application will be licensed, subject to special legal disclaimers.

[91] *See, e.g.*, DOJ-FTC Report at 43.
[92] *E.g., In re Dell Computer Corp.*, 121 F.T.C. 616 (1996).

> When determining whether to approve the issuance of a standard, the Board shall consider whether the committee used diligent efforts, if appropriate under the circumstances, to develop a standard or specification that does not require the use of the patented item.[93]

As with disclosure policies, SSOs employ different approaches to licensing policies: some require a FRAND or RAND licensing commitment; others request but do not require such a commitment; and still others do not require an IP holder to commit to any licensing terms.[94]

Very few SSOs, however, define what constitutes FRAND or RAND terms and only a few provide a process for their members to agree on the terms that will meet this standard.[95] Some SSOs, particularly those promulgating Internet-related standards, require IP holders to license on a royalty-free basis. For example, the World Wide Web Consortium requires royalty-free licensing.[96] Even royalty-free licensing may not solve the hold-up problem, however, because such an approach does not affect non-royalty licensing terms. Recently, the federal antitrust enforcement agencies have made policy statements designed to encourage SSOs to provide a forum in which their members can learn, at least, the maximum terms on which an IP holder is willing to license before they vote to adopt a standard that incorporates that IP.[97]

C. Principles and Commentary

PRINCIPLE III-1

Standard-setting organizations should have a written policy governing intellectual property rights, and members should be fully informed about the policy. As a general matter, policies that require disclosure of intellectual property rights should:

(i) Provide that any party that subjects itself to the disclosure requirement must license its essential intellectual property rights unless it expressly notifies the SSO, at the time of the disclosure, that it will not license those rights;

(ii) To the extent possible, define any applicable licensing terms.

Furthermore, the policies should specify in as much detail as practicable the disclosure obligations, the permissible licensing terms, and any SSO enforcement procedures.

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[93] Joint Elecs. Devices Eng'g Council, JEDEC Manual of Org. & Proc. §§ 8.2, 8.3 (Dec. 2006), available at http:www.jedec.org/Home/Manuals/JM21N.pdf.

[94] *See, e.g.*, Lemley at 1906.

[95] *See, e.g.,* Am. Nat'l Standards Inst., ANSI *Essential Requirements* § 3.1 (Jan. 2010), http://publicaa.ansi.org/sites/apdl/Documents/Forms/AllItems.aspx; Internet Eng'g Task Force, RFC 3979, Intellectual Property Rights in IETF Technology (Mar. 2005), available at http://www.ietf.org/rfc/rfc3979.txt.

[96] W3C Patent Policy, § 5 (Feb. 5, 2004), http://www.w3.org/Consortium/Patent-Policy-20040205/; s*ee also* Lemley at 1905 (identifying four organizations).

[97] *See, e.g.,* DOJ-FTC Report at 54-56; Letter from Thomas O. Barnett, Assistant Attorney Gen., U.S. Dep't of Justice, to Robert A. Skitol, Esq., Drinker Biddle & Reath LLP (Oct. 30, 2006), *available at* http://www.usdoj.gov/atr/public/busreview/219380.pdf; Letter from Thomas O. Barnett, Assistant Attorney Gen., U.S. Dep't of Justice, to Michael A. Lindsay, Dorsey & Whitney LLP (Apr. 30, 2007), *available at* http://www.justice.gov/atr/public/busreview/222978.htm.

COMMENTARY

1. Individuals and companies who join an SSO consent to a system of rules and agreements to govern their practices. Together, an SSO's bylaws, policies and specific membership agreements (if any) frame the members' expectations, rights and obligations with regard to SSO participation. In the absence of a further, written agreement signed by both the SSO and member, the bylaws themselves can provide the basis for a valid, enforceable contract.

2. The primary duties/obligations when dealing with IP issues in the SSO context — *i.e.*, the duties generally addressed by SSO IP policies/agreements — are (1) the duty to disclose patents and/or patent applications or other IP; and (2) the duty to license the IP on FRAND or RAND terms. If bylaws or agreements impose either duty, the determination of breach often turns on a determination of the IP rights involved.

3. It is to the benefit of all of the SSO members for the SSO to set out clear and unambiguous policies regarding the disclosure and/or licensing of intellectual property. This is true whether the SSO has chosen to require or not to require such disclosure or licensing. Clarity and definition are the keys.[98]

4. The SSO's policies should be in writing. Agreements and/or policies that affect the rights and obligations of IP owners should not be based on an unwritten "understanding" or an implied contract; rather, they should be based on a written contract or set of bylaws with notice and consent provisions.[99]

5. Some SSOs may function more efficiently without a policy requiring IP disclosure and/or FRAND/RAND licensing. For example, SSOs that set standards in industries characterized by very rapid technological change and short product lifecycles may find that imposing disclosure and licensing requirements prevents their members from promulgating standards in a timely fashion.[100] In these circumstances, however, it is less likely that hold-up will occur, or if it does occur will have a significant anticompetitive effect. In deciding whether to adopt a policy requiring IP disclosure and/or FRAND/RAND licensing, SSOs should balance the costs and benefits of such policies in the context of the specific industries and products that are subject to their standards. If an SSO decides not to adopt such a policy, it should make that choice clear to its members.

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[98] *Rambus Inc. v. Infineon Techs. AG*, 318 F.3d 1081, 1102 n.10 (Fed. Cir. 2003) (criticizing the JEDEC policy for its "staggering lack of defining details," stating "[w]hen direct competitors participate in an open standards committee, their work necessitates a written patent policy with clear guidance on the committee's intellectual property position").
[99] *See, e.g., Rambus*, 318 F.3d at 1102 n.10 (noting the importance of a written patent policy where direct competitors are participating in an open standards committee and stating, "[j]ust as lack [*sic*] of compliance with a well-defined patent policy would chill participation in open standard-setting bodies, after-the-fact morphing of a vague, loosely defined policy to capture actions not within the actual scope of that policy likewise would chill participation in open standard-setting bodies").
[100] *See, e.g.,* DOJ-FTC Report at 42.

6. SSOs can improve their IP disclosure and licensing policies, and reduce their members' cost of complying with such policies, by moving toward policies that contain common elements.[101] A number of terms are important to a well-defined policy:

a. First and foremost, where an SSO requires disclosure of patents or where a patent is actually known to the SSO, the SSO policy should consider including a corresponding requirement that any party that subjects itself to the disclosure requirement must license its essential IP on FRAND/RAND terms unless it expressly notifies the SSO, at the time of the disclosure, that it will not license those rights. Absent a licensing requirement, members may have no adequate remedy for breach of a duty to disclose.[102]

b. In appropriate industry circumstances, an SSO licensing requirement should provide a detailed process for *ex ante* disclosure or determination of the FRAND/RAND licensing terms. This allows for the SSOs' members to judge the "reasonableness" of the terms before they decide whether or not to adopt the standard. The licensing policy could, for example: (1) require an IP owner to announce the terms, or maximum terms, on which it will license its IP; (2) permit the SSO members to discuss and consider the relative costs of alternative technological inputs; and/or (3) permit the SSOs' members and the IP rights holders to negotiate licensing terms before the competition among the technologies ends.[103]

c. An SSO licensing requirement should apply to any intellectual property that is necessary in order for members to practice the standard. This requirement should be spelled out in the policy.

d. SSOs generally should require that a disclosure duty apply for the duration of the IP owner's membership and at any time that a standard is being considered that implicates the undisclosed patent, and, moreover, that the licensing obligation extend until the expiration of the patent. These are terms that should be clearly defined by agreement rather than left to interpretation after a dispute arises.

PRINCIPLE III-2

Discussions or agreements among the SSO and its members as to the FRAND/RAND terms on which essential patents will be licensed should generally be subject to the rule of reason standard of liability, not the *per se* rule.

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[101] *See, e.g.*, DOJ-FTC Report at 43 ("Complying with differing disclosure policies in different SSOs can be costly to IP holders, especially for those with large patent portfolios who participate in many SSOs.").

[102] *See* Lemley at 1914-17 (discussing the inadequacies of specific performance and damages for a breach of a duty to disclose); *but see Qualcomm Inc. v. Broadcom Corp.*, 548 F.3d 1004 (Fed. Cir. 2008) (Qualcomm's failure to disclose patents in SSO process constituted waiver, and thus rendered patents unenforceable against products that comply with the standard).

[103] *See, e.g.,* DOJ Business Review Letter regarding VMEbus International Trade Association (VITA) (Oct. 30, 2006); DOJ-FTC Report at 37 n.21, 54.

COMMENTARY

1. In order for participants in standard-setting processes to make informed decisions about whether to adopt standards that are covered by one or more patents, the participants must have reliable information about the cost of adopting such standards. For example, in cases where alternative standards are available, the decision whether to adopt a standard that is covered by one or more patents may depend on the terms on which the patent holders will license their patents. SSO members cannot "make tradeoffs between price and [the] technical merit" of a proposed standard, or induce price competition among patent holders that seek to be included in the standard, without this information.[104] In addition, participants in standard-setting processes will have a greater ability to negotiate FRAND/RAND terms at the time that the standard is being evaluated (*ex ante*) as opposed to after the standard is adopted (*ex post*).[105] Consequently, while in some circumstances SSOs may conclude that it is too time-consuming, unproductive, or legally risky to sponsor *ex ante* negotiations of FRAND/RAND terms, there may be other circumstances in which SSOs conclude it would be beneficial to permit or facilitate such negotiations.[106]

2. Because standard-setting processes generally involve competing firms, a concern arises as to whether the collective negotiation of FRAND/RAND terms involving one or more patent holders on the one side, and a group of licensees on the other side, could be regarded as a violation of the antitrust laws - *e.g.*, price fixing or a group boycott.[107] The threat of potential antitrust liability, including treble damages, deters many SSOs from adopting policies and procedures that would enable participants in standard-setting processes to negotiate FRAND/RAND terms *ex ante*. It also deters individual participants in the SSO process from engaging in such discussions.[108]

3. While it is possible that the determination of FRAND/RAND terms in an SSO process could be used to exercise market power, it is also possible that conducting these discussions in a standard-setting process will facilitate the adoption of standards and result in FRAND/RAND terms.[109] After carefully evaluating the potential competitive effects of *ex ante* determination of licensing terms in an SSO process, the Justice Department and FTC concluded that such conduct has "the strong potential for procompetitive benefits."[110]

4. Consequently, where an SSO is considering the adoption of a standard that is covered by one or more patents, courts generally should evaluate any discussion or agreement among the SSO and its members as to the FRAND/RAND terms on which the essential patents will be licensed

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[104] DOJ-FTC Report at 52-53.
[105] *See, e.g.,* DOJ-FTC Report at 53-54 ("[*E*]*x ante* knowledge about licensing terms could help mitigate hold up that is not resolved in the first instance by the existence of SSO rules requiring disclosure of IP or by requirements that SSO members license on RAND terms.").
[106] *Id.* at 55.
[107] *See, e.g., Jones Knitting Corp. v. Morgan*, 361 F.2d 451, 459 (3d Cir. 1966); *Lemelson v. Bendix Corp.*, 621 F. Supp. 1122 (D. Del. 1985), *aff'd*, 800 F.2d 1135 (3d Cir. 1986); *Sony Elecs., Inc. v. Soundview Techs., Inc.*, 157 F. Supp. 2d 180, 190 (D. Conn. 2001).
[108] *See* DOJ-FTC Report at 49 ("many SSOs and companies strictly prohibit discussions of licensing terms within SSOs" in part because of concerns about antitrust liability).
[109] *See* DOJ-FTC Report at 50-56.
[110] *Id.* at 54.

under the rule of reason, not the *per se*, standard of liability. This approach is consistent with the Supreme Court's reasoning in *Broadcast Music, Inc. v. Columbia Broadcasting Sys., Inc.*[111] and *Texaco, Inc. v. Dagher,*[112] which hold that the rule of reason should be applied in judging the lawfulness of joint pricing activity that is related to a procompetitive collaborative venture among the participating firms. In April 2007, the Justice Department and FTC formally stated that they will "evaluate joint *ex ante* activity to establish licensing terms under the rule of reason."[113] The consistent application of this standard will remove the cloud that potential antitrust liability has placed over the legitimate determination of FRAND/RAND terms in open standard-setting processes, while preserving the courts' ability to condemn conduct that genuinely threatens to lessen competition substantially under either the *per se* or rule of reason standard, as appropriate.[114]

PRINCIPLE III-3

SSO policies/agreements governing intellectual property rights should be enforceable by the SSO, and should create legal duties/obligations on intellectual property owners that are enforceable in court.

COMMENTARY

1. SSOs can provide efficient and effective mechanisms for enforcing their IP disclosure and licensing policies. Historically, SSOs have been reluctant to accept this responsibility.[115] They do not see enforcement of such policies as within their core mission or expertise.[116] But history has shown that the courts and antitrust agencies are not particularly well-suited for this task. This is in part because many SSOs' policies do not create legally enforceable obligations and are sometimes fraught with ambiguities, and in part because the available legal tools are not particularly well-designed for resolving the disputes that most commonly arise in the standard-setting process.[117] For these reasons, SSOs should amend their IP disclosure and licensing policies to create clear legal duties/obligations that apply to the owners of affected intellectual property (*see* Principle III-1, *supra*) as well as internal enforcement mechanisms.[118]

2. SSOs should develop enforcement mechanisms and penalties for violating their rules. Even if the SSO does not want to assume the burden of resolving disputes among its members, it can adopt mechanisms – e.g., binding arbitration – for doing so. An SSO enforcement mechanism

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[111] 441 U.S. 1, 19-20 (1979).
[112] 547 U.S. 1, 4 (2006).
[113] DOJ-FTC Report at 54.
[114] *See id.* at 55 (For example, "[i]f intellectual property holders turn joint *ex ante* licensing discussions into a sham to cover up naked agreements on the licensing terms each IP holder will offer the SSO, *per se* condemnation of such agreements among 'sellers' of IP rights may be warranted.").
[115] *See, e.g.*, DOJ-FTC Report at 47.
[116] *Id.* at 43.
[117] *E.g.,* Lemley, *supra.*
[118] Commentators have suggested a variety of other legal reforms to address patent "hold-up" and other issues that may arise in the standard-setting context. For example, Merges and Kuhn advocate the adoption of a new legal doctrine they term "standards estoppel," pursuant to which "intentional non-assertion of a patent in the presence of its widespread adoption should create immunity from patent infringement." Merges & Kuhn at 4. We do not address the relative merits of these various reform proposals. *See also* Mark A. Lemley, *Ten Things To Do About Patent Holdup of Standards (And One Not To),* 47 B.C. L. REV. 149, 168 (2007) ("[I]if we design the patent law and the SSO rules correctly, those cases [that require antitrust intervention] should not arise.").

is more likely to result in resolution of a dispute in a timely fashion than court litigation. In addition, because the principal issue to be resolved in such a dispute is whether an SSO member violated the terms of the SSO's bylaws and policies (as opposed to the antitrust or patent laws), an SSO decision and remedy are more likely to be directed to the conduct at issue.

3. SSOs should adopt bylaws and agreements that expressly state that their IP disclosure and licensing policies are intended for the benefit of their members as third-party beneficiaries. Currently, SSO members must try to use non-contract doctrines – *e.g.,* antitrust, fraud and business tort doctrines, and patent law doctrines of waiver, estoppel, laches and license implied in law – to attack alleged abuses of the standard-setting process, or rely on federal antitrust agencies to bring antitrust actions.[119] These doctrines cannot always solve the hold-up problem, and should be supplemented with breach of contract principles. To best ensure that breach of contract causes of action and remedies are available, SSOs should expressly create third-party beneficiary rights, thereby enabling either the SSO or its members to bring enforcement actions for breach of the SSOs' IP disclosure and licensing policies.

4. Where an SSO's policies require FRAND/RAND licensing, but license terms have not been determined *ex ante*, enforcement mechanisms should include specific performance and the establishment of FRAND/RAND terms.[120] The fifteen criteria listed in *Georgia-Pacific Corp. v. U.S. Plywood Corp.*,[121] which are used regularly in patent litigation to determine a reasonable royalty for use of a patented invention, may provide an appropriate basis for determining the reasonableness of licensing terms.[122] One of these criteria, adapted for the standard-setting context, is what licensees would have paid if there had been an *ex ante* determination of royalty rates, reflecting any competition between available technologies. Likewise, the determination of a FRAND/RAND royalty should account for any "royalty stacking" issue that may arise if there are multiple patents that read on the standard.[123]

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[119] *See, e.g.*, *Rambus, Inc. v. Infineon Techs. AG*, 164 F. Supp. 2d 743, 750-58 (E.D. Va. 2001) (upholding jury verdict finding actual fraud based on firm's non-disclosure of patents related to a standard), *rev'd in part*, 318 F.3d 1081 (Fed. Cir. 2003) (reversing a denial of judgment for defendant as a matter of law upon determining that the record showed no breach of SSO disclosure duty); *Symbol Techs., Inc. v. Proxim Inc.*, No. Civ. 01-801-SLR, 2004 WL 1770290 (D. Del. July 28, 2004) (rejecting an estoppel defense when the firm had no duty to disclose its patent rights); *In re Rambus, Inc.*, No. 9302, 2006 FTC LEXIS 60 (F.T.C. Aug. 2, 2006) (holding Rambus monopolized certain markets in violation of FTC Act Section 5 by misleading SSO members into believing that it neither possessed nor would seek patents that read on a standard), *rev'd*, *Rambus Inc. v. FTC*, 522 F.3d 456, 464 (D.C. Cir. 2008) (holding that if Rambus acquired its monopoly position lawfully (*i.e.*, by owning patents covering the best technology or essential technology) but used deception "simply to obtain higher prices," such conduct "has no particular tendency to exclude rivals and thus to diminish competition" in violation of the antitrust laws), *cert. denied*; 129 S. Ct. 1318 (2009); *Qualcomm Inc. v. Broadcom Corp.*, 548 F.3d 1004 (Fed. Cir. 2008) (Qualcomm's failure to disclose patents in SSO process constituted waiver, and thus rendered patents unenforceable against products that comply with the standard).

[120] *See, e.g., United States v. Microsoft Corp.*, 231 F. Supp. 2d 144, 193 (D.D.C. 2002) (requiring licenses on RAND terms and observing that "'reasonableness' is generally an objective standard").

[121] 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970)

[122] *See, e.g., ESS Tech., Inc. v. PC-Tel, Inc.*, No. C-99-20292 RMW, 2001 WL 1891713, at *3-6 (N.D. Cal. 2001) (applying the *Georgia-Pacific* factors to make a RAND determination).

[123] *See, e.g., Paymaster Technologies, Inc. v. United States*, 61 Fed. Cl. 593, 613 (2004) ("When considering the reasonable royalty of the accused device, the stacked royalty of other patents involved … must also be considered."), *aff'd in part, vacated in part on other grounds*, 180 F. App'x 942 (Fed. Cir. 2006), and establish the duration of a license term – presumably the term of the patents at issue, *see* Lemley, 90 CAL. L. REV. at 1912 & n.74 ("A member that has agreed to license its IP rights covering a standard on reasonable and nondiscriminatory terms has presumably committed to an ongoing license, not a temporary one.").

PRINCIPLE III-4

No unilateral conduct by a patent holder relating to the disclosure or subsequent assertion of intellectual property in a standard-setting context should be unlawful under the antitrust laws unless it lessens competition within the meaning of those laws.

COMMENTARY

1. Cases involving the disclosure or subsequent assertion of intellectual property in a standard-setting context generally involve allegations of monopolization or attempted monopolization - *e.g.*, that a patent holder persuaded a standard-setting organization to adopt a standard that is subject to one or more of its patents by misrepresenting the status of its patent holdings in order to obtain a monopoly in the relevant market.[124]

2. Federal courts and agencies generally evaluate claims of patent "hold-up," under Section 2 of the Sherman Act, 15 U.S.C. § 2, which prohibits monopolization and attempted monopolization. Such conduct also has been subject to attack under federal and state unfair competition laws, including Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, which generally prohibit "unfair methods of competition."

a. In *In re Dell Computer Corp.*,[125] the FTC entered a consent order against Dell for its alleged failure to disclose during a standard-setting process that it owned a patent covering the standard, which Dell later asserted against companies that employed the standard, but neither the complaint nor the accompanying aid to public comment alleged that Dell had monopolized or attempted to monopolize a relevant market within the meaning of Section 2. Likewise, in *In re Union Oil Co.*,[126] the FTC Staff alleged a cause of action under Section 5 of the FTC Act but not under Section 2 of the Sherman Act. The FTC's actions, and the *Dell* consent order in particular, have been the subject of significant discussion, much of which has centered on the proper role of Section 5 in judging the lawfulness of unilateral conduct in a standard-setting context.

b. In *In re Rambus*, the FTC found that Rambus engaged in conduct that was "calculated to mislead [SSO] members by fostering the belief that Rambus neither had, nor was seeking, relevant patents that would be enforced" against products that complied with certain JEDEC standards.[127] This conduct, the Commission held, "constituted deception under Section 5 of the FTC Act" and enabled Rambus to unlawfully monopolize the markets for certain technologies incorporated into the JEDEC standards.[128]

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[124] Lemley, 90 CAL. L. REV. at 1927-28.
[125] 121 F.T.C. 616 (1996).
[126] 138 F.T.C. 1, 194 (2003).
[127] 2006 FTC LEXIS 60, at *159.
[128] *Id.* at *1-7, *159, *284-85. *See also Broadcom Corporation v. Qualcomm Inc.*, 501 F.3d at 315 (citing the FTC's decision and holding that "(1) in a consensus-oriented private standard setting environment, (2) a patent holder's intentionally false promise to license essential proprietary technology on FRAND terms, (3) coupled with an SDO's reliance on that promise when including the technology in a standard, and (4) the patent holder's subsequent breach of that promise, is actionable anticompetitive conduct.")

The D.C. Circuit reversed. *Rambus Inc. v. FTC*.[129] Relying on the Supreme Court's decisions in *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*[130] and *NYNEX Corp. v. Discon, Inc.*,[131] and its own prior precedent involving allegedly deceptive conduct, the court concluded that "[d]eceptive conduct – like any other kind – must have an anticompetitive effect in order to form the basis of a monopolization claim," and that "[e]ven if deception raises the price secured by a seller, but does so without harming competition, it is beyond the antitrust laws' reach."[132] The court held that if Rambus acquired its monopoly position lawfully (*i.e.*, by owning patents covering the best technology or essential technology) but used deception "simply to obtain higher prices," such conduct "has no particular tendency to exclude rivals and thus to diminish competition," and therefore cannot serve as the exclusionary conduct element of a monopolization claim under Section 2 of the Sherman Act.[133] Relying on *NYNEX*, the court rejected the proposition that the loss of an opportunity to obtain a RAND commitment harms competition: "an otherwise lawful monopolist's end-run around price constraints, even when deceptive or fraudulent, does not alone present harm to competition in the monopolized market."[134]

3. Section 2 of the Sherman Act should play its traditional role in regulating unilateral conduct relating to the disclosure or subsequent assertion of intellectual property in a standard-setting context. The purpose of the antitrust laws is to prevent or punish conduct that genuinely threatens to lessen competition and harm consumer welfare.[135] Antitrust should not be used to deter or punish unilateral conduct relating to the disclosure or subsequent assertion of intellectual property in a standard-setting context unless it can be shown that the conduct has this effect.[136] Consequently, courts and agencies should not hold unilateral conduct relating to the disclosure or subsequent assertion of intellectual property in a standard-setting context unlawful under the antitrust laws unless it lessens competition within the meaning of those laws.[137]

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[129] 522 F.3d 456 (D.C. Cir. 2008).
[130] 509 U.S. 209 (1993).
[131] 525 U.S. 128 (1998).
[132] 522 F.3d at 464.
[133] *Id.*
[134] *Id.* at 466.
[135] *E.g.*, *Verizon Commc'ns Inc. v. Law Offices of Curtis v. Trinko, LLP*, 540 U.S. 398, 407 (2004); *Town of Concord v. Boston Edison Co.*, 915 F.2d 17, 21-22 (1st Cir. 1990).
[136] Lemley, 90 CAL. L. REV. at 1935 ("Antitrust is an extreme remedy, and it is properly reserved for cases in which an IP owner's failure to disclose has significant competitive consequences."); s*ee also Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 459 (1993) (Section 2 "makes the conduct of a single firm unlawful only when it actually monopolizes or dangerously threatens to do so").
[137] This chapter takes no position as to whether unilateral conduct relating to the disclosure or subsequent assertion of intellectual property in a standard-setting context should be found to violate federal or state unfair competition laws, including Section 5 of the FTC Act, only if it lessens competition and harms consumer welfare. *See e.g., NYNEX Corp. v. Discon, Inc.,* 525 U.S. 128, 137 (1998) (warning courts not to "transform cases involving business behavior that is improper for various reasons [including regulatory fraud] into treble-damages antitrust cases").

IV. Antitrust & Hatch-Waxman Patent Settlements

A. Introduction

The Working Group has struggled for over six years to reach consensus on a chapter that would present the antitrust issues arising in connection with patent litigation, especially in pharmaceutical patent cases arising under the Hatch-Waxman Act. Several courts have considered antitrust claims that Hatch-Waxman settlements including "reverse payments" are anticompetitive, including the Second, Sixth, Eleventh, and Federal Circuits. For the reasons that follow, the Working Group has concluded that no such consensus is reachable. Thus, we will not propose Principles with respect to patent settlements, nor otherwise analyze them at length.

What we have discovered, however, is that the very act of describing our differences has been useful. This Working Group has, from the outset, included lawyers and economists who act for all sides in this controversy, and our dialogue has enabled us (we hope) to articulate with rigor both sides of the debate – a debate that continues in the courts and, at this writing, in Congress. For that reason, we believe that the following discussion of the issue with which we have grappled, and the viewpoints we have espoused, will be of service to judges, practitioners, and anyone else who approaches this problem with an open mind.

B. The Hatch-Waxman Act and The "Reverse" Payments Scenario

The Federal Food, Drug, and Cosmetic Act requires all new drugs to be approved by the FDA.[138] To gain FDA approval, manufacturers of new drugs must submit a detailed New Drug Application ("NDA") demonstrating that the drug is both safe and effective.[139] The Supreme Court has noted that the "extensive animal and human studies of safety and effectiveness that must accompany a full new drug application" make the NDA process "costly and time consuming." *Eli Lilly & Co. v. Medtronic, Inc.*[140]

The Hatch-Waxman amendments were passed in 1984 for the purpose of "expedit[ing] the approval of generic versions of name brand drugs that already have FDA approval."[141] The principal change was to relieve the generic applicant from the expense and difficulty of producing a New Drug Application. Instead, it could file an Abbreviated New Drug Application ("ANDA") certifying that its product was the bioequivalent of a previously approved brand-name or "pioneer" drug.[142] This procedure allowed the generic manufacturer to rely upon the data and test results previously used by the pioneer manufacturer to establish safety and effectiveness.[143] To ensure that generic drugs would be approved and available immediately upon expiration of the brand-name patent, the statute

[138] 21 U.S.C. § 355(a).
[139] U.S.C. § 355(b).
[140] 496 U.S. 661, 676 (1990).
[141] *Teva Pharm. USA, Inc. v. FDA*, 182 F.3d 1003, 1005 (D.C. Cir. 1999).
[142] 21 U.S.C. § 355(j)(2)(A).
[143] *Id.*

provided that the limited development and testing of the drug necessary for the generic applicant to file an ANDA may *not* constitute a basis for finding that the pioneer's patent had been infringed.[144]

To protect the rights of patent holders, Hatch-Waxman requires a generic applicant to make one of four certifications with its ANDA: (1) that no patent data on the referenced drug was listed with the FDA; (2) that the listed patent has expired; (3) that the applicant seeks approval only upon the expiration of the listed patent; or (4) that the patent is either invalid or will not be infringed by the generic drug.[145] When a generic company asserts invalidity or non-infringement in its "ANDA IV" certification (the type at issue here), it must provide a written notice to the patentee setting forth the factual and legal basis for its claim.[146] Under the statute, these facts alone create a cause of action for infringement on the part of the patent holder against the ANDA IV filer. In other words, even though no marketing of the generic drug has taken place, the mere filing of the ANDA IV application constitutes what the Supreme Court has called "a highly artificial act of infringement" for which the patent holder may sue.[147]

If the patent holder does not sue the ANDA IV filer within forty-five days, the FDA may approve the application immediately.[148] If the patent holder does file a suit, however, the FDA may not approve the ANDA for at least thirty months, unless that period is extended (or shortened) by the patent court. *Id.*

The Hatch-Waxman amendments provide an added incentive for generic drug manufacturers to file an ANDA with a Paragraph IV certification. The first generic manufacturer to file an ANDA IV with respect to a specific drug product is awarded a 180-day period of exclusive marketing rights during which the FDA cannot approve the ANDA of another generic manufacturer to market the same drug.[149] Prior to 2003, the first ANDA IV filer's 180-day exclusivity period began to run from the earlier of (1) the date that the first-filer began commercial marketing of its drug, or (2) the date of a court decision on behalf of any party finding that the pioneer patent is invalid or not infringed.[150]

The scenario that has generated so much controversy is this: A generic drug maker ("G") files an ANDA IV with the FDA for permission to manufacture a generic version of a branded drug before the listed patent expires. The patentee ("P") sues G for patent infringement. The parties then settle the patent litigation. G agrees to drop its suit and not to infringe the patent. In return, P allows the generic manufacturer to sell the drug at a date certain (usually prior to patent expiration, but often after a substantial period of time), and provides other consideration, such as direct payments, to G. Because these payments flow from the patent holder to the challenger, unlike royalty payments which flow from the licensee to the patent holder, they are labeled "reverse" payments.

The FTC, in particular, has investigated and raised concerns about such settlements since the late 1990s. After the FTC obtained consent orders from certain Hatch-Waxman litigants based upon allegedly anticompetitive settlements, numerous private antitrust cases were filed against those parties and others. In the only case brought as administrative litigation by the FTC, *In re Schering-Plough,* the full Commission reversed an opinion by an administrative law judge in favor of the

144 35 U.S.C. § 271(e)(1).
145 21 U.S.C. § 355(j)(2)(A)(vii)(I-IV).
146 21 U.S.C. § 355(j)(2)(B)(i)-(ii).
147 *Eli Lilly, supra*, 496 U.S. at 678 (discussing 35 U.S.C. § 271(e)(2)).
148 21 U.S.C. § 355(j)(5)(B)(iii).
149 21 U.S.C. § 355(j)(5)(B)(iv).
150 21 U.S.C. § 355(j)(5)(B)(iv).

settling parties, found that the settlement contained reverse payments, and concluded that those payments rendered the settlement illegal. On appeal, the 11th Circuit vacated the FTC's order, rejecting the Commission's theory that reverse payments harm competition. After the Supreme Court denied the FTC's petition for certiorari in 2006, the FTC supported bills in both houses of Congress that would declare reverse payments illegal per se.[151] After the election of 2008, the same bills were reintroduced in the new Congress.[152]

Several other cases have reached the Courts of Appeals. The Sixth Circuit's decision in *In re Cardizem CD Antitrust Litig.*,[153] affirmed the District Court's finding that an "interim" settlement agreement including reverse payments was per se illegal. (The debate over the Court's rationale is described below.) Shortly thereafter, however, the Eleventh Circuit reversed a decision finding a similar settlement per se illegal.[154] On a petition for certiorari from the *Cardizem* decision, the Supreme Court requested the views of the Solicitor General, who recommended denial of certiorari in both cases. Both petitions were denied.

The Second Circuit later decided *In re Tamoxifen Citrate Antitrust Litig.*,[155] affirming the dismissal of a complaint alleging that a settlement contained reverse payments. The Supreme Court again requested the Solicitor General's views, he again recommended that certiorari be denied, and it was. In 2008, the Federal Circuit affirmed summary judgment in favor of the settling parties in *In re Ciprofloxacin Hydrochloride Antitrust Litig.*[156] In that case, the Supreme Court denied the petition for certiorari without requesting the views of the Solicitor General.[157]

As of this writing (in early 2010), cases raising similar issues are pending in trial courts in the Third and Eleventh Circuits.[158] They include two cases brought by the FTC directly in District Court, rather than under the Commission's administrative procedure. In addition, the Second Circuit has pending the appeal of another group of plaintiffs attacking the same settlement at issue in *In re Ciprofloxacin*. At the request of the Second Circuit, the new Assistant Attorney General for the Antitrust Division submitted an amicus brief in July 2009. That brief essentially adopted the position of the FTC that any settlement with reverse payments is "presumptively violative of Section

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151 *See* S. 316; H.R. 1902 (110th Congress).

152 Preserve Access to Affordable Generics Act § 3(a), S. 369, 111th Cong. (2009); Protecting Consumer Access to Generic Drugs Act of 2009 § 2(a)(1), H.R. 1706, 111th Cong. The bill was attached to the House version of the war funding Bill for Afghanistan, see Supplemental Appropriations Act of 2010, H.R. 4899, (111th Cong., 2010), but dropped in conference, and was later included in the House Budget bill that the Senate did not enact.

153 332 F.3d 896 (6th Cir. 2003).

154 *Valley Drug Co. v. Geneva Pharms., Inc.,* 344 F.3d 1294 (11th Cir. 2003).

155 466 F.3d 187 (2d Cir. 2006).

156 544 F.3d 1323 (Fed. Cir. 2008).

157 *Id.,* 77 U.S.L.W. 3562 (U.S. 2009). Two other federal circuit courts have considered appeals in cases where reverse payment settlements were attacked. In one, the Eleventh Circuit reversed the district court's dismissal of the complaint for lack of antitrust injury. *Andrx Pharms., Inc. v. Elan Corp., PLC,* 421 F.3d 1227, 1235 (11th Cir. 2005). In the other, the District of Columbia Circuit affirmed the district court's dismissal of the complaint for failure to plead "injury-in-fact" and "causation," but reversed the district court's refusal to allow the plaintiffs to replead. *Andrx Pharms., Inc. v. Biovail Corp. Int'l,* 256 F. 3d 799, 819 (D.C. Cir. 2001).

158 *In Re K-Dur Antitrust Litigation,* No. 01-1752 (JAG) (D.N.J.); *Federal Trade Commission v. Cephalon, Inc.,* No. 08-cv-2141-RBS (E. D. Penn.); *Federal Trade Commission v. Watson Pharms., Inc.,* No. 1:09-cv-00955-TWT (N.D. Ga.). In *K-Dur ,* the court denied the defendants' original motion to dismiss the complaint, *K-Dur,* 338 F. Supp. 2d 517 (D.N.J. 2004), but a Special Master has since recommended that the Court grant summary judgment in favor of the defendants. *K-Dur,* 2009 WL 508869 (D. N.J. Feb. 6, 2009). A California state court proceeding attacking the same settlement at issue in the *Ciprofloxain* case under state antitrust and unfair competition laws is now on appeal. In August 2009, the trial court granted the settling defendants' motions for summary judgment under California law. *COORDINATION PROCEEDING CIPRO CASES I & II,* Case No. JCCP4154 (Sup. Ct. San Diego Cty. CA, 8/21/2009).

1."[159] The Division acknowledged[160] that there is "some tension" between it "current views" and its prior statements to the Supreme Court that there was no support for "a legal standard that subjected patent settlements involving reverse payments to automatic or near automatic invalidation."[161]

C. The Debate

As this report is written, a deep division exists within the antitrust bar concerning the antitrust implications of Hatch-Waxman patent settlements. Indeed, to say that the debate "rages" is not hyperbole. The Eleventh Circuit's opinion in *Schering-Plough*, which reversed the FTC's condemnation of that settlement, characterized the FTC's analysis as result-oriented: "It would seem as though the Commission clearly made its decision before it considered any contrary conclusion."[162] The FTC, for its part, has described the 11th Circuit's analysis in testimony to Congress as "startling,"[163] and has dismissed the arguments against its position as "ignor[ing] both the law and the facts."[164] Despite the FTC's commitment to its views, the Antitrust Division of the Department of Justice and the Solicitor General in 2005 refused to support the FTC's certiorari petition in *Schering-Plough*, and the FTC thus petitioned the Supreme Court on its own for only the third time in its history. When the Supreme Court subsequently asked for the views of the United States, moreover, the perhaps unprecedented result was that one antitrust enforcement agency's petition for review in the Supreme Court was opposed by the other. The Court agreed with the Solicitor General, however, and denied the petition.[165]

1. Viewpoint A: Payments Are Presumptively Unlawful

For the group opposed to reverse payments, such settlements are little more than market division agreements, in which a competitor pays a potential entrant to stay out of the market: "A payment flowing from the innovator to the challenging generic firm may suggest strongly the anticompetitive intent of the parties in entering the agreement and the rent-preserving effect of the agreement."[166] Many advancing these views assert that large payments from a patent holder to a generic imply that the patent is weak.[167] Some would measure the anticompetitive effect by comparing the generic's entry date under the settlement with an "average" entry date determined by the parties' subjective evaluations of the anticipated outcome in the patent case.[168] Others would have the antitrust court make an objective evaluation of the merit of the patent claim that the parties settled.[169]

Some economists argue that payments from a patent holder to a would-be generic entrant provide substantial evidence that generic entry has been delayed by the settlement, and thus short-run

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[159] Brief For The United States In Response To The Court's Invitation at 22, *In Re Ciprofloxacin Hydrochloride Antitrust Litigation,* No. 05-2851-cv(L) (2d Cir. July 6, 2009) ("DOJ Cipro Br.").
[160] *Id.* at 26 n.9.
[161] Brief For The United States as Amicus Curiae at 11, *Joblove v. Barr Labs., Inc.*, No. 06-830 (U.S. May 23, 2007), 2007 WL 151152711.
[162] *Schering-Plough Corp. v. F.T.C.*, 402 F.3d 1056, 1065 (11th Cir. 2005).
[163] "Prepared Statement of the Federal Trade Commission Before the Special Committee on Aging of the United States Senate on Barriers To generic Entry" at 15 (July 20, 2006) (110th Cong.).
[164] *Id.* at 18.
[165] *In re Schering-Plough*, 548 U.S. 919 (2006).
[166] David Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks,* 55 FOOD & DRUG L.J. 321, 335 (2000).
[167] *See* Carl Shapiro, *Antitrust Analysis of Patent Settlements Between Rivals,* 17 ANTITRUST 70, 71-72 (Summer 2003).
[168] DOJ *Cipro* Br., *supra* n. 4, at 28 (analysis would "focus on a comparison between competition under the settlement and [competition] they expected had the patent infringement suit been litigated to judgment.") *See, id.* at 25, 30 & 31-32.
[169] *See In re Tamoxifen Citrate Antitrust Litigation*, 466 F. 3d 187, 228 (2d Cir. 2006) (Pooler, J., dissenting).

consumer welfare damaged because of the delay in lower-priced generics entering the market.[170] They contend that there must have been an offsetting consideration for the payment from the patent holder to the generic challenger, and that consideration would likely have been the generic deferring its entry beyond the date that would have resulted from a different litigation compromise. "Presumably, the patent holder would not pay more than avoided litigation costs unless it believed that it was buying later entry than it expects to face through the litigation alternative."[171] Others have argued that a settlement should be presumed anticompetitive if the generic company obtains benefits greater than the profit it would have gained by winning the patent suit.

2. Viewpoint B: Settlements Within The Patent's Scope Do No Harm Competition

The opposing group challenges both the assumptions and conclusions of the first view, as follows: A patent by its nature excludes infringing competition, and numerous agreements to market a patented good (including all licenses) would be per se illegal but for the patent.[172] The antitrust laws, however, do not protect competition that infringes an intellectual property right, and the burden remains with the antitrust plaintiff to show that any "excluded" competition was *lawful* competition.[173] The fact of cash payments does not relieve that burden, nor make the settlement suspect. On the contrary, cash payments to the generic make possible certain settlements that could not occur if the parties merely negotiated the length of a license.[174] In fact, the Hatch-Waxman procedures (by which a generic challenger can invalidate a patent without any exposure to infringement damages), create an incentive for substantial payments to generics even in the case of exceptionally strong patents.[175]

Contrary to the view that payments are suspect, other economists argue that settlements with cash payments save litigation and other costs, reduce uncertainty for risk-averse firms, and eliminate asymmetric information about the value of the patent. Proper consideration of these and other factors demonstrate that settlements with "reverse" payments can increase consumer welfare in the long run.[176] For all of these reasons, many argue that the controlling issue is not the presence or size of payments, but whether the settlement agreement excludes more competition than would enforcement of the patent: "Whether [the attack on reverse payments] is a sound theory may be doubted, since if settlement negotiations fell through and the patentee went on to win his suit,

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[170] This was the position advanced by the FTC's economic expert, Timothy F. Bresnahan, in the *Schering-Plough* case. *See In The Matter of Schering Plough Corp.,* 136 F.T.C. 956, 987-88 (2003).

[171] Carl Shapiro, *Antitrust limits to Patent Settlements,* 34 RAND J. ECON. 391, 408 (2003).

[172] XII HERBERT HOVENKAMP, ANTITRUST LAW ¶ 2040b at 199 (1999) (but for the patent, patent license agreements "generally would be classified … as per se unlawful naked horizontal market divisions."

[173] *E.g., Rubber Tire Wheel Co. v. Milwaukee Rubber Works Co.,* 154 F. 358, 364 (7th Cir. 1907)("the public [is] not entitled to profit by competition among infringers.").

[174] *See* Marc G. Schildkraut, Patent-Splitting Settlements and the Reverse Payment Fallacy, 71 ANTITRUST L.J. 1033, 1067 (2004).

[175] *See* Kent S. Bernard & Willard K. Tom, *Antitrust Treatment of Pharmaceutical Patent Settlements: The Need for Context and Fidelity to First Principles*, 15 FED. CIR. B.J. 617, 621 (2006) ("Hatch-Waxman creates a context in which payments from the patent owner to the infringer become explicit rather than implicit, but it does not change the underlying nature of the payments or make them more anticompetitive than such payments in the traditional context.").

[176] *See* James Langenfeld & Wenqing Li, *Intellectual Property and Agreements to Settle Patent Disputes: The Case of Partial Settlement Agreement with Payments from Branded to Generic Drug Manufacturers*, 70 ANTITRUST L. J. 3, 777-818 (Spring 2003), and Langenfeld and Li; *Economic Analyses of Patent Settlement Agreements: The Implementation of Specific Economic Tests, the Evaluation of Dynamic Efficiency, and the Scope of Patent Rights*, 39 U. S. F. L. REV. 1, 57-80 (Fall 2004).

competition would be prevented to the same extent."[177] Under this view, unless an attempt to enforce the patent would be "objectively baseless," litigants are free to enter into settlements no more exclusionary than the patent, and "consumers have no right to second-guess whether some different agreement would have been more palatable."[178]

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The experience of our Working Group testifies eloquently to the chasm between these competing views. Not only is there no consensus on the result to be reached in reverse payment cases; there is no consensus as to how the issues should be analyzed, nor even as to what the cases decided to date seem to say. To the extent any common ground exists, as the following subsection indicates, it is narrow indeed.

D. The Origin of the Hatch-Waxman Debate, and Possible Common Ground

The antitrust debate over patent settlements traces its origin to the investigations by the FTC, commencing in the late 1990s, of agreements entered into by parties in two such "Hatch-Waxman" cases. One involved the brand name drug Hytrin, known generically as terazosin hydrochloride.[179] The other involved the brand name drug Cardizem, or diltiazem hydrochloride.[180] Both investigations led to Consent Agreements with the FTC, which were followed by private antitrust class actions by direct and indirect purchasers of the branded drugs. Not long afterward, both resulted in District Court decisions in those private cases finding the underlying agreements *per se* illegal under the antitrust laws.[181] Following those District Court decisions, hundreds of private antitrust actions were filed across the nation attacking Hatch-Waxman settlements by other parties in other cases.

Both the Hytrin and Cardizem agreements arose in the course of litigation, and both contained payments by the patentee to the generic challenger in exchange for promises to refrain from, or to delay, entering the market with allegedly infringing drugs. But the relevance of two aspects of those agreements has been much disputed, and in some cases has proven crucial to courts evaluating Hatch-Waxman settlements:

First, both agreements were found by the courts to go "beyond the scope" of the patents at issue. That is, both agreements were deemed to exclude entry not only of infringing drugs but of non-infringing drugs. That is because the patents in both cases were not "compound" patents claiming the active ingredient of the drug, but were "formulation" patents claiming only certain methods of administering the drug (*e.g.*, capsule versus a tablet, or a time-release mechanism of a certain duration).[182] The settlement agreements, however, were found to preclude all generic formulations, whether covered by the patents or not.

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[177] *Asahi Glass Co. v. Pentech Pharms., Inc.,* 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003, Posner, Circuit Judge, sitting by designation).

[178] *In re Ciprofloxacin Hydrochloride Antitrust Litig.,* 363 F. Supp. 2d 514 (E.D.N.Y. 2005), *aff'd,* 544 F.3d 1323 (Fed. Cir. 2008).

[179] *Abbott Labs.,* FTC Dkt. No. C-3945 (May 26, 2002)(consent order).

[180] *Hoechst Marion Roussel, Inc.,* FTC Dkt. No. 9293 (Apr. 4, 2001)(consent order).

[181] *In re Terazosin Hydrochloride Antitrust Litig.,* 164 F. Supp. 2d 1340 (S.D. Fla. 2001), *reversed sub nom. Valley Drug Co. v. Geneva Pharm., Inc.,* 344 F. 3d 1294 (11th Cir. 2003); *In re Cardizem CD Antitrust Litig.,* 105 F. Supp. 682 (E.D. Mich. 2001), *affirmed,* 332 F. 3d 896 (6th Cir. 2003).

[182] *See, e.g., In re Tamoxifen Citrate Antitrust Litigation*, 466 F. 3d 187, 214 (2d Cir. 2006) (discussing difference in exclusionary effect between formulation and compound patents).

Second, although arising from patent litigation, the agreements in these two cases did not actually settle the litigation. In both cases, the litigation continued. At the same time, the generic challenger agreed not to withdraw or amend its ANDA IV certification, or to sell its rights under it. The courts viewed those provisions as designed to create a "bottleneck," that is, to preserve the generic applicant's 180-day exclusivity rights under the statute, and thus to prevent (or at least to delay) the FDA's approval of other ANDA filers challenging the same drugs.

The potential significance of these aspects was noted at the time by the FTC's Assistant Director of the Office of Policy and Evaluation:

> *The agreement [in* Hytrin*] not to enter with a non-infringing product and the agreement not to relinquish the 180-day exclusivity were not ancillary restraints. These types of agreements typically are treated as illegal per se,* regardless of how one views the principal agreement to defer the generic firm's entry.[183] The findings of per se illegality in both *Hytrin* and *Cardizem* were reviewed on interlocutory appeal – *Hytrin* in the Eleventh Circuit in a case called *Valley Drug*, and *Cardizem* in the Sixth Circuit, in a case called *In re Cardizem*. In *Valley Drug*, the Eleventh Circuit reversed the District Court, holding that the per se rule was inappropriate in the case of a Hatch-Waxman patent settlement. In *Valley Drug*, the Eleventh Circuit suggested a three-step test for evaluating the competitive effects of patent agreements in light of the exclusionary "potential" of the patent, which it later described in *Schering-Plough* as follows: "[P]roper analysis of antitrust liability requires an examination of: (1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects."[184]

The Sixth Circuit in *In re Cardizem*, however, affirmed the finding of *per se* illegality, stating that "it is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competitors by paying the only potential competitor $40 million per year to stay out of the market."[185] The meaning of *Cardizem* is much disputed. Some contend that the sentence quoted constitutes a holding that reverse payments are *per se* illegal, creating a square conflict with the Eleventh Circuit in *Valley Drug*. Others contend, however, that the reference to "bolster[ing] the patent's effectiveness" refers to the exclusion of non-infringing drugs beyond the scope of the patent. In a footnote to the word "effectiveness," they point out, the Sixth Circuit cited with approval the trial court's decision in *In re Ciprofloxacin*, which expressly refused to hold that payments are *per se* unlawful, and distinguished the agreement in *Cardizem* on the ground that it "extended to noninfringing. . . versions of generic Cardizem."[186]

As noted above, the *Cardizem* defendants sought certiorari in the Supreme Court, and the Court asked for the views of the United States. In a brief signed by both the FTC and the DOJ, the Solicitor General stated that there was no necessary conflict between the Eleventh Circuit decision in *Valley Drug* and the Sixth Circuit's decision in *Cardizem*. Relying in part on the footnote to *Ciprofloxacin* in the sentence quoted above, the FTC and the DOJ told the Court that *Cardizem*'s holding turned on the finding that the agreement went beyond the scope of the patents.[187] The FTC and the DOJ also told the Court that if *Cardizem* were construed as a *per se* ban on "every settlement

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[183] Balto, *supra* n. 8, 55 FOOD AND DRUG L.J. at 335-36 (emphasis added).
[184] *Schering- Plough*, 402 F. 3d at 1066.
[185] *Cardizem*, 332 F.3d at 908 (footnote omitted).
[186] *Cardizem*, 332 F.3d at 908 n.13, *quoting In re Ciprofloxacin*, 261 F.Supp.2d at 242.
[187] Brief For The United States as Amicus Curiae at 7, *Andrx Pharms., Inc. v. Kroger Co.,* No. 03-779 (U.S. July 9, 2004), 2004 WL 1562075 ("*Cardizem* Amicus Br.").

agreement that includes a reverse payment in exchange for the exclusion from the market of an allegedly infringing product," the Sixth Circuit's decision "would be erroneous."[188]

After *Cardizem* and *Valley Drug,* decisions in favor of the settling Hatch Waxman litigants were issued by the Eleventh Circuit in *In re Schering-Plough*, the Second Circuit in *In re Tamoxifen*, and the Federal Circuit in *In re Ciprofloxacin*.[189] All of these decisions focused on the exclusionary potential of the patent, although the two sides to the debate continue to disagree on the extent and significance of that focus. After this much litigation and debate, it appears that all that the two sides may agree upon, if anything, relate to the two distinguishing features of *Hytrin* and *Cardizem* discussed above:

First, there appears to be general agreement that a settlement that excludes *more* competition than would full enforcement of the patent as written invites antitrust scrutiny. The Sixth and Eleventh Circuits may differ as to whether the per se rule or the rule of reason applies to the inclusion in such an agreement of non-infringing products, but neither suggests that there is a principle of patent or antitrust law that would make competitive scrutiny unnecessary.

Second, there also appears to be agreement that the 180-day exclusivity provision of the Hatch-Waxman Act may raise antitrust concerns if the parties' agreement is able to manipulate the exclusivity provision (beyond the simple fact of settling with a first-filing ANDA IV applicant) in a manner that actually excludes later entry by others. In the *Cardizem* and *Hytrin* examples, the parties did not settle the underlying patent cases, but still agreed to keep the generic challenger's ANDA IV application in place and unamended, and those courts found that the generic's continuing exclusivity rights would delay subsequent filers, at least by six months. Whether those courts were correct on the facts before them, whether any "bottleneck" results from the settlement rather than the statute itself, and whether the amendments to Hatch-Waxman in 2003 made the potential for a "bottleneck" that actually delays entry more or less likely, remain (as one might expect) much debated.

Finally, we do not suggest that this "common ground," to the extent that it exists, covers a *lot* of ground. These points are clearly not sufficient to resolve the questions presented in most of the cases cited here, where the plaintiffs contended that the settlement was anticompetitive even if it was within the exclusionary effect of the patent as written, and even if the 180-day exclusivity right was unaffected by the settlement. No court has yet suggested that a settlement within the scope of a patent can immunize a settlement involving a patent procured by fraud or otherwise "objectively baseless." But these points may give a common starting point for the analysis, which can be helpful even if it is far from the finish line.

[188] *Cardizem* Amicus Br. at 12.
[189] See ¶ A.1., *supra.*

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