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Adequacy of the 1995 Antitrust Guidelines for IP Licensing: Commentaries from the 2002 FTC and DOJ Hearings

By Clovia Hamilton

In 1995, the Department of Justice (DOJ) and the Federal Trade Commission (FTC) adopted new guidelines for the licensing of intellectual property rights without violating antitrust laws. The 1995 Antitrust Guidelines for the Licensing of Intellectual Property (IP Guidelines) state the antitrust enforcement policy of the DOJ and the FTC.[1] The IP Guidelines drafted by the DOJ and FTC (the agencies) does not provide practitioners with a sufficient level of comfort as they attempt to predict the enforcement initiatives relative to intellectual property licensing.[2] The IP Guidelines are inadequate because they misunderstand the nature of intellectual property markets and provide insufficient guidance in the most difficult areas. The IP Guidelines include a special treatment of a newly defined "innovation market" that is flawed and lack a focus on license-misuse activity that creates entry barriers. Antitrust and patent law practitioners have heavily debated the IP Guidelines.

To address these concerns, in November 2001, the agencies held hearings on "Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy," which were held between February and November 2002.[3] The hearings took place over 24 days at the University of California's Haas School of Business and in Washington, DC, and involved more than 300 panelists of representatives of high-tech industries and law firms, the independent inventor community, leading patent and antitrust organizations, and scholars in economics and patent and antitrust law.[4]

In October 2003, the FTC issued a report entitled "To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy" focused on the patent law system.[5] A second report by both agencies is forthcoming and will make similar recommendations for the antitrust law enforcement system.[6] This article discusses whether the FTC has addressed the three common types of license misuse, that is, the refusal to grant intellectual property licenses; misconduct during industry standards setting; and the improper acquisition of broad intellectual property rights through patent settlement agreements involving patent pools, cross-licenses, and generic drug market entry. Generic drug entry has attracted a great deal of interest in light of the diversion of distribution from wholesalers to the multibillion-dollar shadow market over the Internet, and the controversial Medicare Bill.[7]

REFUSING TO LICENSE

Refusing to license a patent can sometimes constitute improper exclusionary conduct. In the 1992 pre-IP Guidelines case *Eastman Kodak Co. v. Image Technical Services, Inc.*, the Supreme Court considered the unilateral refusal to sell or license a patented or copyrighted product and tying arrangements.[8] Although Section 5.3 of the 1995 IP Guidelines cites *Eastman Kodak*,[9] the IP Guidelines do not provide much guidance in the area of exclusionary conduct.[10] Section 5.5 of the IP Guidelines states that exclusion from a licensing arrangement among competing technologies is unlikely to have anticompetitive effects "unless (1) excluded firms cannot effectively compete in the relevant market for the good incorporating the licensed technologies and (2) the pool participants collectively possess market power in the relevant market."[11] If these circumstances exist, the agencies will evaluate whether the arrangement's limitations on participation are reasonably related to exploiting and developing the pooled technologies and will assess the net effect of those limitations in the relevant market.[12] The IP Guidelines do not provide adequate guidance

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for determining whether and when refusing to license or sell patented technology or copyrighted work is justified as a legitimate business decision. The IP Guidelines merely state that the agencies will determine whether a licensing restraint is reasonably necessary to achieve pro-competitive efficiencies.[13] Specific examples of pro-competitive efficiencies or business justifications are not provided.

In *Eastman Kodak*, Kodak took exclusionary action by implementing a policy to stop selling its replacement parts to independent service organizations (ISOs) and by securing agreements with other parts manufacturers not to sell parts to ISOs.[14] The ISOs alleged that Kodak's new policy of selling replacement parts only to Kodak machine owners that purchased Kodak's repair services constituted both monopolization and attempted monopolization of the market for Kodak repair services under Section 2 of the Sherman Act and a *per se* illegal tying arrangement under Section 1.[15]

Kodak proffered three business justifications for its restrictive parts policy: (1) it wanted to guard against inadequate service to its customers because of its commitment to quality service; (2) it needed to control and lower its inventory costs; and (3) it desired to prevent the ISOs from free-riding on its capital investment in its equipment industry.[16] The Supreme Court held that these reasons were insufficient and pre-textual and that the proffered business justifications really did not play a part in Kodak's decision to implement this policy to refuse to sell or license.[17]

There was evidence that Kodak had control over the availability of parts, resulting in excluded service competition, increased service prices, and forced unwilling consumption of Kodak service.[18] The Supreme Court determined that Kodak controlled approximately 100 percent of the single-brand parts market and 80 percent to 95 percent of the service market with no readily available substitutes.[19] In *Eastman Kodak*, the Supreme Court reaffirmed the *Times-Picayune* principle that power gained naturally from a patent or copyright can give rise to antitrust liability if a seller exploits its dominant position in one market to expand its empire into the next.[20]

After the Supreme Court remanded *Eastman Kodak*, the Ninth Circuit affirmed the trial court's jury verdict in favor of the ISOs.[21] Thus, refusal to deal in the complex high-tech market for photocopier and micrographics equipment, and its derivative aftermarket, proved detrimental to Kodak. Kodak was required to sell all of its patented parts to ISOs for a period of 10 years, and after trebling damages, the ISOs obtained a judgment of $ 71.8 million.[22] The Ninth Circuit held that, "unlike the other cases involving refusals to license patents, this case concerns a blanket refusal that included protected and unprotected products."[23] The presumption that refusing to license or sell is justified by legitimate business reasons may be rebutted by evidence that the monopolist acquired the intellectual property unlawfully, attempted to gain a monopoly beyond the grant of a patent, or relied on a pretextual business justification to mask anticompetitive conduct.[24] Here, there was evidence that the proffered business justification really did not play a part in the decision to act.[25] Kodak's parts manager testified that patent rights did not cross his mind at the time the policy to exclude ISOs was implemented.[26]

Kodak held patents for more than 220 parts needed to service its photocopiers.[27] Before *Eastman Kodak*, no court had ever compelled a patentee to license a valid patent, as doing so imposed antitrust liability on a patentee for refusing to license.[28] The significance of a monopolist's unilateral refusal to sell or license a patented or copyrighted product in the context of a Section 2 claim based on monopoly leveraging was a question of first impression.[29] In fact, the DOJ had not filed a Section 2 case, nor said much about the issue.[30] The Ninth Circuit held that the mere desire to protect intellectual property is not in and of itself a legitimate business justification.[31]

Rather than helping to alleviate this confusion, the 1995 IP Guidelines do not provide much guidance on exclusionary conduct in the form of the refusal to license or sell intellectual property. The agencies should provide guidance on: (1) what types of business justification arguments are valid; (2) when reliance on a business justification is a pretext to mask anticompetitive conduct; and (3) how a claim of legitimate business justification can be rebutted with evidence that the refusal involved intellectual property that was unlawfully acquired, such as by patent misuse, a combination of protected and unprotected products, or a monopoly beyond the grant of a patent or statutory copyright grant.

The Federal Circuit, on the other hand, has upheld refusals to license as proper use of the patent monopoly. The 2000 post-IP Guidelines *CSU v. Xerox* case[32] arose out of a class action antitrust lawsuit with facts very similar to those of *Eastman Kodak*. In 1984, Xerox established a parts policy in which it refused to sell parts to CSU and other ISOs.[33] The district court concluded that a monopolist's refusal to license its patented or copyrighted product could never give rise to antitrust liability on the ground that such a refusal to license is immune from antitrust scrutiny.[34] In considering the effect of Xerox's unilateral right to refuse to license copyrighted manuals and diagnostic software on liability under the antitrust laws, the Federal Circuit in *CSU* embraced the First Circuit's approach on liability under the antitrust laws.[35]

The First Circuit's approach was set out in *Data General Corp. v. Grumman Systems Support Corp.*, in which it stated that copyright monopolies are based on Congress'

assumption that the right to exclude others creates a system of incentives that promotes consumer welfare by encouraging investment in the creation of expressive work.[36] Applying this principle to CSU, the Federal Circuit concluded that exclusionary conduct could include a monopolist's refusal to license.[37] This is presumed to be a legitimate business justification; the antitrust plaintiff has the burden to overcome this presumption.[38] The Federal Circuit rejected CSU's invitation to examine Xerox's subjective motivation in asserting its right to exclude under the copyright laws for pretext.[39]

In November 2001, the FTC Chairman Tim Muris listed the purposes for the Hearings.[40] With regards to refusals to deal, Muris stated that commentators have had varied responses to the *CSU* decision.[41] Some do not follow the *CSU* decision and believe in an antitrust inquiry as to whether the alleged monopolist sacrificed profit in order to exclude competition and in return created additional market power.[42] Others follow the *CSU* decision and believe that in absence of misuse such as filing improper infringement suits or engaging in unlawful tying, a patent owner has an absolute right to refuse to license to others.[43]

Muris also mentioned that some have argued that the Federal Circuit's decision appears to find substantial support in the plain language of 35 U.S.C. § 271(d)(4), which states that no patent owner otherwise entitled to relief for infringement of a patent shall be denied relief or be deemed guilty of misuse or illegal extension of the patent right by reason of his having refused to license or use any rights to the patent.[44] Muris questioned whether 35 U.S.C. § 271(d)(4) should be changed or reinterpreted to reflect competition considerations; and stated that this is one of the issues that would be discussed in the upcoming hearings.[45]

In addition, in February 2002, Charles James of the DOJ provided opening day comments at the Hearings on several issues of concern.[46] James stated that, during the course of the Hearings, the agencies would "encourage participants to examine the degree to which holders of intellectual property are refusing to grant licenses, and whether such refusals to license raise competitive concerns…[and] facilitate discussion of the current jurisprudence in this area, including how it is affecting current licensing practices and if there are circumstances in which a refusal to license may raise antitrust concerns."[47]

Unfortunately, the recent October 2003 FTC report about the Hearings does not adequately address refusals to deal. Although this report is intended to make recommendations targeted at improving the patent law system, it did not answer Muris' inquiry about 35 U.S.C. 271(d)(4) in light of the *CSU* decision.

MISCONDUCT DURING STANDARDS SETTING

The setting of industry standards also can be anticompetitive. Section 5.5 of the IP Guidelines, which covers cross-licensing and pooling arrangements, states that a possible anticompetitive effect may occur if participants are discouraged from engaging in research and development.[48] For example, a pooling arrangement requiring members to grant licenses to each other for current and future technology at minimal cost may suppress technology by reducing the incentive to engage in research and development, because members of the pool have to share their successful research and development and each of the members can free-ride on the accomplishments of other pool members.[49] This may be true of standards-setting organizations that, to some extent, have similar structures and purposes as joint ventures.[50]

As a practical commercial matter, licensees generally want exclusive rights to justify the significant effort and expense incurred in exploiting high technology. The 1995 IP Guidelines do not specifically address participation and conduct in industry standards-setting groups that are prevalent in the high-technology arena. The IP Guidelines should have addressed the potential for monopolies in the development of high-technology standards and interface specifications. Industry standards are agreed upon specifications for the production of functionally compatible goods and services and are vital to many aspects of the economy, since they may be the only way to ensure that technology are compatible with each other.[51] The line between beneficial standards and standards used as anticompetitive devices must be made clearer.

DE FACTO STANDARDS SETTING

The two types of standards setting are *de facto* and *de jure*. *De facto* standards setting occurs when a standard achieves a critical mass and dominates an industry.[52] Companies that set *de facto* industry standards have tremendous economic power in that they can control the interfaces to the products for which they set the standard.[53] If competitors cannot interface with the standards-setting product, then that competitor cannot compete effectively.[54] Thus, interfaces may actually define relevant markets.[55] Further, standards setting can have anticompetitive effects if it thwarts innovation by advocating an older standard when a newer, better, or more widely accepted technology is available.[56] Standards setting might also provide a forum for collusion, such as selecting a standard designed to preclude the use or acceptance of another's product.[57]

The personal computer software industry exhibits a particular set of conditions known to economists as network effects.[58] A network effect is present when the value of a product or service increases with the cumulative number of purchases, and each additional purchase raises the value of the product to existing users as well as the expected value of the product to future adopters.[59] For example, Netscape uses the network effect by not charging anything but increasing the value of its product and itself.[60] Network effects permit a market's first entrant to achieve domination of a market by getting a head start in building an installed base of users that increase the value of that first entrant's product.[61]

In November 1995, the FTC conducted hearings on global and innovation-based competition to consider networks, standards, foreclosure, and strategic conduct.[62] Robert Kohn of Borland International discussed the monopoly in standard interface specifications.[63] Kohn stated that users adopt a particular interface standard by investing time and resources in learning how to operate the product efficiently.[64] Users increase this investment by purchasing complementary products that are compatible with the interface standard of the original product.[65] Ultimately, a market leader in control of an interface standard may substantially raise the cost to consumers of switching to alternative product offerings of subsequent market entrants, and these alternative products might actually be better, cheaper, and more innovative.[66]

Further, promoting innovation is a function of properly circumscribing the scope of intellectual property protection and enforcing antitrust laws to prevent monopoly control over interface standards. For example, Microsoft controls the desktop computer operating system standard.[67] With respect to this operating system, Microsoft won a $13.6 million judgment against Stac Electronics for the misappropriation of its trade secrets.[68] A federal jury awarded Stac $120 million for patent infringement and Microsoft the $13.6 million for trade secret misuse and required the parties to enter into a broad cross-licensing agreement.[69]

In addition to the potential for a market leader in control of an industry standard to raise the cost to consumers, there is potential for exclusionary conduct. According to Robert Kohn, Stac would be out of business if Microsoft had refused to license to it.[70] Kohn recommended requiring compulsory licensing of the source code, subject to a modest royalty that implements the interface standard in order to allow competitors to develop complementary products.[71] Absent such licensing, the users of original software programs will face switching costs if the software is not allowed to be compatible or if follow-on firms are not allowed zero-priced access to *de facto* industry standards.[72] When a competitor so dominates a market by becoming the sole standards-setting authority, its power must be carefully monitored or actively constrained if innovation in related markets is not to be suppressed.[73]

The lengthy legal battle between the Addamax Corporation and the Open Software Foundation (OSF) raised the issue of de facto industry standards setting.[74] Addamax produced B-1 rated security software systems for the computer industry. The OSF is a high-tech joint research and development venture registered under the National Cooperative Research and Production Act of 1984.[75] Eight computer manufacturers established the OSF in 1988, including Hewlett-Packard and Digital, to conduct computer interface research and experimentation and to produce and promote a software alternative to the UNIX operating system.[76]

Addamax lost a bid for the development of OSF's security software and alleged that OSF's conduct with respect to its *de facto* industry standards had an anticompetitive impact on the industry because OSF allegedly had conspired to force the price for security software down below the free-market level, limiting Addamax's ability to compete.[77] The courts did not explore the market issue but examined the causal connection between Addamax's business and OSF's alleged monopsony power.[78] The courts held that antitrust violations were not the material cause of Addamax's business failure because the security software market is a high-risk business and Addamax's product was too expensive and complex.[79]

Had OSF's selection of a security software platform been viewed as a desire to set a *de facto* industry standard, as opposed to merely selecting the lowest bidder, OSF's selection could have been considered an anticompetitive means to preclude the use or acceptance of Addamax's product. The FTC, however, has stated that OSF's actions seemed innocently consistent with competitive rivalry; moreover, OSF's actions were mitigated by the fact that the joint venture was designed to counter AT&T/Sun's alleged attempts to dominate the industry with the UNIX operating system.[80] Given the courts' holdings that all high-tech software business deals are risky and the FTC's view that this is merely a case of competitive rivalry, Addamax did not have a chance to prevail.

DE JURE STANDARDS SETTING

De jure standards setting occurs when an industry group or consortia adopts standards.[81] For example, in February 1992, Dell Computer Corporation joined the Video Electronics Standards Association (VESA), which is composed of all of the major US computer hardware and software manufacturers.[82] In August 1992, VESA adopted a final standard for a computer bus design, the VL-bus, for transferring instructions between a computer's central pro-

cessing unit and peripherals.[83] In line with the common practice of *de jure* industry standards-setting organizations, VESA required that participants disclose their intellectual property rights to one another, and Dell representatives certified on several occasions that the VESA proposal did not infringe on any of their patents.[84]

After the VESA VL-bus design was adopted and incorporated into more than one million computers, Dell revealed that it obtained a VL-bus patent in 1991 and announced that it intended to enforce the patent by requiring patent licenses from users of its design.[85] In 1995, the FTC charged Dell with violating Section 5 of the FTC Act, which covers unfair methods of competition, because of its failure to disclose its patents during open-standards deliberations.[86] The FTC complained that Dell's actions unreasonably restrained competition by hindering the industry's acceptance of the VL-bus design standard, raising the costs of implementing the standard and chilling the willingness to participate in future standards-setting activities.[87] Dell subsequently signed a consent decree with the FTC that prohibited the company from enforcing any of the patents it failed to disclose to the standards group for 10 years.[88]

Hitachi cited the FTC case against Dell when it alleged that Rambus had violated the rules of the standards-setting body called Joint Electron Devices Engineering Council (JEDEC).[89] Hitachi alleged that Rambus had tried to restrain trade by refusing to reveal its patent enforcement intentions during open standards-setting discussions in the early 1990s.[90] Rambus has enforced its proprietary Synchronous DRAM (S-DRAM) by forcing memory chipmakers to pay royalties.[91] Although Hitachi has argued that Rambus's technology is an open industry standard, Samsung Electronics, Oki Electric Industry, Elpida Memory, Mitsubishi Electric, Toshiba, and Hitachi all agreed to license the patents and pay Rambus royalties.[92] Hyundai Electronics Industries, Micron technology, and Infineon Technologies sued Rambus on this issue.[93]

In 2000, the Assistant Director of the FTC Bureau of Competition advised that standards should not overreach, should not restrict or define the product more than necessary, should not be applied to just members but to nonmembers as well, and should not do anything to stifle innovation.[94]

In November 2001, Timothy Muris discussed standards setting when listing the various purposes of the Hearings.[95] Muris stated that standards setting is an area that illustrates the tension between antitrust and intellectual property policy, and knowledge-based standards that rely on intellectual property can raise difficult competition issues.[96]

Muris mentioned the 1992 *Dell* case and discussed a 1985 case involving the American Society of Sanitary Engineering (ASSE).[97] The ASSE had a policy of refusing to develop a standard for a product that is patented or manufactured by only one manufacturer because the existing manufacturers did not sanction an innovative product unless they could also produce it.[98] The FTC entered into a consent order that "required, among other things, that the ASSE stop refusing requests for issuance of a standard or modification of an existing standard for a product merely because only one or a small number of manufacturers patent or make the product."[99]

According to Muris, some commentators have argued that standards that rely on patent rights present a great danger to competition since the standard might give the technology owners unwarranted market power by excluding innovative, patented products from the standards-setting process itself or by placing too great a burden on businesses and thus deter firms from participating in the standard-setting organization in the first place, thereby hindering innovation.[100] Muris concluded that "we could all benefit from a more complete understanding of the standard-setting process."[101] This begs the question of whether the October 2003 FTC report on the Hearings did indeed provide a more complete understanding of potential anticompetive behavior, which is lacking in the IP Guidelines.

In February 2002, on the opening day of the Hearings, Charles James of the DOJ mentioned that one goal for the Hearings is "to improve our understanding of how various standard setting practices promote innovation and competition, and how various practices might result in abuses of market power or disincentives for innovation."[102] According to James, with respect to technical standards for digitizing data have proven vital for the usefulness and commercial viability of Internet communications and other products because after a standard has been established, there are many issues regarding access to the technology embodied in the standard.[103] "[L]imited access could restrict the number of competitors in a market and severely inhibit entry. In some cases, we might want to consider whether consumer welfare is best served by having the industry settle on a single standard or by encouraging the development of multiple competing standards. We will encourage participants in these hearings to discuss the influence of intellectual property and antitrust law on real world standard setting."[104]

Unfortunately, the October 2003 FTC Report did not address these concerns. Hopefully, the proposed joint FTC/DOJ report will do so. There has been an increase in legal actions against misconduct in the standards-setting process. The increase in legal actions against the manipulation of the standards-setting process is evidence that the agencies should have provided guidance on this matter in their IP Guidelines and in the October 2003 Hearings report.

PATENT ACCUMULATION AND SETTLEMENTS

CROSS-LICENSING AND PATENT POOLS

"Cross-licensing, package licenses or patent pools are created to enable all participants to use the intellectual property where, without the licenses, perhaps none could do so because of possible or probable infringement."[105] The IP Guidelines state that the joint marketing of pooled intellectual property with collective price setting or coordinated output restrictions may have anticompetitive effects.[106] The IP Guidelines, however, do not adequately address the entry barrier problem of acquiring broader protection for narrow inventions and the combination of patent rights by cross-licensing.[107]

In 1981, a former Deputy Attorney General for Economics advised that the DOJ should bring an antitrust action when a company with a dominant position enters into extensive cross-licenses with competitors and the licenses featured restrictions on the availability of licenses to new entrants.[108] Thus, practitioners would benefit greatly from a thorough discussion of legitimate and insufficient transactions in the IP Guidelines.

In 1997, the DOJ suggested that it is likely to scrutinize patent cross-licenses and settlements of infringement suits to a greater degree.[109] The DOJ proposed a notification procedure to enable it to investigate significant cross-licenses, licenses in general, and patent infringement suit settlement agreements.[110] Joel Klein, the Acting Assistant Attorney General at the time, stated that cross-licenses had previously remained largely off the DOJ's agenda.[111] Perhaps this is why the discussion of cross-licensing and settlement agreements is limited in the IP Guidelines.

Practitioners must look elsewhere for guidance, and the DOJ Business Review Letters are helpful. For example, in December 1998, pursuant to the DOJ Business Review Procedure,[112] the DOJ provided a statement of its enforcement intentions with respect to a proposed arrangement in which Koninklijke Philips Electronics would assemble, offer a package license, and distribute royalty income under Philips, Sony, and Pioneer Electronic patents.[113] Allegedly, the patents are essential to the manufacturing of Digital Versatile Discs (DVDs) and players in compliance with the DVD-ROM and DVD-Video formats.[114] Essential patents have no substitutes and must be licensed in order to comply with standard specifications.[115]

The DOJ stated that, by reducing what would otherwise be three licensing transactions into one, the pool would reduce transaction costs for licensors and licensees alike.[116] Also, "by ensuring that each Licensor's patents will not be blocked by those of the other two, the pool would enhance the value of all three Licensors' patents."[117] The DOJ concluded that the proposed arrangement is not likely to initiate antitrust enforcement action against the proposed cross-license because the combination would lower costs to manufacturers that need access to the essential patents in order to produce discs and players in conformity with the DVD-Video and DVD-ROM formats.[118]

Another example is a 1999 DOJ statement of its enforcement intentions with respect to a proposed arrangement whereby the Toshiba Corporation would assemble and offer a package license with Hitachi, Matsushita Electrical Industrial, Mitsubishi Electric, and Time Warner for DVD-Rom and DVD-Video formats.[119] Again, the DOJ concluded that the proposed arrangement was not likely to initiate antitrust enforcement action against the proposed cross-license because the combination would lower the costs of manufacturers that need access to essential patents in order to produce conforming products.[120]

Conceptually, the problem of patent accumulation is indistinguishable from the merger problem under antitrust law.[121] In the merger analysis, combinations and collusions eliminate competition from competing patents that would drive royalty rates down to the point at which each patentee could hope to charge a royalty that merely reflected the degree to which its patent was more valuable than others.[122] As with competing patents, there is a significant danger that the cross-licensing of complementary patents will mask price fixing conspiracies.[123]

The cross-licensing of intellectual property rights is sometimes the product of the settlement of an infringement suits. Patent settlements can be an efficient means to avoid litigation, and in general, courts favor settlements.[124] They are not, however, immune from antitrust scrutiny. The IP Guidelines provide that, when cross-licensing involves horizontal competitors, the agencies will consider whether the effect of the settlement is to diminish competition among parties that would have been actual or likely competitors in a relevant market in the absence of the cross-license.[125] "In the absence of offsetting efficiencies, such settlements may be challenged as unlawful restraints of trade."[126] Examples of offsetting efficiencies include the anticipated lower manufacturing costs cited in the aforementioned DOJ business review letters and the decision by the owner of weaker patents to license them only as a package since they might be more valuable and productive as a packaged license.[127]

Cross-licensing remains largely missing from the DOJ's agenda. Therefore, there is a need for more guidance on the entry barrier problem of gaining broad protection for narrow inventions, combining patents and/or other intellectual property, by cross-licensing, using cross-licensing to mask price fixing conspiracies, or using settlement agreements to

diminish competition. According to DOJ Business Review Letters, legitimate transactions include those that prevent blocked patents, enhance patent value, and lower costs to manufacturers that need access to essential patents.

The October 2003 FTC Report mentions that the Business Review Letters discuss features that reduce competitive concerns.[128] However, it does not recommend any changes to the IP Guidelines about patent pools, cross-licensing, or patent settlement agreements.

GENERIC DRUG MARKET ENTRY

With respect to the purpose of the Hearings, in November 2001, Timothy Muris discussed pharmaceutical patent settlements as related to the 1984 Hatch-Waxman Act.[129] Muris discussed the FTC's investigations of patent settlements between the manufacturers of pioneer drugs and competing generic drugs.[130] The concern is that some settlements might deter generic market entry by paying generic entrants to not compete beyond the limitations already imposed, such as by patent law and the Hatch-Waxman Act.[131]

In July 2002, the FTC released a report titled "Generic Drug Entry Prior to Patent Expiration: An FTC Study" on a study of the generic drug industry's activities between 1992 and 2000 that is intended to provide a more complete picture of how generic competition has developed under Hatch-Waxman.[132] The study involved 28 brand-name companies and more than 50 generic drug companies.[133] It recommends legislative action designed to ensure that the 180-day exclusivity and the 30-month stay provisions of the Hatch-Waxman Amendments do not delay generic drug entry to market.[134] The FTC's recommendations would permit only automatic 30-month stay on the entry of a generic drug (per drug product, per generic entry application, and only resolve infringement disputes over patents listed in the "Orange Book") prior to the filing of the generic's entry application during pending patent-infringement litigation.[135] The FTC supports new legislation that would require brand-name companies and first generic applicants to provide copies of certain agreements to the FTC and the Department of Justice (DOJ) for review.[136]

Under the current law, Hatch-Waxman requires the applicant to state either that the patents for the brand-name drug products are invalid or not infringed by the generic product, technically, a Paragraph IV certification.[137] "[I]f a brand-name lists an additional patent in the Orange Book *after* the generic has filed its application, the generic firm would be required to re-certify to this later-listed patent. If the branded firm then sued the generic manufacturer within 45 days claiming patent infringement, generic entry would be stayed for an additional 30 months [under Hatch-Waxman]."[138] Therefore, some brand-name manufacturers list additional patents in the Food and Drug Administration (FDA) Orange Book shortly before their original patents expire, enabling them to file patent infringement suits against generic drug firms. The concern is that brand-name manufacturers may be acquiring overly broad, invalid additional patents. The 180-day marketing exclusivity period has enabled generic and branded companies to enter into agreements that had the potential to stay the 180-day period for some time. In these circumstances, the first generic applicant does not trigger the running of the 180 days, so the FDA is prevented from approving any other generic applicants to enter the market.[139]

"During the time period covered by the study (1992-2000), the report states, there were 20 settlements of patent litigation related to generic entry prior to patent expiration . . . [and] 14 of the 20 had the potential to delay the start of the generic applicant's 180-day marketing exclusivity."[140] Although the October 2003 FTC report is intended to address patent related concerns such as these, there is no mention of generic drug market entry (*i.e.*, the listing of patents in the Orange Book, patent related settlement agreements).

In addition, in February 2002, during the opening day comments at the Hearings, Charles James discussed patent pooling.[141] James stated that the agencies are interested in facilitating discussion of collective intellectual property rights organizations created by patent pools, patent settlement, and cross-licensing agreements involving new (or generic) technology that is covered by many overlapping intellectual property rights.[142]

James mentioned the business review process of proposals to jointly license patents to an MPEG patent pool (a video compression technology) and two DVD patent pools.[143] In each of these cases, the DOJ concluded that the proposed arrangements did not appear to pose antitrust concerns since the pools (1) would license only those patents essential for a manufacturer to comply with an established standard; (2) were designed to capture the efficiencies that may come from licensing complementary technologies; and (3) were designed to limit the anticompetitive effect that can arise from pooling technology (such as the elimination of competition or the increase in prices that could arise if substitute technologies) were placed in a pool.[144] According to James, the Hearing would explore "a number of broad questions about patents pools, such as whether pools actually result in the competitive problems they are hypothesized to cause and whether the antitrust authorities have focused on the right criteria when evaluating patent pools…how the term "essential" should be defined and whether the identity of the administrator of the pool matters."[145]

Unfortunately, the October 2003 FTC report on the Hearings did not address these issues. It addressed only the

general issue of whether the US Patent and Trademark Office is issuing overly broad, invalid patents.[146]

With respect to access to affordable pharmaceuticals, on November 25, 2003, the controversial Medicare bill's conference report cleared.[147] It included amendments to patent provisions in Title 35 that modify the patent enforcement mechanisms as to generic drugs.[148] There is a special infringement liability created by 35 USC § 271(e)(2) for generic entrants seeking pre-market approval by the FDA of drugs subject to patents listed in the Orange Book. House Resolution 1 "includes provisions that: (1) limit patentees to a single 30-month stay of FDA approval for a generic drug . . .; (2) give a drug applicant standing to bring a declaratory judgment against a patentee that fails to sue under 35 USC § 271(e)(2) within the 45-day time limit; (3) gives drug applicants that are sued under Section 271(e)(2) the right to assert a counterclaim that challenges the relevant patent information listed in the FDA Orange Book; (4) allow damages determinations in infringement suits to consider the propriety of the Orange Book listings; and (5) forfeit the generic drug 180-day exclusivity period on evidence of an anti-competitive deal between the generic and patented drug companies."[149]

In conclusion, it is a necessitated that the proposed joint FTC/DOJ report on intellectual property and competition law address the continuing concerns about patent settlements related to both cross-licensing and patent pools and generic drug entry.

CONCLUSION

Innovation is encouraged and is necessary for economic growth. Since licensing is a key phase of market entry for the development of innovative products and services,[150] agency guidance should focus on conduct in the high-tech arena that constitutes potential entry barriers. Key high-tech entry barriers include refusals to license, misconduct during standards-setting activities, and patent accumulation methods such as cross-licensing, package licensing, and patent pools. These activities merit closer attention and practitioners need better guidance from the agencies.

Looking back to statements made in November 2001 about the purposes of the Hearings, it was clearly articulated that standards setting, cross-licensing, and patent pools, unilateral refusals to deal, other business practices, the proliferation of patents, the changing scope of patents, and the role of the Federal Circuit will be among the topics on the agenda.[151] However, the only issues addressed in the October 2003 FTC report was patent quality as defined by the proliferation of patents, and the scope of patent protection.[152]

The mere fact that the agencies have chosen to report the findings and recommendations from the Hearings in a bifurcated manner signified the tension between antitrust law, which seeks to prevent monopolization, and patent law, which grants monopolies. Alternatively, this bifurcated report process could merely be a stall tactic to further delay providing practitioners with the clear guidance needed when licensing intellectual property in high-tech industries.

NOTES

1. US Dep't of Justice and Fed. Trade Comm'n, Antitrust Guidelines for the Licensing of Intellectual Property 1.0 (April 1995).
2. Clovia Hamilton, "Adequacy of the 1995 Antitrust Guidelines for the Licensing of Intellectual Property in Complex High-Tech Markets," 7 *Comp. L. Rev. & Tech. J.* 23, Fall 2002.
3. *See* Timothy Muris, "Competition and Intellectual Property Policy: The Way Ahead" (Nov. 15, 2001), available at *http://www.usdoj.gov/atr/public/speeches/1123.htm* (last visited Dec. 3, 2003).
4. "FTC Issues Report on How to Promote Innovation Through Balancing Competition with Patent Law and Policy," Press Release, FTC (Oct. 28, 2003), available at *http://www.ftc. gov/opa/2003/10/cpreport.htm*.
5. *Id.*
6. *Id.*
7. Gilbert M. Gaul and Mary Pat Flaherty, "U.S. Prescription Drug System Under Attack," Oct. 19, 2003, *Washington Post*.
8. *See* Eastman Kodak Co. v. Image Technical Servs., Inc., 504 U.S. 451, 459-62 (1992).
9. IP Guidelines, *supra* n.2, at 5.3.
10. *See id.* at 5.4.
11. *Id.* at 5.5.
12. *Id.*
13. *Id.* at 4.2.
14. *Eastman Kodak*, 504 U.S. at 458.
15. *Id.* at 459.
16. *Id.* at 461.
17. *See id.* at 483-484.
18. *See id.* at 464-465.
19. Id. at 481.
20. *See id.* at 479 n.29 (quoting Times-Picayune Pub. Co. v. United States, 345 U.S. 594, 611 (1953)).
21. *See* Image Technical Servs., Inc. v. Eastman Kodak Co., 125 F.3d 1195, 1201, 1228 (9th Cir. 1997).
22. *Id.* at 1201, 1227-1228.
23. *Id.* at 1219.
24. *Id.* at 1216, 1219. *See also* Richard J. Gilbert, Patents, Sleeping Patents, and Entry Deterrence, in Strategy, Predation, and Antitrust Analysis 205, 206-207 (Steven C. Salop ed., 1981).
25. *Image Technical Servs.*, 125 F.3d at 1219.
26. *Id.*
27. *Id.* at 1214.
28. Tonya Trumm, "Expansion of the Compulsory Licensing Doctrine? *Image Technical Services, Inc. v. Eastman Kodak Co.*," 24 *J. Corp. L.* 157, 158 (1998).
29. *Image Technical Servs.*, 125 F.3d at 1214.
30. Steven Reynolds, "Antitrust and Patent Licensing: Cycles of Enforcement and Current Policy," 37 *Jurimetrics J.* 129, 147 (1997).
31. *Image Technical Servs.*, 125 F.3d at 1218-1219.
32. *See* CSU, L.L.C. v. Xerox Corp., 203 F.3d 1322 (Fed. Cir. 2000).

33. *Id.* at 1324.
34. *Id.*
35. *Id.* at 1329.
36. *See* Data Gen. Corp. v. Grumman Sys. Support Corp., 36 F.3d 1147, 1186-1187 (1st Cir. 1994).
37. *See CSU, L.L.C.*, 203 F.3d at 1327.
38. *Id.*
39. *Id.* at 1329.
40. Muris, *supra* n.4.
41. *Id.*
42. *Id.*
43. *Id.*
44. *Id.*
45. *Id.*
46. *See* Charles James, "Joint DOJ-FTC Hearings on Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy" (Feb. 6, 2002), available at *http://www.usdoj.gov/atr/public/speeches/1123.htm* (last visited December 3, 2003).
47. *Id.*
48. *See* Guidelines, *supra* n.2, at 5.5.
49. *Id.*
50. Mark Lemley, "Antitrust and the Internet Standardization Problem," 28 *Conn. L. Rev.* 1041, 1094 n.169 (1996).
51. David Healey, "Group Standard-Setting Grows More Significant: De Jure Standard-Setting Raises Patent Enforceability Issues as well as Antitrust Implications," 20 *Nat'l L.J.* 38 at C36 (May 18, 1998).
52. *See* Dictionary of PC Hardware and Data (1996), available at *http://www.oreilly.com.*
53. Joseph Farrell & Garth Saloner, "Converters, Compatibility, and the Control of Interfaces," 40 *J. Indus. Econ.* 9, 35 (1992).
54. *Id.*
55. *Id.*
56. David A. Balto, "Standard Setting in a Network Economy," Remarks at the Cutting Edge Antitrust Law Seminars International (Feb. 17, 2000) available at *http://www.ftc.gov/speeches/other/standardsetting.htm* (last visited Aug. 12, 2002).
57. *Id.*
58. Michelle M. Burtis & Bruce H. Kobayashi, "Intellectual Property and Antitrust Limitations on Contract," Mercatus Center Symposium on Dynamic Competition and Public Policy, 22 (2000), available at *http://www.gmu.edu/department/law/faculty/papers/chronology.html* (last visited Aug. 9, 2002).
59. *See* Addamax v. Open Software Found., 152 F.3d 48, 50 n.4 (1st Cir. 1998).
60. John M. Gallaugher & Yu-Ming Wang, "Network Effects and the Impact of Free Goods: An Analysis of the Web Server Market," 3 *Int'l J. of Elec. Com.* 67, 88 (1999).
61. *Id.*
62. *See* Robert Kohn, Remarks at Hearings on Global and Innovation-Based Competition (Nov. 29, 1995), available at *http://www.ftc.gov/opp/global/GC11 2995.htm* (last visited Aug. 27, 2002).
63. *Id.*
64. *Id.*
65. *Id.*
66. *See* S.J. Liebowitz & Stephen E. Margolis, "Should Technology Choice Be a Concern of Antitrust Policy?," 9 *Harv. J. L. & Tech.* 283, 288 (1996).
67. *See* George Willingmyre, "International Standards: At the Crossroads," available at *http://www.gtwassociates.com/answers/international.html* (last visited Aug. 27, 2002).
68. *See* Stac Electronics v. Microsoft Corp., 38 F.3d 1222 (Fed. Cir. 1994).
69. *See* "Three Significant Court Cases, Software Patent Institute Database of Software Technologies," available at *http://www.spi.org/3cases.htm* (last visited Aug. 27, 2002).
70. Kohn, *supra* n.62.
71. *Id.*
72. *See id.* This zero-priced access is compulsory licensing provided for when standards can be treated as essential facilities. *See* Lemley, *supra* n.50, at 1091.
73. *See* John Flynn, "Antitrust Policy, Innovation Efficiencies, and the Suppression of Technology," available at *http://www.econ.utah.edu/les/version 2.0/papers/ FlynnAntitrust.htm* (last visited Sept. 23, 2002).
74. *See* Addamax Corp. v. Open Software Found., 888 F. Supp. 274, 277 (D. Mass. 1995).
75. *Id.* at 277 n.3.
76. *Id.* at 277.
77. *Id.* at 278.
78. *See* Addamax v. Open Software Found., 152 F.3d 48, 53 (1st Cir. 1998).
79. *Id.*
80. *Id.*
81. *See* Healey, *supra* n.51.
82. Dell Computer Corp.; Consent Agreement with Analysis to Aid Public Comment, 60 Fed. Reg. 57,870, 57,872 (Nov. 22, 1995).
83. *Id.*
84. *Id.*
85. *Id.*
86. *Id.*
87. *Id.*
88. *Id.* at 57,870-871.
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90. *Id.*
91. *Id.*
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93. "Korea Hyundai Elec Adds Plaintiffs to Rambus Lawsuit," *Reuters*, Oct. 19, 2000.
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95. Muris, *supra* n.4.
96. *Id.*
97. *Id.*
98v*Id.*
99. *Id.*
100. Id.
101. Id.
102. James, supra n.46.
103. Id.
104. Id.
105. Robert A. McTamaney, "Antitrust and Intellectual Property Rights: The Devil is in the Details," 219 N.Y. L.J. 21 (1998).
106. Guidelines, supra n.2, at 5.5.
107. James B. Kobak, Jr., "Intellectual Property, Competition Law and Hidden Choices Between Original and Sequential Innovation," 3 Va. J. L. & Tech. 6, P27 (1998).
108. See Reynolds, supra n.30, at 147.
109. See Joel Klein, "Cross-Licensing and Antitrust Law," Remarks at the Meeting of the American Intellectual Property Law Association (May 2, 1997), available at http://www.usdoj.gov/atr/public/speeches/1123.htm (last visited Aug. 9, 2002).
110. Id. at 17.
111. Id. at 3.
112. This procedure is set out at 28 C.F.R. § 50.6.
113. Letter from Joel Klein to Garrard Beeney (Dec. 16, 1998) (discussing DVD ROM and DVD Video Business Review), available at http://www.usdoj.gov/atr/public/busreview/2121.htm (last visited Aug. 9, 2002).

114. Id.
115. Garrard Beeney, "Pro-Competitive Aspects of Intellectual Property Pools: A Proposal For Safe Harbor Provisions," Submission to the United States Department of Justice Antitrust Division and the Federal Trade Commission, Joint Hearings on Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy, available at http://www.ftc.gov/opp/intellect/ 020417garrardrbeeney.pdf (last visited Sept. 23, 2002).
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117. Id.
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119. Letter from Joel Klein to Carey Ramos (June 10, 1999) (discussing DVD ROM and DVD Video Business Review), available at http://www.usdoj.gov.
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121. Louis Kaplow, "The Patent-Antitrust Intersection: A Reappraisal," 97 Harv. L. Rev. 1813, 1867 (1984).
122. Id. at 1868.
123. Id. at 1860-1861.
124. Guidelines, supra n.2, at 5.5.
125. Id.
126. Id. (citing United States v. Singer Mfg. Co., 374 U.S. 174 (1963)).
127. McTamaney, supra n.105.
128. FTC Report, supra n.4, at 25.
129. Muris, supra n.3.
130. Id.
131. Id.
132. "FTC Recommends Legislative Changes to Hatch-Waxman Act," Press Release, FTC (July 30, 2002), available at http://www.ftc.gov/opa/2002/07/genericdrugstudy.htm.
133. Id.
134. Id.
135. Id.
136. Id.
137. Id.
138. Id.
139. Id.
140. Id.
141. James, supra n.46.
142. Id.
143. Id.
144. Id.
145. Id.
146. FTC Report, supra n.5, at 5-7 and 32-33 with regard to the fact that in fast moving technologies such as computer hardware and software, there is a dense web of overlapping patent thickets, which leads to royalty stacking and increased IP litigation. See also 14-15 and 30 regarding Internet business method patents.
147. "Generic Drug Amendments in Medicare Bill Are Cleared for White House," AIPLA Report, December 4, 2003.
148. Id.
149. Id.
150. Milton Handler, et al., Trade Regulation: Cases and Materials 152 (4th ed. 1997).
151. Muris, supra n.3.
152. See FTC Report, supra n.4.