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FTC Releases Report on Intellectual Property and Antitrust

Last year the FTC and the Department of Justice jointly held hearings focused on the current balance of competition and patent law and policy. (See our December, 2001 *Antitrust and Trade Regulation Bulletin* at www.haledorr.com/antitrust.) The hearings spanned more than 24 days, involving more than 300 panelists and 100 separate written submissions. The first tangible by-product of those sessions came on October 28, 2003, with the release of a 266-page FTC report containing specific recommendations for changes in the existing patent system (the Patent Report)(http://www.ftc.gov/opa/2003/10/creport .htm). A second, joint report with DOJ, containing specific recommendations for antitrust, is promised for the future.

The Patent Report begins with a general discussion of the common aims of both competition and patent law and policy. Competition stimulates innovation by spurring the innovation of new or better products or more efficient processes. Patent policy can also stimulate innovation by rewarding the innovator with a right to exclude others from making, using or selling the invention claimed by the patent. As the FTC sees it, the two systems are not inherently in conflict, but any failure to strike the appropriate balance between them can harm innovation.

Although the Patent Report states that "for the most part" the patent system achieves a proper balance with competition policy, it concludes that in some ways the system is "out of balance." As a result, the report makes a number of specific recommendations for reforming the legal systems, procedures and institutions of the patent system. Most, but not all, of the proposals would require enabling legislation. The FTC's recommendations include the following:

1. Measures should be implemented to reduce the number of invalid patents issued or those that contain claims that are overly broad. These poor quality or questionable patents can cause competitors to forgo R&D in the areas the patent improperly covers, and can increase the practice of "defensive patenting," contribute to the "patent

FTC recommends sweeping changes in the balance between competition and patent law.

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thicket" and create licensing complexities and costs. In order to address this issue, the Patent Report recommends a variety of changes in the existing patent system:

a) The first change would be the introduction of legislation to create a new administrative procedure to allow post-grant review of, and opposition to, patents. This procedure would be designed to allow for meaningful challenges to patent validity short of federal court litigation.

b) The second change would be the enactment of legislation to modify the legal standard governing challenges to the validity of a patent from the present "clear and convincing evidence" to a "preponderance of the evidence." According to the Patent Report, the existing circumstances surrounding the issuance of a patent by the U.S. Patent and Trademark Office (PTO) suggest that an overly strong presumption of a patent's validity is inappropriate.

c) The third recommended change is a general tightening in the legal standards used to evaluate whether an invention is "obvious" or not, in order to better assure that a development is significant enough to merit a patent.

d) Lastly, the Patent Report proposes that the PTO be provided with the funding necessary to address issues of patent quality, and that various PTO procedural rules and regulations be modified to enable it to improve the process of patent issuance.

Many of the FTC's recommendations would result in significant changes to both patent law and practice.

2. Legislation should be enacted to require the publication of all patent applications 18 months after the filing of the application. During the time that otherwise passes between the filing of a patent application and the issuance of a patent, an applicant's competitor could have invested substantially in designing and developing a product and bringing it to market, only to discover, once the patent had finally issued, that it was infringing. Relatively recently, the law was changed to require the publishing of all patent applications except those filed only within the United States. The Patent Report recommends the elimination of this exception to publication, in the interests of increasing business certainty and promoting rational planning.

3. Legislation should be enacted to create intervening or prior user rights to protect parties from infringement allegations that rely on patent claims first introduced in a continuing or other similar patent application. The Patent Report concludes that, if the patent applicant uses procedures such as continuing applications to extend the period of patent prosecution, the potential for anticompetitive hold-up increases. Intervening or prior-user rights should shelter inventors and users that infringe a patent only as a result of claim amendments following a continuation, provided that the sheltered invention was developed and used before the amended claims were published.

4. Legislation should be enacted to require—as a predicate for liability for willful infringement—a patentee to either show actual, written notice of infringement, or to demonstrate that the infringer deliberately copied the patentee's invention, knowing it to be patented. According to the Patent Report, this requirement would allow firms to read patents for their disclosure value and to survey the patent landscape without risking liability for willful infringement.

5. Finally, the FTC promises to take steps to increase communication between the antitrust agencies and the patent institutions. These steps will include filing amicus briefs in important patent cases, asking the PTO Director to reexamine questionable patents that raise competitive concerns and establishing a Liaison Panel between the FTC, the DOJ and the PTO.

Obviously many of these recommendations would result in significant changes to both patent law and practice, affecting a wide variety of industries. Whether Congress shares the FTC's concerns, and is ready to enact major legislation to address those concerns, remains to be seen.

Circuits Disagree over *Per Se* Treatment of Agreements to Settle Patent Infringement Suits

Two United States circuit courts of appeals have reached opposite conclusions regarding the appropriate antitrust analysis to apply to a payment by a patent holder to an alleged infringer in settling patent infringement litigation. First, in June, the Sixth Circuit found such payments (and the settlement agreements incorporating them) to be *per se* illegal under the antitrust laws. *In re Cardizem CD Antitrust Litigation*, No. 00-24836 (6th Cir. June 13, 2003). More recently, the Eleventh Circuit declined to find similar a patent infringement settlement *per se* illegal even though the patent holder paid the alleged infringers and the patent was later held invalid. *Valley Drug Co. v. Geneva Pharma.*, No. 02-12091 (11th Cir. Sept 15, 2003). The Eleventh Circuit acknowledged that its analysis ran contrary to the Sixth Circuit. The split in the circuits on this issue may ultimately invite Supreme Court review.

In the case before the Sixth Circuit, Hoescht Marion Roussel, the manufacturer of the prescription drug Cardizem CD, sued Andrx Pharmaceuticals—then a potential manufacturer of a generic version of that drug—in January 1996, alleging patent infringement. While the litigation was pending, the FDA approved the generic version, allowing it to go to market at the latest in July 1998 and perhaps sooner if the litigation resulted in a finding of non-infringement. Shortly after the FDA decision, the two companies entered an interim agreement by which the branded manufacturer agreed to pay the generic manufacturer $40 million per year, payable quarterly, from July 1998 until the termination of the litigation. In return, the generic manufacturer agreed not to bring its generic product to market even though, under the law, the generic product could have been marketed from that date forward (subject, of course, to damages for infringement if the litigation resulted in a finding of patent infringement).

The litigation finally ended in June 1999 when the FDA approved a reformulated version of the generic drug that the generic manufacturer certified did not infringe the patent at issue. With that approval, the two companies settled the litigation, with the branded manufacturer paying nearly $51 million in additional funds to the generic manufacturer.

> Conflicting court rulings leave significant unresolved questions surrounding the status of patent settlements.

On a motion for partial summary judgment, the district court determined that the interim agreement was an illegal restraint of trade and certified the issue for interlocutory appeal. The Sixth Circuit held that the interim agreement was "a naked horizontal restraint of trade that is *per se* illegal because it is presumed to have the effect of reducing competition in the market for [the branded drug] and its generic equivalents to the detriment of consumers." *In re Cardizem*, No. 00-24836 (6th Cir. June 12, 2003). The court concluded that the agreement was of the type that predictably resulted in antitrust injury because at its core it eliminated competition in the market for the drug.

In so finding, the court refused to accept a characterization of the agreement as an attempt to enforce a patent or to settle litigation. Instead, it saw the agreement as a way for the branded manufacturer to share its monopoly profits with its only potential competitor in an effort to prolong the patent monopoly as long as possible. "[I]t 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 competition by paying the only potential competitor $40 million per year to stay out of the market." *Id.*

The challenged agreement in *Valley Drug* was not significantly different from the one in *Cardizem* in essential respects. In *Valley Drug*, Abbott Laboratories, the branded manufacturer, sued two generic manufacturers—Zenith Goldline Pharmaceuticals and Geneva Pharmaceuticals—for patent infringement as they were pursuing FDA approval for their generic versions of Abbott's pioneer drug, Hytrin. Before the termination of the infringement litigation, Abbott, Zenith and Geneva entered into interim agreements by which the generics agreed not to enter the market and Abbott agreed to make substantial periodic payments. The payments were to be reduced in the event another generic entered the market and were to cease if Abbott ultimately won its patent suit. Abbott, however, lost the patent litigation at the district court level in 1998 and after appeal in 1999. In apparent response to an FTC investigation, the agreements were terminated in August 1999.

Unlike the *Cardizem* court, the *Valley Drug* court determined that the alleged exclusionary aspects of the agreements "are at the heart of the patent right and cannot trigger the *per se* label." *Id*. In reversing a grant of partial summary judgment by the district court, the Eleventh Circuit found that, because the patent gave Abbott the right to exclusively market its drug until 2014, any agreement merely continuing its right to exclusivity did not necessarily impair competition. "If Abbott had a lawful right to exclude competitors, it is not obvious that competition was limited more than that lawful degree by paying potential competitors for their exit." *Valley Drug Co. v. Geneva Pharma.*, No. 02-12091 (11th Cir. Sept 15, 2003).

The fact that Abbott's patent had later been determined to be invalid was of no relevance to the Eleventh Circuit's analysis because the reasonableness of such agreements is to be judged at the time the agreements were entered into. "Exposing settling parties to antitrust liability for the exclusionary effects of a settlement reasonably within the scope of the patent merely because the patent is subsequently declared invalid would undermine the patent incentives." *Id.*

As a result, the case was remanded to the district court to determine the actual competitive effects of the agreements in light of all the circumstances. "To hold that an ostensibly reasonable settlement of patent litigation gives rise to *per se* antitrust liability if it involves any payment by the patentee would obviously chill such settlements, thereby increasing the cost of patent enforcement and decreasing the value of patent protection generally." *Id.*

These two conflicting opinions create considerable uncertainty for parties settling patent infringement suits (or entering into agreements pending the outcome of the litigation) in similar circumstances. They suggest the need for great care in crafting such settlements because both private litigation and government investigations may result.

FTC Clarifies Use of Monetary Remedies in Competition Cases

The FTC recently issued a policy statement on the use of monetary equitable remedies such as disgorgement and restitution in competition cases. While the Commission will continue to rely primarily on traditional, prospective remedies, the statement suggests that disgorgement and restitution will be sought in "exceptional" circumstances. Three factors are identified that will be considered in this determination. First, whether the underlying violation is clear. Second, whether there is a reasonable basis for calculating the amount of the remedial payment. Third, whether other

FTC policy statement says challenged consummated mergers may be subject to disgorgement in "exceptional" circumstances.

remedies available are likely to fail to fully accomplish the purposes of the antitrust laws.

For parties to consummated mergers challenged after closing, for example, this means that the agency may seek not only to dissolve the transaction but also, in "exceptional" circumstances, to have the parties repay profits earned while operating as a merged company. However, as with all such statements of policy, the true import of this pronouncement will not be known until the FTC puts it into practice.

ABA Publishes Updated HSR Manual

The Section of Antitrust Law of the American Bar Association has published the third edition of the Premerger Notification Practice Manual. The manual provides summaries and discussions of both the informal interpretations of the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (HSR or the Act) given by the Premerger Notification Office of the Federal Trade Commission (PNO) and enforcement actions brought by the antitrust agencies related to the Act. Hy David Rubenstein of Hale and Dorr LLP's Antitrust and Trade Regulation Group, formerly an attorney with the PNO, was a member of the working group that developed and edited the third edition.

The Act authorizes the PNO to provide informal, typically oral, interpretations as well as formal written interpretations of HSR issues. Although the PNO has issued only 17 formal written interpretations in the 27 years since the Act was passed, the office has issued thousands of informal oral interpretations. Many of these oral interpretations have been confirmed in written correspondence to the PNO. These written confirmations formed the basis of the first two editions of the manual, published in 1985 and 1991. This third edition of the manual continues to be the most comprehensive published source for such information to date. In addition, the editors of this edition collaborated with the PNO on the preparation of a discussion of other issues that have not been the subject of written confirmation.

Although the manual brings the materials completely up-to-date, incorporating the PNO's latest positions on various issues and adding summaries of interpretations relating to changes that have occurred in the HSR laws since 1991, new rules and interpretations of the Act are constantly occurring. As a result, parties requiring advice on HSR issues should continue to consult with antitrust counsel.

Personnel Changes at Both Antitrust Agencies

Department of Justice

Bruce McDonald recently joined the DOJ and will serve as the deputy assistant attorney general for regulatory matters in the Antitrust Division, overseeing airline, transportation, energy and other regulatory matters. McDonald was formerly in private practice. Robert Kramer, a career attorney with the Division and for many years chief of one of its litigation sections, succeeds Connie Robinson as director of operations.

Deborah Majoras, principal deputy attorney general for Antitrust, recently announced her intention to leave DOJ and is expected to rejoin the private bar next year. Majoras joined the Division in the spring of 2001 and was involved in the General Electric–Honeywell International and Microsoft cases.

Federal Trade Commission

Commissioner Sheila Foster Anthony served on the Commission for nearly six years until her term expired recently. Often a dissenting voice, Commissioner Anthony disagreed with other commissioners in the cruise industry consolidation, and in the PepsiCo–Quaker Oats (Gatorade) and General Mills–Pillsbury merger decisions. Pamela Jones Harbour recently replaced Commissioner

Both the Department of Justice and Federal Trade Commission have experienced numerous personnel changes in recent months.

Anthony. Commissioner Harbour, an independent, has most recently been in private practice and is a former New York assistant first deputy attorney general. Her term extends until September 2009.

Joseph J. Simmons recently resigned his position as the director of the Bureau of Competition. Simmons presided over 60 enforcement actions during his two years at the Commission, including 25 non-merger cases and two challenges to consummated mergers. Susan Creighton has been named the new director of the Bureau of Competition. Creighton has been deputy director since August 2001, when she joined the FTC. She previously clerked for Judge Pamela Ann Rymer in the Central District of California and Associate Justice Sandra Day O'Connor.

Barry Nigro, Ann Malester and Bruce Hoffman all have become deputy directors of the Bureau of Competition. Nigro joins the FTC from private practice. Malester has led one of the merger groups within the FTC for a number of years. Hoffman has been the associate director for regional litigation for the past two years.

David Scheffman resigned his position as director of the Bureau of Economics. Scheffman, who served as director for two years, will return to the private sector as an economic consultant and adjunct professor at Vanderbilt University. Luke Froeb will replace Scheffman. Froeb joins the FTC from the Owen Graduate School of Management at Vanderbilt University. Froeb was previously an economist with the Antitrust Division.

The FTC recently enhanced its intellectual property expertise, evidencing yet more institutional interest in this subject. Armando Irizarry and Thomas Mays joined as counsels for intellectual property. Irizarry comes from Michigan State University, where he was teaching law. Mays joins the Commission from private practice and was previously a patent examiner at the U.S. Patent & Trademark Office.

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