Paper Trail: Working Papers and Recent Scholarship

Editor's Note: *Editor Bill Page comments on two papers that consider the relationship between intellectual property and antitrust as policies to promote innovation. Send suggestions for papers to review to: page@law.ufl.edu or jwoodbury@crai.com.*

—*William H. Page and John R. Woodbury*

Recent Papers

Mark A. Lemley, Industry-Specific Antitrust Policy for Innovation
http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1670197

C. Scott Hemphill & Mark A. Lemley, Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act, forthcoming Antitrust L.J. (2011)
http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1736822

The first of these papers considers the general relationship between intellectual property and antitrust as policies to promote innovation; the second considers a specific instance of that relationship. In the first paper, Mark Lemley argues that the roles of competition and monopoly in the process of innovation differ across industries and that antitrust and intellectual property should take account of the differences to foster innovation more effectively. The paper is a useful introduction to Lemley's extensive scholarship on the intersections between antitrust and IP.

Lemley notes that innovation is far more important than static competition in promoting consumer welfare—few, he observes tellingly, would trade a middle-class life today to be the richest person in the world in 1700. The more difficult question is how best to promote innovation. The old oversimplification that antitrust promotes competition and patent law promotes monopoly, Lemley argues, has been displaced by a new oversimplification that antitrust promotes static efficiency while patent law promotes Schumpeterian or dynamic efficiency.[1] In reality, competition may promote innovation, and monopoly (and the practices of monopolists) may impede it.[2] More generally, monopoly and competition spur innovation to varying degrees depending upon the nature of the industry. Both antitrust and IP recognize these differences within their domains, but antitrust ignores them in defining its relationship to IP. Antitrust, Lemley argues, defers excessively to IP rights in contexts in which competition would enhance innovation.[3]

In the pharmaceutical industry, patent monopolies are appropriate because of the enormous costs of research, development, and regulatory approval. According to Lemley, pharmaceutical

[1] *See* Ward S. Bowman, Jr., Patent and Antitrust Law: A Legal and Economic Appraisal (1973).

[2] *See* Kenneth J. Arrow, *Economic Welfare and the Allocation of Resources for Invention*, *in* National Bureau of Economic Research, The Rate and Direction of Inventive Activity: Economic and Social Factors 609 (1962).

[3] Lemley has argued for this position for years. *See* Mark A. Lemley, *Property, Intellectual Property, and Free Riding*, 83 Tex. L. Rev. 1031 (2005).

production exemplifies Schumpeterian prospect theory,[4] which emphasizes the importance not only of invention but also development and commercialization in the process of innovation. Patents provide necessary incentives for the development of new drugs and tend to cover a complete product without the necessity of ancillary licenses. Moreover, they do not generally block the development of chemically analogous and therapeutically similar drugs. Thus, Lemley suggests, "[p]rospect theory works in the pharmaceutical industry."[5]

It does not work, however, for other industries or products where "R&D cost is small, where the ratio of innovator cost to imitator costs is small, or where first-mover advantages or network effects can provide the needed incentives." Business methods, for example, require little R&D support and provide ample rewards without patent protection. Consequently, Lemley notes, routine patenting of new business methods reduces welfare. Patent protection is also less obviously necessary in software markets. Lemley compares the explosive development of the Internet, which is built on nonproprietary protocols, with the relatively lackluster pace of innovation in communications when AT&T controlled U.S. telephony.

These differences among markets call for different legal policies toward innovation. In a recent book,[6] Lemley and Dan L. Burk have argued that courts should adapt patent law's protections based on the characteristics of the industry. Lemley likewise suggests that antitrust has made some appropriate adaptations. Antitrust enforcement agencies, for example, recognize the importance of detailed understanding of industries by organizing themselves along industry lines. Courts recognize differences among industries both by formulating industry-specific rules, like the platform-software tying standard announced in *Microsoft*, and by adapting general rules, like market definition, to industry characteristics.

Where antitrust fails, Lemley argues, is in deferring to patents regardless of their competitive effects. (*Walker Process* and sham litigation claims, he suggests, are rarely effective.) Antitrust, for example, defers entirely to conditions that a patentee imposes on its licensees. Lemley argues that antitrust should take the lead in industries and circumstances in which competition is necessary for innovation, while deferring when the prospect of monopoly is necessary to induce investment. Most provocatively, Lemley suggests that antitrust should be willing to regulate conduct protected by patents if doing so would better advance innovation:

> Antitrust might, for instance, impose restrictions on patent pools in industries in which we think competition is important, driving competitors to litigate the validity and infringement of patents that would otherwise have been included in the pool. Or it might limit the acquisition of an array of patents that fence off a particular field such as a new business model. It might constrain the ability of patent owners to condition the license of their IP rights on a restriction in other forms of competition. Most radically, it might restrain the enforcement of patent rights themselves where that enforcement will prevent competition.

Interestingly, one of the examples Lemley offers of antitrust's failure to take a leading role in promoting innovation is its deference "to settlements of even 'fatally weak' patent claims" in the pharmaceutical industry. Thus, Lemley argues that antitrust should not necessarily defer to patent rights in industries in which patent protection is necessary. Even in industries like pharmaceuticals, exclusive rights can be excessive and actually impede innovation.

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[4] *See* Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & Econ. 265, 266 (1977).

[5] *See also* Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 Va. L. Rev. 1575, 1615–30 (2003).

[6] Dan L. Burk & Mark Lemley, The Patent Crisis and How the Courts Can Solve It (2009).

Lemley and Scott Hemphill of Columbia Law School make this point in more detail in the second paper, which proposes an amendment to the Hatch-Waxman Act in order to correct what Lemley views as the failure of antitrust to set appropriate limits on the settlement of patent disputes. The Hatch-Waxman Act confers 180 days of market exclusivity to the first manufacturer to file an "Abbreviated New Drug Application" (ANDA) for FDA approval of a "bioequivalent" generic drug in the market for a patented drug. The idea behind this feature of the law is to encourage generic entry and consequent challenges to weak pharmaceutical patents. If the courts decide that the patent is valid and infringed, the generic entrant loses its exclusivity. Lemley and Hemphill argue that this mechanism "isn't working" because the patent holders regularly pay the first entrants to drop their challenges. After a settlement, the potentially invalid or weak patent remains. As the courts have interpreted the law,[7] however, the entrant keeps its 180-day exclusivity, which may account for upwards of half of the entrant's profit on the drug, because the entrants charge consumers only slightly less than the branded drug's monopoly price during this period. The settlement may also include a provision paying the challenger to delay entry. The framework of incentives, as Lemley and Hemphill show, strongly encourages settlements that harm consumers.

The settlements that keep out generic entrants, particularly those that involve payments to delay entry, have spawned numerous antitrust challenges. An enormous scholarly literature considers how antitrust law should treat these arrangements. According to Lemley and Hemphill, however, the antitrust approach has failed to reduce the frequency of anticompetitive deals. The authors support their argument by presenting the results of a study of all 49 drugs that received exclusivity awards during 2005-2009. Almost half of the entrants faced no suit at all; 10 were sued and settled, but without opening markets to competition. Only 9 entrants actually won a patent infringement suit. The authors also check the timing of entry after the exclusivity period ended and conclude that exclusivity does indeed delay subsequent generic entry.

Consequently, Lemley and Hemphill propose that Congress amend Hatch-Waxman to confer the "mini-patent" of exclusivity only if the generic entrant "earns it" by proving either that an incumbent patent is invalid or that the generic entrant's drug does not infringe the patent. The generic entrant would forfeit exclusivity by settling an infringement case in a way that does not permit immediate generic entry. Somewhat reluctantly, the authors would permit the entrant to retain exclusivity if the branded drug manufacturer never sues for infringement. The authors recognize that an "earned exclusivity" rule will deter some generic challenges that would otherwise be brought. But it would do so mainly by removing the perverse incentive the present regime creates to file challenges automatically in hopes of being bought off. ●

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[7] *See, e.g.*, Mova Pharm. Corp. v. Shalala, 955 F. Supp. 128, 130 (D.D.C. 1997), *aff'd*, 140 F.3d 1060 (D.C. Cir. 1998).