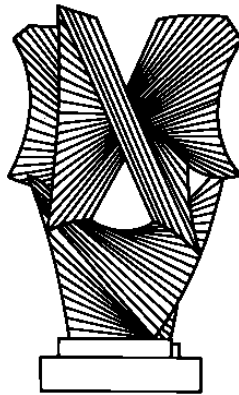


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Navigating the Anticommons for Pharmaceutical Patents: Steady the Course on Hatch-Waxman

Richard A. Epstein and Bruce N. Kuhlik

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Navigating the Anticommons for Pharmaceutical Patents: Steady the Course on Hatch-Waxman

Richard A. Epstein* & Bruce N. Kuhlik**

Six years ago in *Science*, Michael Heller and Rebecca Eisenberg asked the disarmingly simple question whether patent protection could deter biomedical research.¹ They treated patent protection as a two-edged sword. Happily, patents spur innovation by securing to inventors the fruits of their labors. Unhappily, patents also create a vast thicket that gives each patent holder a potential veto right over the innovations of others. This last risk they dubbed the tragedy of the anticommons, which results when property rights are too strong instead of too weak, as in the traditional tragedy of the commons.² The problem is that too many people are in a position to exercise a veto right over some productive venture. The extent of the anticommons is highly disputed with respect to intellectual property. But it rises, without question in other contexts. One notable example occurs when the output of two sequential monopolists (like toll stations operated by rival princes along the river) sharply reduces traffic along the river, thereby reducing social welfare by reducing profits for the toll operators and travelers along the river.³ Their clear implication for patent law is that inventive activity could be reduced as well,

*James Parker Hall Distinguished Service Professor of Law, The University of Chicago and Peter and Kirsten Bedford Senior Fellow, The Hoover Institution. Mr. Epstein has worked extensively with PhRMA on various patent issues, including those discussed in this article.

**Senior Vice President and General Counsel, Pharmaceutical Research and Manufacturers of America. The views expressed are solely those of the authors.

¹Michael A. Heller & Rebecca S. Eisenberg, Can Patents Deter Innovation? The Anticommons in Biomedical Research, 280 *Science* 698 (1998)

²Garrett Hardin, Tragedy of the Commons, 162 *Science* 1243 (1968).

³See, James Buchanan & Yong J. Yoon, Symmetric Tragedies: Commons and Anticommons, 43 *J. Law & Econ.* 1 (2000)..

as the blocking power of patents stymies innovation by product users. As with the waterways, the total value of the resources under patents (if not the number of patents themselves) should diminish as productive avenues for research cannot be pursued by individuals are cut off from the nourishment that their own inventive efforts obtain from a rich public domain. The pursuit of private gain leads to a loss of social welfare.

Heller and Eisenberg supplied little, if any, empirical evidence for their assertion that the patent blockade dominates patent innovation. Even so, we have witnessed a persistent hue and cry for the weakening of patent protection. Just recently, the Needham Commission Report for the Royal Society decried the expansion of patent activities within university. Closer to home, Congress and the Food and Drug Administration have heeded strong calls for weakening the patent protection supplied under the Hatch-Waxman Amendments to the basic patent and food and drug laws,⁴ which govern the relationship between holders of pharmaceutical patents and their eventual generic competitors.

We think that Heller and Eisenberg have overstated the case against patent protection at both the theoretical and empirical level. The number of patents filed in recent years has continued to move sharply upward across the board. We see no reason to believe that the sole or dominant purpose for individuals is to block innovations by others. Patents themselves are expensive to acquire. The inventor only makes income to the extent that it can assign, license or sell the patent in question. Any patent that created a blockade without revenue would provide a service to holders of existing patents, mainly to *other* individuals. If in fact the return to new inventions had turned downward as

⁴Drug Price Competition and Patent Term Restoration Act (Public Law 98-417, 98 Stat. 1585 (1984), codified at 21 U.S.C. § 355 and 35 U.S.C. 156 & 271,.

Eisenberg and Heller suppose, then we should expect to a decline in the levels of research and development, the value of new patented materials, or the number of patents filed and granted. Yet there is little evidence that this has taken place, and none that would assign any of that supposed decline to the creation of an anticommons, as opposed to the general insecurity that could arise from a fear that the current intellectual and political climate will undermine the present levels of patent protection.

One reason why the Heller and Eisenberg model fails is that it is based, we believe, on a set of faulty analogies. Above we instanced the blocking power that exists whenever multiple owners control different segments of a river. In that instance, nature supplies an effective barrier against any form of innovation that could offer new routes to travel along the river. It is only when the railroads and highways are built that technological circumvention is possible, and even here, the possibility remains that the same political forces that block the effective utilization of the river will also disrupt any alternative modes of transportation that have to pass through multiple sovereign jurisdictions. There is a natural rigidity here that has no parallel in the rapidly moving world of biomedical research.

Within the American framework, for example, the great institutional achievement of the “dormant” commerce clause jurisprudence is that it provided a judicial counterweight to this form of favoritism. To be sure, the commerce clause itself (Congress has the power to regulate commerce . . . among the several states,”) does not in any obvious sense impose a limitation on the power of states to regulate transportation and communication that cuts across state lines. But the Supreme Court’s early willingness to find an implicit negative predicate to that grant of power—states cannot

discriminate against out of state commerce without an explicit blessing from Congress—made it very difficult for states to favor local businesses at the expense of outsiders and thus effectively countered the tendency of states to stop traffic at the border. With a few exceptions, this open access system has held firm. The common sovereign over the local territories provides the antidote to the dangers of blockade. The institutional setting must be taken into account before conceding the power of the analogy.

The same conclusion applies with even greater force to the examples that Heller relied on in his original article on the now-fabled Anticommons.⁵ That article started with the observation that the socialist system in place in the Soviet Union had all sorts of empty storefronts, as merchants set up informal stands on the sidewalks. It rightly attributed the utter lack of economic activity to the veto power that different branches of Soviet government could exercise through their permit power. But permits and patents differ in many important particulars. The permit power requires an individual to get permission for some activity from a state bureaucrat. But the state bureaucrat is not the owner of any asset whose value will remain unlocked unless he brings it to market. Whether some activity goes forward or not may make an enormous difference to the power of that office, but often in perverse ways. The greater the level of supervision, the larger the credible demands for expanded budget allocations. The stronger the holdup potential of the office, then the greater the willingness of individuals to bribe. But the more permits that are needed to open any individual business, the less any individual bribe will achieve, so that in the end the rational result may well be to shutter windows and lock doors altogether except for the would-be entrant with high-level political clout

⁵Michael A. Heller, *The Tragedy of the Anticommons: Property in the Transition from Marx to Markets*, 111 Harv. L. Rev. 621 (1998).

that allows him to circumvent the permit process altogether. There is indeed an enormous difference between a permit thicket through which all entrepreneurs must pass and the traditional judicial system of injunctive relief that provides in effect that some neighbor can stop activities that either cause harm or hold out the threat of imminent harm, to his own property.⁶

The patent system, however, differs from the permit system that prompted Heller's original investigation. The holder of a patent has the intention to make money from its utilization. The refusal to deal in any individual case is not the source of additional political power; nor a source of additional claims from public revenue. It is the loss of opportunity. In addition, the patent is always a wasting asset. Not only is it limited in time, but even during the period of its unquestioned validity, its holder faces the possibility that new patents, old patents that have expired, new techniques that come into the public domain, will all erode its dominance. Those who do not deal will not prosper, so that the entire culture works in ways that encourage various forms of cooperation. Precisely because any patent holder can legitimately claim a share of the profits from a cooperative venture, the patent system differs decisively from the permit system, with its evident pathologies.

We think our view of the patent system is borne out by the empirical evidence. We have already noted the high velocity of transactions in cultures that are dominated by entrepreneurs. That same result is confirmed in connection with research tools in a recent study a recent study,⁷ briefly summarized in *Science*.⁸ Walsh, Arora and Cohen surveyed

⁶Richard A Epstein, *The Permit Power Meets the Constitution*, 81 *Iowa L. Rev.* 407 (1995).

⁷John P. Walsh, Ashish Arora, and Wesley M. Cohen, *Research Tool Patenting and Licensing and Biomedical Innovation*

⁸J.P Walsh, A. Arora, W.M. Cohen, *Science* 299: 1021 (2003),

70 attorneys, scientists and managers in the pharmaceutical and biotech industries to detect evidence of the patent blockade. Almost none of the recipients thought that the current legal patent regime had posed insurmountable obstacles that prevented the effective use of research tools. Instead they noted that both in industry and universities, researchers had adopted strategies of “licensing, inventing around patents, going offshore, the development and use of public databases and research tools, court challenges and simply using the technology without a license (i.e. infringement) to achieve their particular goals.”⁹ In principle, we have to have some licensing of new inventions for otherwise they would not be patented at all. Any blockade therefore is undermined pro tanto by this activity. Inventing around a current patent need not, moreover, be regarded as a wasteful activity for it will expand the options available to others whether that invention is patented or put into the public domain. The legal monopolies created by patents do not necessarily translate into economic blockades. Patent proliferation could easily provide alternative stepping-stones to new production, creating perhaps Cournot duopolies with lower prices across the board.¹⁰ Or a new family of anti-inflammatory drugs could compete with an old one, as happens with Celebrex® and Vioxx®. The rapid development of new inventions with limited term protection, moreover, only hastens the time at which technology falls into the public domain. Even patent infringement should not necessarily be regarded as dangerous in this context, for most patent holders reported “tolerating” academic research in the hopes that it would increase the commercial market for their products.¹¹ The situation is far from elegant, but

⁹Id

¹⁰See, e.g. Robert Gibbons, Game Theory for Applied Economists 14-21 (1992).

¹¹Walsh et al.

it surely seems preferable to a wholesale revision of the patent laws to take into account a hypothetical set of risks.¹²

Nonetheless, the predisposition to treat the blockade problem as paramount has exerted a disproportionate influence on government agencies. For example, the Federal Trade Commission recently issued a report that accepted the possibility of an anticommons relating to biotechnology patents, despite the survey evidence from Walsh even though the testimony before the Commission from specialists in the field took the position that licensing activity minimizes this problem in practical terms: “One panelist observed: ‘licensors tend to be ‘fairly sensitive’ to the implications of royalty-stacking for product commercialization. If the licensor . . . is about to propose a royalty that’s going to kill the product, [the licensor] is not going to make any money. And most of the players in this field are sophisticated enough to understand that,’¹³ In the face of this evidence, the FTC still speculated that “[b]iotechnology patents might harm follow-on innovation through the creation of an anticommons and by restricting access to inventions.”¹⁴

The specter of the anticommons looms large if one imagines that each patent operates in a stand-alone fashion. But in most instances, an aggressive program of patent pooling seriously changes the overall landscape. Many patents, moreover, do not operate in stand-alone fashion, but are pooled with other patents. First the original patent inventor assigns his patent to his employer. Next that firm takes its patent portfolio and enters into various cross-licensing and pooling agreements with other firms which effectively overcomes much of the blockade effects, subject to antitrust concerns, which can be

¹²FTC, “To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy” (Oct. 2003).

¹³*Id.* at 25.

¹⁴*Id.* at 29.

independently addressed. In addition, there is a strong self-help mechanism available to overcome the holdout question. For example, a single producer, Merck & Co., has sought to place express sequence tags in the public domain so as to preclude their receiving patent protection by others. Its own rationale is that pharmaceutical companies are in the business of selling treatment, not tags. We think that all these developments, taken together, strongly support the position of Robert Merges¹⁵ that strong property right protection—as opposed to the compulsory licensing schemes advocated by others, or no patent protection at all—should remain the dominant approach in patent law.

The debate over the nature and scope of patent protection has taken on special urgency in connection with pharmaceutical products. Industry estimates place the cost of bringing a successful new drug to market at around \$800 million per drug, including the cost of "dry holes," with a 12 to 15 year period of gestation.¹⁶ Yet the *marginal* cost of another pill is often tiny by comparison. Once the prescription drug goes off patent, its price as a generic plummets because the new entrants do not have to amortize the initial costs of R&D over the life of the drug. The high-initial but low marginal costs of drug development leave many groups clamoring to hasten the introduction of low-cost generics. Right now the rates of return for pharmaceutical firms have been high, but these reflect the riskiness of the venture given the free entry into the industry, and, some would argue, the implicit protection against competition supplied by the stringent set of nonnegotiable FDA licensing requirements. Moreover, market capitalizations have fallen in recent years in part because of the looming uncertainty as to the future protection of

¹⁵Robert P. Merges, Contracting into Liability Rules: Intellectual Property Rights and Collective Rights Organizations, 84 Cal. L. Rev. 1293 (1996),

¹⁶Joseph A. DiMasi, "Tufts Center for the Study of Drug Development Pegs Cost of a New Prescription Medicine at \$802 Million," press release, Tufts University, Nov. 30, 2001.

patents. Any call for short-term relief will surely lead to a massive contraction of private capital, well below today's \$33 billion earmarked domestically for new industry research, leaving few new drugs for future generic sales.¹⁷

The key policy question recently addressed by Congress and the FDA is whether to maintain the basic structure under Hatch-Waxman. That Act has a number of key features. First, it extends the length of a patent to partially offset the reduction in patent useful length for the pre-approval clinical trials required by the FDA: one day is restored to a patent for each two days consumed in the clinical study process and for each day consumed by FDA review of the new drug application, up to a maximum of five years, so long as the total useful patent life does not exceed 14 years. That restoration of course comes at the *end* of the patent period, where its present value is far lower than the early years that are lost, even if we ignore the potential depreciation in product value. Given this restoration period, moreover, effective patent lives in the pharmaceutical industry typically run only 6-9 years, as compared with more than 18 in other industries.¹⁸

Second, Hatch-Waxman simplifies and expedites the process for developing and approving generic copies of innovator drugs in several respects. It takes away innovator patent rights by creating a special exemption under the patent law, which permits the generic firm to manufacture and test its drug during the incumbent's patent period. It also strips innovators of the exclusive and perpetual rights to their data on safety and effectiveness. In its stead they receive only limited exclusivity periods of five years for new chemical entities and three years for other approvals. Further, Hatch-Waxman

¹⁷See, James W. Hughes, Michael J. Moore, & Edward A. Snyder, "'Napsterizing' Pharmaceuticals: Access, Innovation, and Consumer Welfare (mss. June 12, 2002).

¹⁸Stephen A. Stack, Jr., "Afterword: Some Further Observations on the 'Pharmaceutical Wars,'" 71 Antitrust L.J. 705, 706-707 & notes 8-11 (2003). Henry Grabowski & John Vernon, "Returns to R&D on New Drug Introductions in the 1980s," 13 J. Health Econ. (1994).

greatly simplifies the data requirements for generic drug applicants, substituting a simple bioequivalence test for the exhaustive safety and effectiveness testing required of the innovator. These provisions speed the entry of generic drugs at the back end of the patent period. For the most part this system has proceeded smoothly, with generic drug market share rising from less than 20 percent of prescriptions before Hatch-Waxman to almost 50 percent today.¹⁹ The Federal Trade Commission, after an exhaustive survey, identified a small number of what it regarded as dubious strategies intended to expand the scope of patent protection—late registrations, registration of patents of dubious validity and the like. At most these strategies can provide protection for the patent improvement, but not for the original product that has gone off patent. And whatever the dramatic tales in individual cases, litigation is the exception and not the norm. In the vast majority of cases—approximately 95 percent of the time—generics are content to wait until patent expiration to begin commercial sales.²⁰ And in most cases a 30 month automatic stay (if that patent and litigation run that long) permits the holder of the current patent to protect against infringement before its market is destroyed.

In response to the alleged abuses under current law, the FDA has recently issued regulations to limit the holder of any patent to a single 30-month period under Hatch-Waxman,²¹ and Congress made changes in the statute to accomplish the same result.²²

¹⁹IMS Health, National Prescription Audit Plus™, 2001.

²⁰Letter from Robert D. Bajefsky to Russel A. Bantham, (Executive Vice President PhRMA), June 5, 2001, on file with the authors.

²¹68 Fed. Reg. 36676 (June 18, 2003) (amending 21 C.F.R. sec. 314.95). The regulations also clarify the requirements for listing patents in the FDA Orange Book, which is a prerequisite to eligibility for the 30-month stay.

²²Pub. L. No. 108-173, §1101 (Dec. 8, 2003). The statute provides that only patents listed with FDA before the generic files its application will be eligible for the 30-month stay. As a practical matter, this will usually mean that there is only one stay, but in some cases a second stay will be available based on the timing of the generic's challenges to the eligible patents. The new law supersedes FDA's regulations and

This change in Hatch-Waxman is said to be justified by the fear that patent holders will string together several weak patents to keep generics out of the marketplace beyond the initial patent period. But this rationale is flawed for a number of reasons. First, the basic patent system denies any patent for new inventions that do not constitute a nonobvious advance over the prior art.²³ Second, even if such small advances did run the patent gauntlet, they will by definition provide only limited protection for any patent holder. On expiration of the original patent, the generic need only market the older product at a small price discount to offset the supposedly trivial improvements from the new patent. Alternatively, if a single valuable product is protected by multiple patents, that combination should not obtain generic status when the first of its ingredients does. What Senator Hatch said in 1984 remains true today: "The public receives the best of both worlds—cheaper drugs today and better drugs tomorrow."²⁴

A broader set of legislative initiative had threatened to undermine this long-term stable compromise. In July 2002, the Senate passed S. 812, The Greater Access to Affordable Pharmaceuticals Act of 2001. We believe that S. 812 was ill-advised on a number of fronts. First, the Reid Amendment to S. 812, for example, proposed to make unlawful for any manufacturer to discriminate against any pharmacist or purchaser of prescription drugs.²⁵ In addition, the bill would have set that single nondiscriminatory price for the drug at the *lowest* price charged to any nonhumanitarian and noncharitable organization, domestic or foreign. With one stroke, this bill would have eliminated

provides a technically superior approach in any event (since FDA was bound by the prior statutory terms, which it and others had consistently interpreted to allow for multiple stays).

²³See 35 U.S.C. sec. 103.

²⁴Congressional Record—Senate at 23764 (August 10, 1984).

²⁵S. 812, Section 804(i)(1). Price discrimination by single producers without collusion was held legal in *Brand Name Prescription Drug Litigation*, 186 F.3d 781, 786-789 (7th Cir. 1999).

virtually all the pecuniary benefits that patents supply to their owners. Price discrimination is always greeted with public unease, but in this case it is justified by the long-term social benefits it provides. Only price discrimination by the patent holder allows it to reach potential consumers who are able to pay the competitive but not the monopoly price for the drug. The higher prices paid by high-demanders increase the returns from the patent and thus spur new invention. Setting *any* single price will cut some consumers out of the market while reducing the level of product innovation. Setting that unitary price at the lowest commercial price, domestic or foreign, not only places domestic policy at the mercy of foreign governments, but also threatens economic ruin if firms must sell huge quantities of the patented product at, or perhaps below, marginal cost. In effect, the Reid Amendment makes a patent holder behave like generic manufacturer. Such drastic limitations on price operate as a de facto repeal of the original patent, which should, one hopes, expose the Amendment to a constitutional challenge for a taking of patent rights without just compensation.²⁶

Second, the Stabenow Amendment would authorize any state to extend the minimum 15 percent and "best price" rebate now allowed the Medicaid program²⁷ to any drug purchaser selected by the state—a practice whose legality was reviewed by the Supreme Court, but only in the context of a preliminary injunction.²⁸ But its wisdom is highly questionable. The entire market will be thrown out of whack if the rebates are extended beyond Medicaid, for now the drug company will be forced to settle for lower

²⁶See, *Ruckelshaus v. Monsanto, Inc.*, 467 U.S. 986 (1984).

²⁷See 42 U.S.C. sec. 1396r-8.

²⁸*Pharmaceutical Research & Manufacturers of America v. Walsh*, 538 U.S. 644 (2003), upholding the circuit court's reversal of a preliminary injunction against implementation of a Maine Statute, 2000 Me. Legis. Ch. 786 (S.P. 1026 (L.D. 2599) "An Act to Establish Fairer Pricing for Prescription Drugs." The Court's opinions do not preclude a subsequent challenge based on further factual development, but the state has changed the statute and the further course of proceedings is not clear at this point.

revenues than it could have collected through market-based pricing even in the absence of Medicaid. In cases where the Medicaid subsidy is no longer in play, no system of patent protection is worth its salt if it can be defeated by a clever system of price controls. Indeed even if some nominal subsidy is provided by the states, the restrictions on pricing should never be raised to the point where they reduce the returns from the patent monopoly, lest an ounce of subsidy be used to authorize a pound of compensation.

Third, S. 812 proposed very short registration and limitation periods for patents on new and established drugs. In principle registration performs useful social functions by allowing all new entrants in the field to know the level of patent protection afforded to current drugs. That system can only operate if the party who fails to give notice through registration must forfeit its statutory protection. For that reason these systems have long been sustained against challenges that they take property without just compensation, even when they require, as here the reregistration of existing interests. Hatch-Waxman already achieves this purpose by depriving patent holders of the critical 30-month stay protection on patents that have not been timely registered through listing with FDA. But the registration of patents contemplated under S. 812 was no routine ministerial affair, for the required filings must be made on a claim by claim basis within 30 days with no grace period. Failure to register correctly under S. 812 would not simply bar the 30-month stay but cut off the right to enforce the patent altogether. Similarly, its 45-day statute of limitations period for bringing infringement claims under Hatch-Waxman serves no purpose other than to destroy these claims without any trial at all. Longer statutes of

limitations dealing with easier subject matter have been struck down for failing to allow "a sufficient opportunity to vindicate a claim."²⁹

Conclusion Biomedical innovation is always at political risk because firms must risk huge amounts of capital today that they can only recover with tomorrow's sales. Without ample patent protection, no combination of first mover advantages or altruism will generate the capital sums needed. Reducing the patentees' right to exclude or its power to price counts as a partial repeal of the patent grant with mischievous social consequences. A direct frontal assault on the patent system generates little support given the social demand for innovation. But indirect attacks on the patent system could escape widespread social condemnation while eroding the protection that the patent system can supply its holders. It is therefore critical that we recognize that the past successes in biomedical innovation arise because the gains from innovation exceed any small dislocations from the so-called anticommons. Whatever one thinks of the recent changes to Hatch-Waxman, the legal institutions now in place are not in need of any major repair.³⁰ But new fronts are constantly emerging, and these institutions must be held firm against the multiple attacks on their integrity.

²⁹*Lamb v. Powder River Live Stock Co.*, 132 F. 434 (8th Cir 1904). The Hatch-Waxman amendments recently passed by Congress do not include these other objectionable provisions from S. 812. The 30-month stay provision as passed is better than what was in S. 812 because more patents are eligible for the stay under the new law. The new law also includes other changes in Hatch-Waxman, most notably in the operation of the 180-day exclusivity provision intended as an incentive to generics to challenge patents.

³⁰The generic industry's trade association, the Generic Pharmaceutical Association, supported the recent law and stated that it was sufficient to address the alleged abuses that had been identified and to speed generics to market. See http://www.prnewswire.com/cgi-bin/micro_stories.pl?ACCT=913120&TICK=GPHA&STORY=/www/story/11-25-2003/0002065158&EDATE=Nov+25,+2003.

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Richard A. Epstein
University of Chicago Law School
1111 East 60th Street
Chicago, IL 60637
repstein@uchicago.edu

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