

*Patent holders have a strong interest in profiting from their patents.*

# Is There a Biomedical Anticommons?

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SIX YEARS AGO IN SCIENCE, MICHAEL HELLER and Rebecca Eisenberg asked the disarmingly simple question whether patent protection could deter biomedical research. They treated patent protection as a two-edged sword: Happily, it spurs innovation by securing to inventors the fruits of their labors but, unhappily, it also creates a vast thicket that gives each patent holder a potential veto right over the innovations of others. They dubbed that potentially dangerous veto right “the tragedy of the anticommons.” According to Heller and Eisenberg, that tragedy occurs when property rights are too strong and too many people can block some productive venture.

The extent of the anticommons is highly disputed with respect to intellectual property. But, without question, it arises in other contexts. One notable example is sequential monopolists, e.g., toll stations on a river that are operated by rival princes. Because of the multiple tolling, traffic along the river would be sharply reduced, thereby decreasing social welfare by reducing profits for the toll operators and travelers alike.

Heller and Eisenberg’s clear implication for patent law is that inventive activity could be reduced as well, 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 who 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. In the United Kingdom, the recent 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 heard calls for weakening the patent protection supplied under the Hatch-Waxman Amendments to the basic patent and food and drug laws, which govern the relationship between holders of pharmaceutical patents and their eventual generic competitors.

## FAULTY ANALOGIES

We think that Heller and Eisenberg have overstated the case against patent protection at both the theoretical and empirical levels. 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 individual patentees 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 creates a blockade

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without revenue would provide a service to holders of existing patents — mainly to inventors and innovators other than the blockader. If, in fact, the return to new inventions has turned downward as Eisenberg and Heller suppose, then we should expect 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 the supposed decline to the creation of an anticommons.

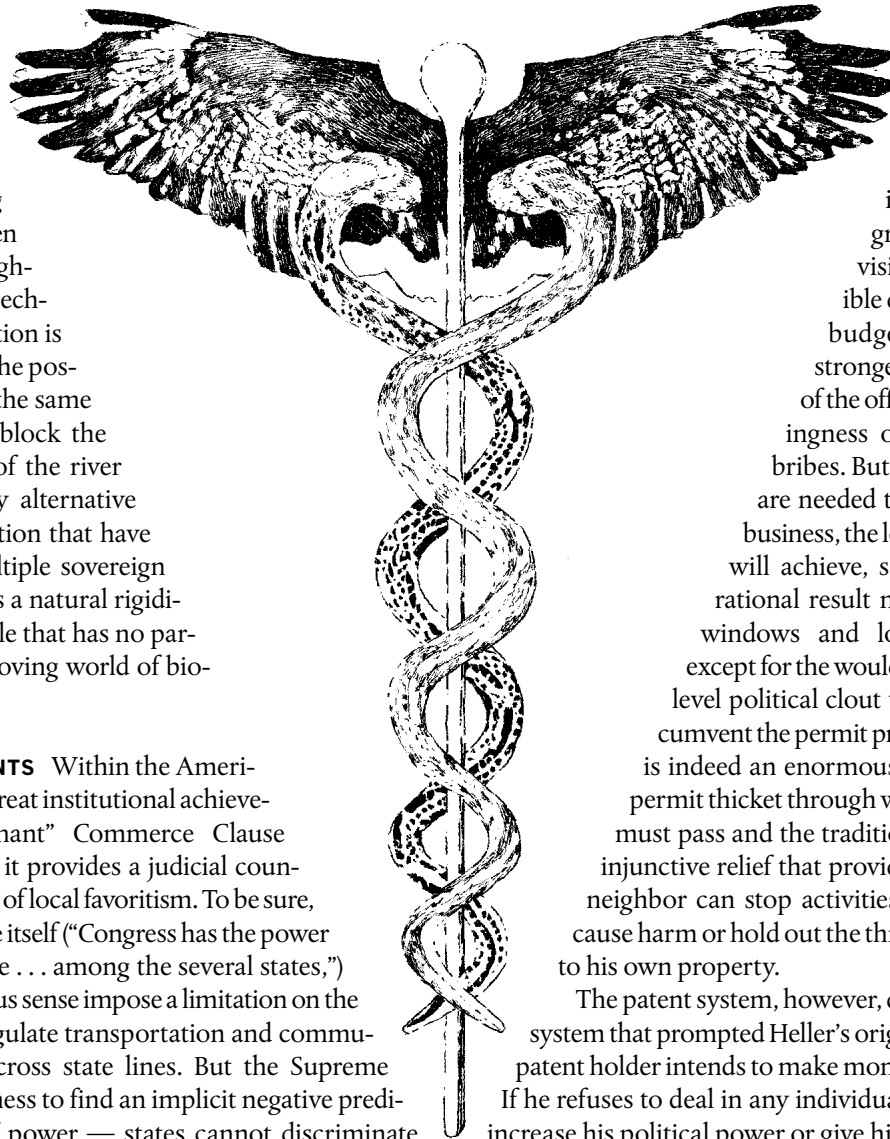
One reason why the Heller and Eisenberg model fails is that it is based, we believe, on a set of faulty analogies. Above, we instantiated the blocking power that exists whenever multiple owners control different segments of a river. In that instance, nature supplies an effective barrier against any form 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. Even then, 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 to the river example that has no parallel in the rapidly moving world of biomedical research.

**PERMITS AND PATENTS** Within the American framework, the great institutional achievement of the “dormant” Commerce Clause jurisprudence is that it provides a judicial counterweight to this form of local 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. 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.

Permits and patents differ, however, 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, the greater the willingness of individuals to offer bribes. 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 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 presently cause harm or hold out the threat of imminent harm to his own property.

The patent system, however, differs from the permit system that prompted Heller’s original investigation. The patent holder intends to make money from its utilization. If he refuses to deal in any individual case, that would not increase his political power or give him additional claims to public revenue. Refusing to deal is a 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, and new techniques that come into the public domain will all erode its dominance. Those who do not deal will not prosper, so the entire culture works in ways that encourage various forms of prompt 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 a recent study by John P. Walsh, Ashish Arora, and Wesley M. Cohen that was briefly summarized in a recent issue of *Science*. The authors surveyed 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 posed insurmountable obstacles that prevent the effective use of research tools. Instead, they noted that researchers both in industry and universities 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.”

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 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. Or a new family of anti-inflammatory drugs could compete with an old one, as happens with Celebrex and Vioxx. “Me-too” drugs are often criticized, but only by those who overlook their virtues; expanded choice leads to higher quality and lower costs simultaneously. 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. And proper application of the requirements for patentability should guard against unearned and unwarranted removal of wide swaths of research leads from the public domain prior to any effective commercialization. The situation is far from elegant, but it surely seems preferable to a wholesale revision of the patent laws to take into account a hypothetical set of risks.

**FEDERAL ACTION** 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 and testimony before the FTC that licensing activity minimizes this problem in practical terms.

The specter of the anticommons looms large if one imag-

ines 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 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. 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. Merck’s rationale is that pharmaceutical companies are in the business of selling treatment, not tags. We think that all those developments, taken together, strongly support the position of Robert Merges 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.

## DRUG PATENTS

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 to \$1.7 billion per drug, including the cost of “dry holes,” with a 12–15 year period of gestation. 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 research and development 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 those 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 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.

## HATCH-WAXMAN

The key policy question recently addressed by Congress and the FDA is whether to maintain the basic structure under the 1984 Hatch-Waxman Act. The act has a number of key features. First, it extended the length of a patent to partially offset the time lost when the drug is under patent but is going through FDA-mandated pre-approval clinical trials. 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. It should be kept in

mind that the restored time, in a sense, comes at the end of the patent period when its present value is far lower than the early years that are lost, even if we ignore the potential depreciation in product value. Effective patent lives in the pharmaceutical industry typically run only six to nine years, as compared with more than 18 years in other industries.

Second, Hatch-Waxman simplified and expedited the process for developing and approving generic copies of innovator drugs. It took away innovator patent rights by permitting the generic firm to manufacture and test its drug during the incumbent's patent period. It also stripped innovators of the exclusive and perpetual rights to their data on safety and effec-

But that rationale is flawed for a number of reasons. First, the basic patent system denies any patent for new inventions that are not "novel" (i.e., they must not be anticipated by the prior art). Second, even if such small advances did run the patent gauntlet, they would 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 Sen. Orrin Hatch (R-Utah) said about his co-

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tiveness; instead, they receive only limited exclusivity periods of five years for new chemical entities and three years for other approvals. Further, Hatch-Waxman greatly simplified the data requirements for generic drug applicants, substituting a simple bioequivalence test for the exhaustive safety and effectiveness testing required of the innovator.

Those provisions have increased 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.

**MISCHIEF** The FTC, 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, the 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 (although recent trends point toward more patent challenges). And in most cases, a 30-month automatic stay (but only if the 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 recently issued regulations to limit the holder of any patent to a single 30-month period under Hatch-Waxman, and Congress made changes in the statute to accomplish the same result. Those efforts are 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.

sponsored bill in 1984 remains true today: "The public receives the best of both worlds — cheaper drugs today and better drugs tomorrow."

**ATTACKS** A broad set of legislative initiatives now threatens to undermine this long-term, stable compromise. In July 2002, the Senate passed S. 812, The Greater Access to Affordable Pharmaceuticals Act of 2001. One key amendment to that act offered by Sen. Henry Reid (D-Nev.) proposed to make it unlawful for any manufacturer to price-discriminate against any pharmacist or purchaser of prescription drugs. The proposal would have set the single nondiscriminatory price for the drug at the lowest price charged to any non-humanitarian and non-charitable organization, domestic or foreign. With one stroke, the bill would have eliminated virtually all the pecuniary benefits that patents supply to their owners, including the revenue needed to produce that all-critical first pill.

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 could not otherwise pay 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 a single price would 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, would not only place 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 would have made a patent holder behave like a generic manufacturer. Such drastic limitations on price operate as a de facto repeal of the original patent.

The specter of price regulation is present again today in the

form of S. 2328, The Pharmaceutical Market Access and Drug Safety Act of 2004, which is yet another ill-thought out response to the misunderstood problem of price discrimination in pharmaceutical products. As is now well known, many Americans have taken to purchasing their drug products abroad from nations, such as Canada, that place strict government limitations on the prices that may be charged for sales in the domestic market. So long as they can recover at least their variable costs, American manufacturers typically accede to those demands rather than lose their foreign markets altogether. But some reportedly have sought unilaterally to restrict the supplies sold in order to reduce the likelihood of illegal and potentially unsafe resales into the United States that would undercut their domestic markets.

Spurred on by the large political discontent, S. 2328 seeks to prevent pharmaceutical companies from taking any self-help measures against importation of their own products by a three-part coercive regime that introduces by indirection a novel scheme of price controls into the United States. Ironically, this mischief is done under the banner of "free trade." First, S. 2328 requires under penalty of treble damages under a new provision of the Clayton Act that all American pharmaceutical companies sell to approved distributors in foreign countries in whatever quantities they demand at a price equal to that which the product is sold in those countries for their own local consumption. Second, the quantities can then be resold in the United States at whatever price the market will bear, free of all liability for patent infringement. Third, the original manufacturers are required at their own expense to seek FDA approval for the domestic sale of competitive products if they are sold in dosages or forms that are not currently approved for usage in the United States.

This triple-whammy combines the worst features of a system of domestic price controls with additional threats to public health and private enterprise. In order to restrain prices, S. 2328 extends the line of supply, which both adds costs and, more importantly, poses threat to drug purity and safety. In addition, it places the prices that drugs could be sold in domestic markets at the mercy of political decisions overseas, and thus threatens to make it impossible to recover the high fixed costs of drug investment noted earlier. Those provisions in effect use a system of price controls to gut the entire system of patent protection. We can think of few things less wise than this crude effort to convert pharmaceuticals into a regulated industry, especially when S. 2328 does not even address the thorny question of whether the regulated firms will, with their regulatory shortfall, receive the constitutionally required rate of return on their invested capital.

We wish to stress that these are not the only efforts to attack the basic structure under Hatch-Waxman. Other initiatives have sought to allow the state to extend the special drug prices for Medicaid recipients to ever broader classes of consumers. Still other efforts have sought to weaken patent protection by imposing ever more strict statutes for recordation of patented drugs and extremely short statutes of limitations for some patent infringement cases. Other devices to erode the current system of property rights are surely in the wings.

## CONCLUSION

As these price control initiatives illustrate, 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 is 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. But new fronts are constantly emerging, and the institutional arrangements for intellectual property must be protected against the multiple attacks on their integrity. **R**

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