The Shifting Functional Balance Of Patents And Drug Regulation

These two legal regimes operate in tandem to limit competition in lucrative drug markets. Both regimes also add to the costs of drug development.

by Rebecca S. Eisenberg

ABSTRACT: Patents are often portrayed as the necessary reward to compensate pharmaceutical firms for the huge costs and risks associated with Food and Drug Administration (FDA)–mandated clinical trials of new drugs. But the relationship between the patent system and other regulation of drugs is more complex than this simple formulation suggests. Drug regulation operates in tandem with patents to make proprietary products profitable, and patents themselves increasingly threaten to limit profitability by diverting profits elsewhere. At the same time, resistance to high drug prices is prompting new state and federal regulatory initiatives that threaten to reduce the value of drug patents. The distinctive intertwining of patents with other regulatory regimes and the shifting role of patents in the biopharmaceutical sector call into question how this singular success story for innovation policy will play out in the future.

After a long period of obscurity the patent system has been getting a lot of media attention lately, and much of that attention has been unfavorable. As recent judicial decisions have swept away limitations on the reach of the patent system into such fields as information technology and business methods, critics have questioned whether these new patents are doing more harm than good. Patent law offers a unitary set of rules for inventions in all fields, but empirical research suggests that its impact and importance vary considerably from one industry to the next. A recent analysis of the 1994 Carnegie Mellon Survey on Industrial R&D (research and development) indicates that in most industries patents are less important for appropriating returns to innovation than are secrecy, lead time, and complementary capabilities. In “discrete” product industries such as chemicals and pharmaceuticals, in which
new products typically include relatively few patentable elements, firms are more likely to use patents to collect monopoly rents, whether by commercializing the inventions themselves, licensing them to other firms, or blocking rivals from developing competing technologies. In “complex” product industries such as electronics, in which new products typically include numerous separately patentable elements, firms are more likely to use patents to enhance their bargaining positions in cross-licensing negotiations.5

Given these and other differences in perceptions among different firms in different industries, it stands to reason that incursions of the patent system into previously patent-free territory would provoke concerned skepticism among market incumbents who have prospered without patents. As economist Fritz Machlup observed a half-century ago in a report to Congress,

>If we did not have a patent system, it would be irresponsible, on the basis of our present knowledge of its economic consequences, to recommend instituting one. But since we have had a patent system for a long time, it would be irresponsible, on the basis of our present knowledge, to recommend abolishing it.6

But if prior history offers little support for introducing patents to such already innovative fields as information technology and business methods, the compelling logic of “if it ain’t broke, don’t fix it” surely cuts the other way for biopharmaceutical innovation. The long-standing availability of patent protection for drugs, at least in lucrative first-world markets, has been a fixture in the expectations of firms during a period of tremendous growth in R&D spending.7 In the past decade private funding of biomedical R&D has overtaken government funding, despite annual increases from Congress that have more than doubled the budget for the National Institutes of Health (NIH) over the same time period.8 Although drug patents have always had outspoken critics, these patents are urgently justified by pharmaceutical research firms as necessary to provide them with enough revenue to cover costly and risky product development and expensive government-mandated clinical trials of new drugs. According to the pharmaceutical industry, their R&D costs average hundreds of millions of dollars per new product, while costs of developing generic imitations are lower by orders of magnitude.9 Although some might dispute the numbers, this is as clear a success story for patents in promoting investment in innovation as may be found in any industry.10

Whether or not the current system is “broke,” the role of patents in biopharmaceutical innovation is undoubtedly changing. The patent system interacts with other legal regulation of drugs in complex and idiosyncratic ways that limit the relevance of drug patents in understanding the role that patents might play elsewhere in pro-
moting innovation. A standard account from the pharmaceutical industry pictures patents as the necessary reward to compensate for costs and risks that are augmented considerably by government regulation of new drugs. Upon closer inspection, however, the relationship between patents and drug regulation is more complex than this simple formulation would suggest. Beyond adding to the costs of drug development, drug regulation does much to support the profitability of new drugs. Beyond forestalling competition and supporting profits, the patent system increasingly threatens to divert profits away from drug-developing firms toward other patent claimants. This complex and changing symbiosis among legal regimes is becoming more apparent as governments seek new ways to control the rising costs of new drugs.

The Shifting Functional Balance

The patent system and drug laws both limit entry into markets for drugs, although ostensibly for different purposes. As a formal matter, the purpose of patents is to promote scientific progress by awarding potentially lucrative limited-term monopolies in new inventions, while the purpose of drug regulation is to protect consumers from unsafe or ineffective products. As a practical matter, the functions of the two systems are pervasively intertwined. Patents on drugs enhance profits directly by forestalling competition from generic products during the patent term. Drug laws, although delaying the commercial launch of new drugs while the patent meter is ticking, have a silver lining for the research pharmaceutical industry: They also limit the entry of generic substitutes, sometimes even after the patent expires. The regulatory hurdle facing the manufacturer of a copy of a product that has previously been approved and used extensively in patients is lower than that facing the manufacturer of a pioneering new chemical entity (NCE). But the potential profitability of these off-patent products is also lower, and the reduced regulatory burden therefore remains a significant entry barrier.

Patent law. Congress drew an uneasy balance between these regulatory regimes in the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Act), a complex legislative compromise that made changes in both the drug laws and the patent laws. It provides a streamlined procedure for approving a generic version of a previously approved drug
through use of an Abbreviated New Drug Application (ANDA) that is considerably less burdensome than a standard New Drug Application (NDA). At the same time, it extends the patent term for new drugs for up to five years to compensate for delays during regulatory review prior to first commercial marketing of the product. To accelerate the introduction of generic versions as soon as drugs go off patent, it relieves generic manufacturers from infringement liability for conducting clinical tests during the patent term.

The Hatch-Waxman Act blurs the distinction between drug regulation and the patent system, directing the U.S. Food and Drug Administration (FDA) to take patents into account in granting or withholding regulatory approval for products and directing the U.S. Patent and Trade Office (PTO) to take regulatory review into account in determining patent expiration dates. It requires holders of approved NDAs to disclose all patents that they believe would be infringed by unauthorized sales of the approved drug. Generic manufacturers that believe that their products do not infringe these patents, or that the patents are invalid, may file ANDAs seeking FDA approval for their products prior to patent expiration, but they must certify to the FDA and give notice to the patent owners of their legal arguments. If the patent owner files an infringement action within forty-five days, FDA approval of the generic product may not become effective for another thirty months, except in the unlikely event of earlier judicial resolution of the dispute. By taking an expansive approach in listing the patents covering their products (including, for example, patents covering aspects of the product formulation, such as tablet coating, that are easy for generic competitors to design around to avoid infringement), innovator firms preserve opportunities to file lawsuits that will trigger a thirty-month stay of FDA approval for the generic product. In effect, the thirty-month stay may prolong the profitable period of market exclusivity beyond what the listed patents, which may be invalid or not infringed, could do on their own.

To motivate generic applicants to challenge these patents, the Hatch-Waxman Act provides a 180-day period of exclusivity to the first generic applicant to file a patent challenge against any approved drug. This valuable right, intended to spur generic competition with products covered by questionable patents, has instead provided a strategic opportunity to defer generic competition in products that patent law would otherwise leave unprotected. Because the 180-day exclusivity does not begin until the first challenger either prevails in court or brings a generic product to market, and because there is no requirement of diligence in pursuing either goal, the first challenger may find it more profitable to enter into a
collusive settlement agreement with the patent owner that affirms the validity and infringement of the patent and defers generic competition until the patent expires. Subsequent challengers are ineligible for exclusivity and thus are unlikely to bring other generic versions to market in the interim. Here again, the combination of patents and drug regulation prolongs the period of effective market exclusivity beyond what the patent system alone provides.

**Government regulation.** Other provisions of the Food, Drug, and Cosmetic Act (FDCA) of 1938 direct the FDA to confer market exclusivity through the regulatory process alone, completely outside the patent system. The Orphan Drug Act of 1983 directs the FDA to provide seven years of exclusivity for new drugs to treat rare diseases and conditions affecting fewer than 200,000 patients in the United States. The Hatch-Waxman Act added provisions for five years of exclusivity for NCEs not previously approved by the FDA and three years of exclusivity for introducing changes in approved drug products (for example, changes in dosage form, new indications, or switches from prescription to over-the-counter status) that require new clinical studies for approval. A similar provision in the Food and Drug Administration Modernization Act (FDAMA) of 1997 grants six months of market exclusivity to encourage companies to conduct and submit studies on the pediatric uses of drugs. Each of these provisions is in part an economic measure designed to promote costly investments in innovation rather than merely a consumer protection measure designed to keep unsafe or ineffective products off the market. Considered together, they show a trend toward directing the FDA to use its gatekeeper role in timing approval of pharmaceutical products to serve a function traditionally relegated to the patent system: promoting and rewarding innovation by granting valuable exclusionary rights.

Although this functional allocation marks a departure from tradition, and arguably involves the FDA in economic regulation lying outside its core scientific competence, there is some logic to using FDA regulation rather than patents to confer market exclusivity. The pharmaceutical industry's need for market exclusivity is driven in part by the costs of regulatory burdens that do not apply to innovations in other industries. It is awkward to meet such industry-specific needs for exclusivity through provisions of a unitary patent system designed to provide innovation incentives for all industries. The Hatch-Waxman Act attempts to adjust the patent term for pharmaceutical inventions to account for this regulatory burden, but it necessarily involves the FDA alongside the PTO in administering these provisions, and it might be simpler and more elegant to concentrate industry-specific rules in the agency that
specializes in oversight of the pharmaceutical industry. Indeed, it is questionable how far Congress can go in fine-tuning the patent system to provide different protection for different industries without violating treaty prohibitions against discrimination in the terms of patent rights on the basis of field of technology.24

There is another advantage of looking to the FDA rather than the patent system for market exclusivity in pharmaceuticals. Although in the past patents on new drugs have corresponded closely to product markets, that correspondence is shifting as more firms and institutions involved in biomedical research seek patents on inventions that feed into drug development. In this emerging environment, patents are both good news and bad news for drug developers, sometimes preserving lucrative product monopolies and sometimes diverting monopoly rents toward other patent claimants. In a unitary patent system, it is difficult to enhance the value of drug patents without also enhancing the value of the upstream patents that threaten to divert revenues toward other institutions. By providing exclusivity that corresponds more closely to product markets, FDA regulation may prove to be more unequivocally helpful than patent law in securing profits for product developers, particularly when regulatory exclusivity extends beyond the term and scope of patent rights.

The Limited Value Of Patents In Securing Monopoly Profits

Although patents on new drugs ultimately support the high prices and profits that motivate firms to invest in biomedical research, they are by no means the only intellectual property claims that accompany new drugs on the road to the market. Patents on “upstream” discoveries that feed into “downstream” product development exert growing pressure on pharmaceutical firms to share the wealth with biotechnology firms and universities.25 The prospect of developing pharmacogenomic diagnostic products, while offering hope of resurrecting new products from the ashes of failed clinical trials, also offers opportunities for yet another set of patent claimants to share the wealth. At the same time, rising drug prices are encountering market and political resistance, while falling trade barriers challenge the viability of international price discrimination as a means to sustain profits in developed countries while permitting cheaper access elsewhere. In the absence of effective patent protection against parallel trade in imported versions of patented products, international differences in drug regulatory laws may prove more important than patent laws in maintaining profitable markets for drugs.

- **Upstream patent claims.** Successful new drugs typically draw on many prior research discoveries made in biotechnology
firms and universities, including DNA sequences, clones, databases, software, animals, reagents, and techniques. The institutions that develop these research tools are increasingly likely to view them as valuable proprietary resources that give their owners an opportunity to share in the bounty of the next pharmaceutical blockbuster.

For more than twenty years U.S. law has encouraged universities and other recipients of federal research dollars to patent their inventions. This federal policy, codified with passage of the Bayh-Dole Act (P.L. 96-517) and Stevenson-Wydler Technology Innovation Act of 1980 (P.L. 96-480) at the end of the Carter administration, began as an effort to promote technology transfer of discoveries emerging from federally sponsored research to the private sector for the benefit of U.S. industry. Rather than behaving as selfless benefactors of U.S. industry, universities and other owners of patents on government-sponsored research discoveries were quick to see their intellectual property rights as an opportunity to capture a share of the profits that flow from downstream product development. At the same time, new biotech firms have proliferated in market niches lying between fundamental academic research and end-product development. These firms find patent portfolios a valuable asset in efforts to attract funding from investors and collaborators.

The prospect of tapping into pharmaceutical revenues undoubtedly motivates valuable investments in upstream biomedical research, accelerating new product development as well as scientific progress. But from the perspective of the pharmaceutical industry, biotech firms and universities that hold patents on these research inputs are like so many tax collectors, diluting their anticipated profits on potential new products. Indeed, patents on these inventions may be transforming the role of patents in the pharmaceutical industry from a discrete product model, in which patents correspond to new product markets and serve primarily to secure monopoly rents, to a complex product model, in which patents serve as bargaining chips in negotiations that distribute rents from products that include numerous patentable elements. Such a transformation could enhance the importance of drug laws relative to patents as a source of exclusivity in product markets.

**Pharmacogenomics.** Advances in pharmacogenomics offer the tantalizing prospect of using genetic tests to predict patients’ responses to drugs. By one estimate, as few as one-third of patients now derive the intended benefits from prescribed medications. Excluding from the market at the outset all patients who will not benefit from use of a drug or who will suffer side effects could greatly reduce sales. At the same time, by limiting sales to genetically screened patients for whom products appear reasonably safe and effective, pharmacogenomics could permit the introduction of
“The research drug industry hopes that pharmacogenomics will lower drug development costs and speed new products to market.”

products that otherwise would have looked too risky or ineffective to approve. Moreover, pharmacogenomic tests should increase the expected value to consumers of taking drugs that have been pre-selected for them. The result could be more new products reaching smaller markets. By integrating the development and marketing of therapeutic and diagnostic products, pharmacogenomics also could further shift the functional balance between patent law and FDA regulation in determining the profitability of drug development.

The research drug industry hopes that pharmacogenomics will lower drug development costs and speed new products to market, reducing regulatory delays and permitting a longer period of exclusivity before products go off patent. Initially, it might permit firms to revive products with large sunk costs that previously failed to win FDA approval because of harmful side effects in some patients. Since these products have already generated significant sunk costs, the prospect of making sales to limited, genetically screened patient populations looks better than the current alternative of no sales at all. But many of these previously failed products will have little or no remaining patent term. They might nonetheless be eligible for FDA-administered market exclusivity beyond the protections of the patent laws, including five years of Hatch-Waxman exclusivity for NCEs or seven years of Orphan Drug Act exclusivity for products for patient populations of fewer than 200,000.

Pharmacogenomics also has the potential to alter the relationship between therapeutic and diagnostic product markets, further shifting the balance of power among patent holders. In the past, therapeutic product development has been a high-cost, highly regulated, high-margin business, while diagnostic product development has been a relatively low-cost, minimally regulated, low-margin business. Pharmacogenomics presents a challenge to this bifurcated model, suggesting a future in which high-cost, proprietary diagnostic products are developed and marketed in tandem with proprietary therapeutic products. If claims to safety and efficacy of new therapeutic products turn on the results of diagnostic tests, coordinated marketing and regulatory approvals of the two products might at some point be legally required. Numerous firms are now seeking to identify single nucleotide polymorphisms (SNPs), or common single base points of variation, in the human genome that might serve as pharmacogenomic markers. Presumably, these same
firms are pursuing patents that might permit them to share in rents from future products.

Therapeutics and diagnostics. The implications of this shift in the relationship between therapeutic and diagnostic products are not yet clear. As a practical matter, it may be easier to extract high rents from sales of therapeutic products to treat chronic diseases over an extended period of time than it is to extract rents from the same patients for a one-time diagnostic test. Payers may balk at high up-front prices for diagnostic products. Some physicians are also showing resistance to proprietary DNA diagnostic products, particularly in academic medical centers that might otherwise prefer to run their own “home brew” tests to identify mutations. On the other hand, owners of patented diagnostic products may have considerable leverage in negotiating with firms that cannot market new therapeutic products without them, and might use their leverage to secure a promise of royalties on future product sales. The relative bargaining positions of the parties may depend on the strength of their patent positions and the availability of non-infringing tests that are equally predictive.

Pharmaceutical firms, aware of the risk that patents on pharmacogenomic markers could pose to future revenues, have joined in a consortium to fund the identification and disclosure of SNPs in the public domain. An acknowledged part of the strategy of the SNP Consortium is to create patent-defeating “prior art” that will prevent anyone else from patenting the same SNPs. The consortium candidly describes this strategy on its Web site as follows:

The overall IP objective is to maximize the number of SNPs the [sic] (1) enter the public domain at the earliest possible date, and (2) to be free of third-party encumbrances such that the map can be used by all without financial or other IP obligations. To meet objective (2), the [SNP Consortium] intends to withhold public release of identified SNPs until mapping has been achieved to prevent facilitating the patenting of the same SNPs by third parties.

Although it may seem extraordinary for firms that usually sing the praises of the patent system to collaborate in a concerted effort to put new discoveries in the public domain, it makes perfect sense from the perspective of the pharmaceutical industry. The patents that matter to pharmaceutical firms are the drug patents that secure the revenues that fill the pharmaceutical feeding trough. Patents on the many prior discoveries that facilitate drug development look like siphons, diverting those revenues to the troughs of other firms.

A Shifting Political Climate

As growing numbers of patent claimants try to stake out their positions at the feeding trough of future drug sales, the high drug prices that firms count on to fill the trough are under assault. After a brief
pause in the mid-1990s, U.S. health care costs are again on the rise, and increased spending on prescription drugs is emerging as a key component in the renewed upward trend. According to a recent report in Health Affairs, prescription drugs accounted for 44 percent of the increase in health costs covered by private insurance last year, with drug spending increasing 18.4 percent. Another recent study of spending by PCS Health Systems, a large pharmacy benefits management firm, found that prescription drug spending rose an average of 24.8 percent each year between 1996 and 1999. Explanations for this upward trend include new product introductions, increased use of existing drugs, and price increases. These cost increases are drawing concerned attention, if not yet organized resistance, from health insurers.

The rising cost of prescription drugs is also a powerful political issue, particularly among seniors, who are disproportionately represented among both voters and drug consumers. The political salience of this issue presents a looming challenge to the willingness of policymakers to continue sustaining the complex legal web that keeps drug prices high. In the recent presidential election, the Gore campaign cast “big drug companies” in the villain’s role played by tobacco companies and the oil industry in prior political dramas. The election-year focus on high U.S. drug prices led to legislation authorizing the reimportation of cheaper versions of U.S.-made drugs from abroad, although the Clinton administration, in a more sober, postelection mood, ultimately decided not to implement the legislation. The Bush administration has put implementation on hold and slashed funds for administering the program by 90 percent in its proposed budget. Drug reimportation and other cost containment measures continue to enjoy bipartisan support in Congress. Rising drug costs have also figured prominently in pre- and postelection debates over the form and cost of a potential Medicare outpatient prescription drug benefit.

Some state legislatures have stepped into the fray with their own proposals to control drug costs. Maine passed legislation that leverages the state’s market power as a bulk purchaser of Medicaid drugs to pressure drug manufacturers to offer the state-negotiated Medicaid prices to uninsured residents. A federal District Court issued a preliminary injunction preventing the legislation from taking effect, but the U.S. Court of Appeals for the First Circuit reversed that decision. In this environment, recent media attention to the struggle over the availability of acquired immunodeficiency syndrome (AIDS) drugs in less-developed nations has been a public relations disaster for the pharmaceutical industry. In addition to picturing the indus-
try as callous and rapacious in the face of desperate public health needs, the controversy has drawn embarrassing attention to the considerable gap between prices charged to U.S. consumers and manufacturing costs. The pharmaceutical industry’s recent decision to abandon a legal challenge to a South African law designed to improve access to affordable drugs gave a big boost to critics of the industry and revealed major weaknesses in its legal position.

**The Problem Of Parallel Trade**

These events highlight an important limitation on patents that could seriously constrain drug pricing strategies in the absence of drug regulation: parallel trade. Free trade makes it difficult to maintain international price discrimination for goods that are easy to move across national borders. This problem goes a long way toward explaining why the pharmaceutical industry has been reluctant to provide cheap AIDS drugs in sub-Saharan Africa. The charging of different prices for the same drug in different markets is galling to consumers who buy in the high-price market, but it makes sense as a matter of economics. By charging high prices in the United States and low prices in sub-Saharan Africa, pharmaceutical firms maximize revenues on product sales (and corresponding incentives to develop new drugs) while making their products available to consumers who could not otherwise afford them. But price discrimination is difficult to maintain without legal restrictions on arbitrage. Otherwise, exporters could buy the product in low-price markets and resell at a profit in high-price markets. Laws regulating drug sales are at least as important as patent laws are in restricting the flow of drugs across borders and thereby preserving the viability of price discrimination.

- **Patent law and arbitrage.** Patent law has limited value in restricting arbitrage because many nations permit the importation and resale of patented products that were purchased abroad without further obligation to the patent holders. Members of the World Trade Organization did not agree to prohibit this practice in negotiating the terms of the Agreement on Trade-Related Aspects of Intellectual Property Rights (the “TRIPS agreement”). Although the TRIPS agreement requires member nations to give patent owners the exclusive right to “import” products covered by a patent, this provision is expressly qualified by another stating that “nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.”

Once the owner of an intellectual property right (such as a patent) sells or authorizes the sale of an item that incorporates the patented technology, the doctrine of exhaustion provides that the
The purchaser is free to resell that particular item without further obligation to the patent owner. Under one variation of this principle, known as “national exhaustion,” authorized resales are limited to the nation in which the first sale of the item occurred. But many nations follow another variation known as “international exhaustion,” which permits importation so long as the patent owner consented to the original sale abroad.\textsuperscript{54} Intellectual property owners favor national exhaustion because it permits them to maximize revenues by charging different prices in different national markets. Proponents of international exhaustion stress the value of free trade and competitive markets, and note that patent owners have an opportunity to profit from their intellectual property at the time of the first authorized sale.\textsuperscript{55} As a general rule international exhaustion is more popular in less-developed countries, but a recent decision of the Japanese Supreme Court supports a qualified rule of international exhaustion, and the European Union follows communitywide exhaustion for sales within the European Community.\textsuperscript{56}

Although the United States has advocated international agreement on a rule of national exhaustion, it is by no means clear that that is the prevailing rule under U.S. patent law.\textsuperscript{57} Some authorities cite an 1890 decision of the U.S. Supreme Court as establishing a rule of national exhaustion.\textsuperscript{58} But subsequent lower-court decisions have construed that case more narrowly and have held that U.S. patent rights are exhausted as to articles sold abroad with permission of the U.S. patent owner.\textsuperscript{59} On the other hand, courts have permitted U.S. patent owners to exclude imported goods when the foreign sales were made on the express condition that the product not be imported or sold in the United States, and the defendant had notice of this restriction.\textsuperscript{60} Some commentators have wishfully interpreted 1994 legislation adding importation to the statutory acts of patent infringement as providing U.S. patent owners with a right to block parallel imports, but this interpretation is questionable.\textsuperscript{61} The change in statutory language was part of a package of changes adopted to bring the United States into compliance with the TRIPS agreement, which requires that member nations provide patentees with an exclusive right to import their inventions but explicitly disclaims any position on the issue of parallel imports.

Decisions under U.S. copyright and trademark laws offer no clearer support for a rule of national exhaustion. The U.S. Supreme Court recently construed the Copyright Act as calling for international exhaustion in a case involving goods manufactured in the United States and sold to foreign purchasers.\textsuperscript{62} The Court previously held that U.S. trademark owners may not compel the Customs Service to exclude parallel imports of goods bearing marks applied by
either the U.S. mark owner or an affiliated business entity.\textsuperscript{51}

- **The U.S. intellectual property arena.** In sum, although the United States has pushed for adoption of a rule of national exhaustion in treaty negotiations, U.S. intellectual property owners have had at best mixed success in promoting such a rule at home. Conflict between owners and consumers of intellectual property in developed nations may explain this apparent paradox. Parallel trade, as a form of arbitrage, draws goods from high-price markets to low-price markets, offering at least a short-run prospect of lowering prices to consumers who are paying the high prices. A treaty-backed consensus rule of national exhaustion would not be necessary to preserve price discrimination in patented goods if developed nations themselves followed such a rule in their own national laws. (It is of little consequence what rule applies in the less-developed nations, because they are far less likely to find themselves on the receiving end of price-lowering parallel trade.) But in the face of conflicting political pressures from patent owners on one hand and consumers on the other, it might be easier to compel by treaty a rule that developed nations would otherwise have trouble enacting. The interests of intellectual property owners are more likely to be paramount in treaty negotiations, which are typically framed in terms of competing national interests, than in the legislative arena, which is more visible and accessible to representatives of consumers and other competing domestic interest groups.

Despite the uncertain effect of U.S. patent law on parallel imports, the pharmaceutical industry has nonetheless managed so far to forestall parallel imports of drugs into the United States through provisions of the FDCA. The FDCA prohibits the introduction into interstate commerce (including by importation) of new drugs except pursuant to approved NDAs.\textsuperscript{64} Approvals of NDAs are limited to products made in specified manufacturing facilities and sold under an approved label.\textsuperscript{65} These health and safety measures have the practical effect of excluding from importation products manufactured without the NDA sponsor’s authority, as well as products made for foreign markets governed by different labeling requirements. The pharmaceutical industry obtained further protection from parallel imports under the Prescription Drug Marketing Act of 1987, which prohibits the reimportation of previously exported U.S.-manufactured drugs except by the manufacturer, unless required for emergency medical care.\textsuperscript{66} Once again, the FDCA provides protection from competition where the scope of patent protection is unclear. Indeed, in an interesting twist on the push toward harmonization of laws to promote free trade, the most enduring obstacle to parallel trade in drugs may prove to be national differences in drug...
regulation that make products manufactured for one market difficult to sell elsewhere. In the regulatory arena, differences in national laws operate to the advantage of the pharmaceutical industry, and harmonization efforts loom as a long-term threat to profits.

The pharmaceutical industry, with its high profit margins and investments in high-risk R&D, provides impressive testimony to the benefits of a patent system. But the patent system does not work alone in this context. Although patents often take most of the credit for the profits of drug development, while drug regulation takes much of the blame for its costs, upon closer inspection these two legal regimes operate in tandem to limit competition in lucrative markets for drugs. The core function of drug regulation is to protect health and safety, while the core function of patent law is to promote innovation. The constraints of a unitary patent system might suggest the expedience of fine-tuning the terms of market exclusivity for new drugs by adjusting the FDCA rather than the Patent Act. But this strategy risks distorting the requirements of health and safety in furtherance of economic goals. Policymakers should be clear about what they are doing and why. To the extent that regulatory measures are driven by economic goals, they should not sail under the false colors of health and safety.

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NOTES

5. Ibid., 16–24, Figures 7 and 8.
13. 21 U.S. Code, sec. 355(j).
14. 35 U.S. Code, sec. 156.
15. Ibid., sec. 271(e)(1).
16. 21 U.S. Code, sec. 355(b)(1).
17. 35 U.S. Code, sec. 271(e)(2); also see 21 U.S. Code, secs. 355(c)(3)(C), 355(j)(4)(B)(iii).
22. 21 U.S. Code, secs. 355(c)(3)(D)(ii), (iii).
34. <snp.cshl.org/about/program.html> (19 June 2001).
38. Merlis, “Explaining the Growth.”
41. In a press briefing, Secretary of Health and Human Services Tommy G. Thompson said that prospects for implementing the legislation were “doubtful,” although he had not yet made a final decision. “Secretary Thompson Holds Briefing on the Budget,” Federal Document Clearing House Political Transcripts (9 April 2001) (LexisNexis news service).
47. See, for example, M. Schoofs and M. Waldholz, “AIDS Epicentrum Traps Drug


52. WTO, “Agreement on Trade-Related Aspects of Intellectual Property Rights.”

53. Ibid., TRIPS Agreement, Article 28, sec. I(a), and Article 6.


59. See, for example, *Curtiss Aeroplane Co. v. United Aircraft Engineering Corp.*, 266 F. 71 (2d Cir. 1920); and *Kabushiki Kaisha Hattori Seiko v. Recfac Technology Development Corp.*, 690 F. Supp. 1339 (S.D.N.Y. 1988).

60. See, for example, *Dickerson v. Tinling*, 84 F. 192 (8th Cir. 1897); and *Dickerson v. Matheson*, 57 F. 524 (2d Cir. 1893).


64. 21 U.S. Code, sec. 355(a).

65. Ibid., secs. 355(b)(1)(D), (F).