

FACILITATING ACCESS OF AIDS DRUGS WHILE MAINTAINING STRONG PATENT PROTECTION

The AIDS pandemic has thrust the subject of patent protection into the spotlight, a spotlight that has attracted the attention of broad audience including interested parties from the political, legal, and medical communities. Can the United States' scheme of strong patent protection for pharmaceutical products withstand the increased attention?

Introduction

In general, protecting intellectual property with patent rights seems like a simple, sensible plan: encourage innovation by rewarding those who invest in research and development with a temporary monopoly. The plan becomes less simple and less sensible when during that period of temporary monopoly, millions of people die because they can't afford treatment. Protecting intellectual property rights for pharmaceutical products inherently creates tension between the conflicting goals of encouraging discovery and facilitating consumer access.¹ The tension between discovery and access has never been more apparent than when viewed in the context of the AIDS crisis in developing countries. Consider that "90% of the 33 million worldwide cases of HIV/AIDS [are] located in Africa, South America and Asia."² Of what use is discovery, if the vast majority of those in need of a new drug cannot afford it? To those frustrated with the lack of drug availability to developing countries, the pharmaceutical companies seem to have shrugged a cold shoulder and responded bluntly: expensive drugs are better than no drugs at all. Thus, the stage is set for the tug-of-war between discovery and access. With an eye toward strong patent protection, the following discussion takes a closer look at the conflicting goals of discovery and access.

Information as a Commodity

In the market for AIDS drugs, the physical good—the actual pill—is merely the tangible end product of the true scarce commodity: information. Treating information as a scarce commodity helps to solve the public goods problem that so often raises its ugly head in the

¹ Theodore C. Bailey, "Innovation and Access: The Role of Compulsory Licensing in the Development and Distribution of HIV/AIDS Drugs," 2001 U. Ill. J.L. Tech. & Pol'y 193, 194 (2001).

² Id. at 196.

information market. One author uses the example of International News Service v. The Associated Press to explain the problem of information as a public good and the solution that commodification of information offers.³ Associated Press (AP), a news service, used reporters stationed worldwide to collect and then print news stories for subscribers. A competitor, International News Service (INS), took a less expensive news gathering approach—reprint the AP reports and make a profit by taking advantage of the time delay to the West coast. When AP sued INS for unfair competition, the court supported AP's right to protect their investment in information.⁴ By treating information as a form of property, information becomes subject to the forces of a traditional economic market like any other good. Consumer demand plays an integral role to manage the market price of the information. The price is high enough to give an incentive for AP to supply the information, and the price is low enough to elicit demand from consumers. Treating information as a commodity provides incentive, the crucial first step to innovation.

Because the commodity perspective of information leads to the conclusion that investment in information must be protected as a property right to ensure innovation, this is the perspective most often advocated by the pharmaceutical industry. The basic conclusion of the commodity perspective is that weakened incentives, i.e., weakened intellectual property rights, result in less innovation. Thus, patent protection of innovative products ensures that companies will continue to undertake the research and development costs necessary to come up with the next blockbuster drug.

The general formula for patent protection—no incentive, no innovation—does possess some inherent logic. Why would a pharmaceutical company invest large amounts of resources in a product if a free rider could come along and reap the gains of innovation without incurring the R&D costs? However, some studies have shown only a weak correlation between patent protection and the amount of innovation.⁵ The results of these studies imply that patent protection is not a necessary precursor for innovation. If patent protection is not really necessary for innovation, then creating intellectual property rights merely serves as an impediment to public access of information. This opposition to the commodity perspective of information views strong patent protection as restricting the free flow of information while doing little to encourage

³ James Boyle, Shamans, Software, & Spleens: Law and the Construction of the Information Society, 37 (1996).

⁴ Id.; see International News Service v. The Associated Press, 248 U.S. 215 (1918).

⁵ Shamans at 43.

innovation. While the booming voice of big business supports the commodity perspective, the advocates of a more “public policy oriented perspective” are speaking up.⁶

The public policy approach focuses less on providing the incentive for original innovation (which seems, according to the previously mentioned studies, to perhaps be ineffectual anyway) and more on providing the raw materials for future innovation.⁷ Innovative technology is built atop a foundation laid by past innovators. By restricting access to the building blocks of past innovation, the pathway to future creation is severely impeded.⁸ The United States paradoxically seems to hold strong patent protection in high esteem while at the same time praising the benefits of free flowing access to information. Such a position is certainly precarious considering the conflicting intellectual property regimes necessary to achieve each goal. Strong patent protection encourages current discovery but hinders follow up innovation. Weak patent protection allows future innovators access to raw materials while dangerously threatening the creation of raw materials in the first place. The information market seems halted at an impasse. However, a clever detour—the research exemption—holds the promise of a feasible compromise.

Research Exemptions and Public Policy

To date, the United States patent regime does not include an exemption from infringement claims for commercial research or experimental use.⁹ Some countries choose to make such an exemption thereby allowing companies engaging in commercial research to use a patented product for research without liability for infringement. In Japan, for example, companies may use a patented product as a building block for their own innovation as long as the resulting discovery is not marketed until the patent expires.¹⁰ Conversely, a company in the United States would still be held liable for patent infringement if its use of the patented product is for commercial research purposes. Allowing a research exemption maintains the incentive effects of strong patent protection while also clearing an open path for follow up innovation. Some countries choose to place an even greater importance on follow up innovation by simply not

⁶ James Thuo Gathii, “Construing Intellectual Property Rights and Competition Policy Consistently with Facilitating Access to Affordable AIDS Drugs to Low-End Consumers,” 53 *Fla. L. Rev.* 727, 751-52 (2001).

⁷ *Shamans* at 38.

⁸ *Id.*

⁹ Rebecca S. Eisenberg, “Patents and the Progress of Science: Exclusive Rights and Experimental Use,” 56 *U. Chi. L. Rev.* 1017, 1021-22 (1989).

¹⁰ John A. Tessensohn, “Reversal of Fortune: Pharmaceutical Experimental Use and Patent Infringement in Japan,” 4 *J. Int'l Legal Stud.* 1, 1 (1998).

allowing patent protection of pharmaceutical products.¹¹ Despite the weak correlation between incentive and innovation suggested by the studies discussed previously, the total elimination of patent incentives seems too heavy a blow for pharmaceutical innovation. Rather than deny incentives in the form of patent rights altogether or restrict access by creating a rigid patent regime, the research exemption balances these goals. Although the research exemption keeps the scales tipped in favor of industry incentive rather than public access, this slight advantage is necessary. Both incentive and access are important objectives, but one cannot ignore the fact that discovery is the mandatory prerequisite that must exist before access can be achieved. Those who advocate the public policy perspective of intellectual property take this consideration to heart. Usually, public policy advocates do not argue that pharmaceutical companies should not be compensated at all for their investment in R&D, but that they are over-compensated.

Innovation and Compensation

To be sure, the pharmaceutical companies *appear* to be over-compensated for their investment in research and development. First, opponents of the pharmaceutical companies point to the gross mark-up in price compared to production costs. For example, “in 1991, a single capsule of AZT cost only forty cents to produce, but costs one and a half dollars to buy.”¹² While pharmaceutical companies certainly have the right to make a profit by producing valuable drugs, the drastic mark-up seems to go far beyond recovering R&D costs and instead approach the point of greedily exploiting patients. Perhaps the consumer price hike remains unconvincing. After all, a pretty hefty mark-up must be necessary to cover the obscenely high cost of research and development. Undoubtedly, describing R&D costs as obscene is no exaggeration when “in 1990, the United States government estimated that a single new drug took ten to twelve years to come to market at a cost of \$359 million.”¹³ Even taking this considerable expense into consideration, the pharmaceutical companies do not seem to be hurting: “Even after plowing \$21 billion back into R&D, the 10 largest U.S. drug makers had \$100 billion more in sales than manufacturing costs [in one year]...the rate of return on assets [is] the highest of any industry.”¹⁴ Furthermore, the argument that weaker patent protection would lead to less pharmaceutical R&D is countered

¹¹ John A. Harrelson, “TRIPS, Pharmaceutical Patents, and the HIV/AIDS Crisis: Finding the Proper Balance between Intellectual Property Rights and Compassion,” 7 Wid. L. Symp. J. 175, 179 (2001).

¹² Bailey at 204.

¹³ Harrelson at 184.

¹⁴ Barton Gellman, “A Turning Point That Left Millions Behind; Drug Discounts Benefit Few While Protecting Pharmaceutical Companies’ Profits,” Wash. Post, A01 (Dec. 28, 2000).

by the sheer magnitude of resources devoted to R&D in this industry. The trend toward investment in pharmaceutical research is described by the following:

“The amount of investment in research has increased from \$2 billion in 1980 to \$8.2 billion in 1990 to a present level of approximately \$19 billion. This is evidence of an incredibly strong impetus for firms to shift resources *into* research and development and that a weakening of patent protection...would likely only lead to a slowing in the increase in investment...”¹⁵

Significant price mark-ups, evidence of ample profit by the pharmaceutical companies, and the general industry trend toward research and development all suggest that strong patent protection over-compensates pharmaceutical companies.

Agreeably, the pharmaceutical companies run a profitable enterprise, but a more discerning eye reveals that the over-compensation cited by opponents of the industry is quite overstated. Especially in the struggle to provide affordable drugs to low-income consumers, the price mark-up is often the most disconcerting effect of the temporary monopoly resulting from patent protection. The mark-up on AZT from forty cents to one and half-dollars as a case in point seems particularly extravagant. Understandably, in the midst of an urgent AIDS crisis, trying to provide such expensive drugs to the world’s poorest nations is a painfully frustrating task. However, pharmaceutical companies also face a frustrating task: getting a drug from research and development through clinical trials and FDA approval. Approximately only one out of every 4000 drugs researched makes it to the market. 3999 times out of 4000, a pharmaceutical company loses all incurred research costs. So when a drug finally does find its way into the hands of consumers, the mark up in price must not only cover the research and development expense for that one drug, it must also cover the research and development costs it took to eliminate the other 3999 failed attempts.¹⁶ With such bad odds for success, the pharmaceutical company must consider the opportunity cost of other more lucrative and less risky endeavors. Thus, the price mark up which appeared so gruesome when simply compared the cost of production, now looks more reasonable when the odds of failure and the opportunity costs of other activities are factored into the equation.

Even when the number crunching lends sympathy to the pharmaceutical companies, many remain convinced that the industry as a whole is overcompensated for R&D investment. The aforementioned industry-wide profit of \$100 billion is more glaringly obvious than whatever rationale may be implied by number crunching the unfavorable statistics of R&D.¹⁷ In addition to

¹⁵ Bailey at 215.

¹⁶ See Cooter and Ulen, at 128. Explanation found in Bailey at 203.

¹⁷ See Gellman at A01.

monopolistic pricing, the U.S. patent system has another inherent over-compensation argument. The way the patent regime operates creates a “rivalry to innovate.”¹⁸ In other words, many different companies compete in a race to the patent office. Expenditure on R&D is not simply responsive to the level of R&D investment that would maximize social utility. Instead of considering just utility, firms must also consider the competition. For example, “the greater is firm B’s expenditure rate on R&D, the more firm A will find it optimal to spend on its research programme... it implies that R&D expenditures under competitive conditions exceed the collusive rates that maximize joint profits.”¹⁹ By this model, the pharmaceutical industry as a whole is spending too much on R&D by competing in a winner-takes-all race to the patent office.

The proposal that the patent race leads to over-investment in R&D is misguided because it ignores basic truths about the market for AIDS therapies. The flawed version of the patent race envisions that only one competitor can win the race. Admittedly, patent rights are granted on a first come, first served basis. But when the number of solutions to a particular problem are finite, functionality acts as a funnel to narrow the possibilities of patentable innovations.²⁰ Simply stated, there are only so many answers that work. The image of a functionality as a funnel helps one to understand the argument that the patent race creates over-investment in R&D. Only the first pharmaceutical company to file with the patent office squeezes through the funnel. The other competitors finish empty-handed, carrying only the weight of apparently wasted R&D expenses. In reality, this is *not* how the race ends! At the risk of sounding warm and fuzzy, everyone who finishes the patent race is a winner. Although many competitors might come up with similar treatments for HIV/AIDS, each slight variation can make a drug distinctive enough to obtain patent protection. For instance, ten patented anti-retroviral drugs using nucleoside or nucleotide reverse transcriptase inhibitors are currently available.²¹ Three non-nucleoside reverse transcriptase inhibitors and six different protease inhibitors have earned patent protection.²² Each type of treatment fights the HIV virus in a slightly different way. Often, combining several different treatments yields more favorable results than using any single treatment alone.²³ Because genetic mutation enables the virus to develop into resistant strains, the importance of

¹⁸ Bailey at 212.

¹⁹ Gene M. Grossman and Carl Shapiro, Dynamic R&D Competition, 97 *Econ. J.* 372, 375 (1987).

²⁰ Boyle, *supra* note 23.

²¹ “Currently Approved Drugs for HIV: A Comparative Chart” found at <http://aidsmeds.com/lessons/DrugChart.htm> accessed November 24, 2001.

²² *Id.*

²³ Steven Epstein, *Impure Science: AIDS, Activism, and the Politics of Knowledge*, 246 (1996).

persistently creating slightly altered treatments is critically important.²⁴ Also, treating an HIV positive patient requires individualized treatment. Not all patients can tolerate the severe toxicity of some drugs, and patients often respond better to some drug regimens than others.²⁵ For these reasons, investing in multiple companies to find solutions for the same problem is not necessarily over-investment. Even though many variations of treatments can be used to combat HIV/AIDS, each one is worth pursuing first because of the demonstrated benefits of using multiple treatments and secondly because the unique way individuals respond to treatment.

Hopefully, the analysis thus far has erased or at least marred the portrait of a selfish and black-hearted pharmaceutical industry. Steep consumer price mark-ups often used to show obscenely high industry profits can also tell a different story. In the version of the story told here, high mark-ups are an economic necessity to account for both the remarkably slim odds of finding a marketable drug and the opportunity cost of other activities less monetarily risky than research and development. The broader over-compensation argument, that the industry as a whole creates over-investment because of the patent race, is also over-stated. Because the market for AIDS drugs not only allows, but in fact *requires* many treatment variations, money invested in similar R&D projects is not spent in vain. Thus, the economic incentives in place to encourage pharmaceutical research and development do not drastically over-compensate the industry. With these economic underpinnings in place, the reader is now ready to objectively tackle the task of facilitating drug access to low-income consumers while effectively maintaining incentives to innovate.

TRIPS Compulsory Licensing Compensation Implications

Just as the most ardent advocates for low-income consumers do not ignore the need to encourage innovation, the pharmaceutical industry does not ignore the need for access to new drugs. In fact, many pharmaceutical companies donate large quantities of drugs to poorer nations that cannot afford the expensive treatments.²⁶ Certainly, these countries appreciate the generous gesture, but addressing the sub-Saharan AIDS crisis will require bigger and more formalistic means of access than mere philanthropy. The following discussion shows one weakness of a popular suggestion: compulsory licensing. Compulsory licensing facilitates access to low income consumers by prematurely shifting a company from monopolistic pricing (under patent protection) to competitive pricing by allowing the production of a generic drug. Introducing competitive pricing often causes the market price to plummet, thereby making the drug affordable

²⁴ *Id.* at 265.

²⁵ *Id.* at 246.

to more consumers.²⁷ Despite the United States' rather forceful opposition to compulsory licensing, the practice has earned support as a promising compromise. One clear piece of evidence that demonstrates increasing support is the approval of compulsory licensing by the recent Agreement on Trade-Related Aspects of Intellectual Property (TRIPS).²⁸ TRIPS allows compulsory licensing in specific, limited circumstances:

- i) in national emergency or some other extreme urgency or for public non-commercial use,
- ii) in other cases, if the proposed user has made efforts to get authorization from the owner on reasonable commercial terms and conditions and not been able to get the authorization within a reasonable period of time.²⁹

Even when a country meets these restrictions, compulsory licensing does not strip the patent holder of all rights. TRIPS includes the following safeguards for the rights of the patent holder:

- i) the owner will be paid adequate remuneration,
- ii) the authorization of such use will be mainly for the supply to the domestic market,
- iii) the scope and duration of such use will be limited to the purpose for which it is used.³⁰

With the TRIPS regulations in place, compulsory licensing seems to merely weaken patent protection, not completely defeat its purpose. By requiring royalty payments to the patent holder, TRIPS continues to ensure incentive to innovate. Granted, royalty payments are not as strong of an incentive as the right to monopolistic pricing, but the desperate need for AIDS drugs accentuates the importance of access. In this way, compulsory licensing nudges the balancing act in favor of access while still respecting the importance of encouraging discovery. However, what appears to be a slight nudge in favor of access actually threatens to effectively destroy, as opposed to merely weaken, patent protection.

The main reason U.S. pharmaceutical companies oppose compulsory licensing is because such a practice encourages parallel importing, a major threat to the industry's ability to make a profit in developed countries. By making a cheap, generic version of the drugs available in developing countries, other developed countries might seize the opportunity to obtain drugs by

²⁶ Gathii at 735; Gellman at 19.

²⁷ See Bailey at 204.

²⁸ See Bailey 199-200.

²⁹ See Bailey at 200; Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Annex 1C, 33 I.L.M. 1125, art. 31(b) (1994).

³⁰ *Id.* at Art. 31(c), (f), and (h).

circumventing the original supplier and going through the more inexpensive markets.³¹ In this way, compulsory licensing does not merely nudge the innovation/access balance toward access by lowering prices in developing countries. Instead, compulsory licensing threatens to destroy the industry's ability to make a profit in any market worldwide, a more devastating blow to innovation incentives. Compulsory licensing, a seemingly feasible way to produce affordable generics for needy consumers, is complexly entangled with the kind of large-scale profit loss that frightens the pharmaceutical industry. The link between compulsory licensing and parallel importing does not just exist as a pharmaceutical industry nightmare; the results of generic drug production currently allowed in countries such as India, Thailand, and Brazil show that this connection is quite real.³² Instead of mandating that all countries adopt TRIPS standards immediately, some developing countries have been given a grace period lasting up until the year 2006 during which to implement the TRIPS standard of twenty year patent protection. So for now, some countries are producing generic versions of drugs that would ordinarily still be enjoying patent protection. The availability of generic drugs in India, Thailand, and Brazil create an almost irresistible temptation for less developed countries to gain access by parallel importing. In an effort to prevent the worldwide price drop anticipated by this behavior, less developed countries have felt "intense pressure from the pharmaceutical industry and western governments not to [parallel import]."³³ In short, compulsory licensing under TRIPS does not per se pose a threat to pharmaceutical companies because the agreement places restrictions on when and how a country can utilize this strategy. However, the inability to separate compulsory licensing from parallel importing and the ensuing catastrophic worldwide price effect creates an enormously dangerous threat to U.S. pharmaceutical patent holders in particular and incentives to innovate in general.

The key to obtaining the benefits of compulsory licensing while avoiding the dangers of parallel importing lies in a TRIPS omission. The TRIPS agreement does not choose between national and international patent exhaustion, a choice that could sever the connection between compulsory licensing and parallel importing.³⁴ The problem of parallel importing arises when a patent holder cannot claim rights regarding the patented product after the initial sale. For a domestic sale, the rights of the patent holder are relatively uncomplicated. The patent holder makes the initial sale, but then "has no right to control the further sale of that product within the

³¹ Chirac, von Schoen-Angerer, Kasper, and Ford, "AIDS: Patent Rights versus Patient's Rights," *The Lancet*, 356 (9228): 502 (2000).

³² *Id.*

³³ *Id.*

³⁴ Harrelson at 194.

country.”³⁵ For persons with patents in multiple countries, the important issue is what happens when further sales of the products are *not* within the country. National patent exhaustion means that although a patent holder does not have control over further domestic sales, the patent holder has the right to “prevent importation of the sold product into another country where he has a patent.”³⁶ Under international patent exhaustion, the patent holder only has authority over the first sale. The patent holder has no rights regarding the further sale of the product worldwide. Thus, national patent exhaustion allows the patent holder to prevent parallel importing while international patent exhaustion embraces a free trade approach.³⁷ This dichotomy brings the reader in a full circle back to the abstract views of information examined at the very beginning of this discussion. Treating information as a commodity is in line with the national patent exhaustion scheme—award intellectual property rights to provide adequate incentives to innovate. Viewing information from a public policy perspective and adopting the international patent exhaustion scheme places more importance on the free flow of information. In the abstract argument, allowing a research exemption was proposed as a feasible compromise. The patent exhaustion question requires a more black and white answer: the patent holder either does or does not have rights to control further sales of the product internationally. Because the potential harm to innovation is so great, preventing parallel importing through national patent exhaustion is the best choice. If the TRIPS negotiations had resulted in the choice of national patent exhaustion instead of leaving the matter open to debate, perhaps compulsory licensing would face less opposition from the pharmaceutical industry.

Conclusion

Responding to the AIDS crisis requires not only compassion for its victims, but also an acceptance of the economic incentives necessary to drive pharmaceutical research and development. In order to combat such a crisis, leaders must carefully consider available legislative tools such as the research exemption and national patent exhaustion that can be used to balance innovation and access. In the meantime, when evaluating the benefits of practical solutions like compulsory licensing, keep a watchful eye on the preservation of research incentives. Hopefully, this analysis has demonstrated the importance of strong patent protection in an industry whose lifeblood is innovation. By continuing to encourage innovation, perhaps we can face the battle against AIDS with a cure, as well as compassion.

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³⁵ Id. at 193.

³⁶ Id.

³⁷ Id.

