PATENTS AND INNOVATION IN THE PHARMACEUTICAL INDUSTRY

Kyle A. Marchini *

ABSTRACT: *For more than a century protections on intellectual property have been used to encourage innovation in a wide range of industries. This article argues that patents in the pharmaceutical industry discourage innovation on net by stifling sequential innovation and skewing the research that does occur. In the absence of patent protections, firms would be able to recover research costs through first-mover advantages and temporary technological monopoly which leads to a more dynamic and innovative industry.*

* Kyle Marchini is a junior double-majoring in economics and music at Grove City College. After graduation, he plans to pursue his Ph.D. in economics.

Fritz Machlup concluded his 1958 analysis of the U.S. patent system by writing: "If we did not have a patent system, it would be irresponsible, on the basis of our present knowledge of the economic consequences, to recommend instituting one."[1] While the current system may be too ingrained in the business and legal culture of America to ever entirely banish, rigid intellectual property protections may do more harm than good to the promotion of innovation. In few places is this understanding more important than in the pharmaceutical industry. While patents are widely thought to be necessary for the creation of new drugs and treatments, the opposite is true. Patents discourage innovation on net and skew innovation in the unhampered market. This results in misallocation of resources and inefficiencies for all firms in the market.

In many ways, the pharmaceutical industry is a poster child for proponents of intellectual property. No one disputes the social necessity of a thriving pharmaceutical industry; the historical benefits have been clear. This industry is also unique in the extremely high fixed costs of innovation, due to regulations on drug testing and certification. The estimated average cost of bringing a single new drug to market exceeds $400M.[2] Much of the cost of producing a new drug lies in the research and development stage rather than actual production, since drug manufacturing tends to face significant economies of scale across a large range of production.

---

1 S. REP. NO. 15 at 80 (1958).

2 Joseph A. Dimasi, Ronald W. Hansen & Henry G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 151 (2003).

Thus, it is feared that enabling competitors to enter the market and produce new drugs without incurring the innovator's research costs would almost immediately strip him of profits, rendering further development nearly impossible. Based on this analysis, many scholars assume that the pharmaceutical industry simply could not operate without patent protection.[3]

The second reason to critically analyze intellectual property (IP) in the pharmaceutical industry is the integral nature of sequential innovation in medicine. Sequential innovation is highly dependent on prior technology or research for its existence. While all innovation is sequential by nature since it expands on what has already been discovered, particular areas exhibit more dependency than others, such as the use of gene sequences in pharmaceutical research. Because gene sequences are not merely discrete molecules but also pieces of information, they provide a foundation for many other areas of innovation from diagnosis to targeted treatments.[4] This means that monopolistic restrictions, such as patents, on the foundational technology can significantly limit other firms' ability to innovate in related areas. In other highly sequential fields this has resulted in a significant decrease in innovation when IP protections were initially applied.[5]

Because regulation which enables patents on pharmaceuticals creates significant factors that both encourage and discour-

---

3 S. REP. NO. 15 at 77 (1958).

4 Brian Jackson, *Innovation and Intellectual Property: The Case of Genomic Patenting*, 22 J. POL'Y ANALYSIS & MGMT. 5, 10 (2003).

5 James Bessen & Eric Maskin, *Sequential Innovation, Patents, and Imitation* 2 (Mass. Inst. of Tech. Dep't of Econ., Working Paper No. 00-01, 2000), *available at* http://www.researchoninnovation.org/patent.pdf.

age innovation, it is impossible to determine the net effect from a purely theoretical analysis. However, an overview of the incentives created on both sides of the equation is necessary for evaluating the historical cases and determining the underlying causal factors. The benefits accrued from being granted a monopoly on the production of a particular good, including substantial profits from the restriction of competition, provide a direct incentive to innovate. Balancing that incentive are increased innovation costs for all other firms in the market, whether from direct legal prohibition or from rents paid for the use of a patent. This is especially pernicious when a significant body of research rests upon a patented technology, as is the case with gene sequences. Third, patenting skews the type of innovation in which firms engage. By preventing direct competition for the most efficient means to produce a given drug, patents encourage companies to research "work alike" drugs in an attempt to capture market share from the monopolist.

Indisputably, protections on IP are beneficial to the monopolist. The firm that owns patented technology receives guaranteed monopoly profits through direct restriction of competition. Potential competitors are prevented from utilizing cheaper production methods even if they are discovered. Advocates of IP argue that this is necessary because reverse engineering is likely less expensive than the original production of a new drug. DiMasi et al. estimated the cost of bringing a new drug to market exceeds $400M pre-tax dollars. Assuming a discount rate of 11 percent annually over the time of development and certification, this figure adjusts

to a cost estimate of $802M prior to the approval of the drug.[6] If competitors were able to reverse engineer the new drug at a fraction of the cost and bring it to market, it would be difficult for the original innovator to recoup the costs of research, presumably rendering research a competitive liability rather than an asset.[7] While the monopolist will incur some additional costs in obtaining the patent, they will be small relative to increased revenues from monopoly pricing.

For some, the benefits accrued by holding a patent provide a direct incentive to increase the pace of innovation while discouraging competitors. Not only are firms guaranteed monopoly profits, but to the extent that they are able to identify lucrative future areas of innovation, they can prevent competitors from bringing products to market based on those technologies.[8] While these strategies ultimately aim to restrict competitors' ability to innovate, each approach requires the firm itself to be highly innovative since other companies are also attempting to stake their claim to the emergent technologies. In abstract, this cannot be said to increase or decrease net innovation, as it may be offset by the restrictions on competition stemming from reduced market access.

Competitors' initial costs stem from the direct restriction of market access imposed by patents. Any firm wishing to enter the market for a patented drug must purchase that patent from the owner or face legal sanction. For the monopolist, there are signifi-

6 DiMasi et. al., *supra* note 2, at 151.

7 Earl L. Grinols & James W. Henderson, *Replace Pharmaceutical Patents Now*, 25 PHARMACOECON. 355, 357 (2007).

8 Michele Boldrin and David K Levine, AGAINST INTELLECTUAL MONOPOLY 183 (Cambridge University Press) 2008.

cant incentives to block competitors' access to the market, as outlined above. A firm cannot only guarantee monopoly profits, but also significant future revenue from preventing other companies from building on their technology, thus putting future competitors at a disadvantage. Perversely, the larger the potential area controlled by the patent, the more likely a firm is to retain ownership and thus retain their future options.[9] This results in inefficiency for potential competitors, who are prevented from accessing the most efficient technologies and from innovating.

For firms allowed to enter the market, the rent in royalties will likely be prohibitive. In perfect market conditions the price to purchase even temporary patent use will fall between the opportunity costs of the monopolist's loss of the patent and the competitor's expected gain. This price would include the discounted revenue stream from development of the innovation, the benefit the monopolist gains from restricting its competitors, and the expected benefit from future innovation based on the product. These costs would not exist in a normal market without government intervention. In cases where innovation is highly sequential and dependent upon the ability to use and reproduce particular preexisting technologies, the restrictions imposed by patents can dramatically reduce competitors' ability to innovate.[10] To illustrate, the example of gene sequences in the pharmaceutical industry may again prove useful. Because they are not simply a particular molecule, as with

9 Rita Gunther McGrath & Atul Nerkar, *Real Options Reasoning and a New Look at the R&D Investment Strategies of Pharmaceutical Firms*, 25 STRATEGIC MGMT. J. 1, 16 (2004).

10 Jackson, *supra* note 4, at 17.

many drugs, but also a means of conveying biological information, a given gene sequence may have the potential to provide the basis not only for direct treatment, such as gene therapy, but also for diagnoses, genetically targeted traditional treatment, and other potential developments.[11] In many cases, a patented gene sequence or genetic protein can be an effective moratorium on any downstream innovation as there are no substitutes for the information contained in the gene sequence.[12]

When innovation does occur from firms attempting to enter into competition with a patent monopolist, the type of innovation that occurs will also be of a substantially different form than would occur in an unhampered market. When a firm patents a particularly lucrative drug, other firms are unable to compete on the basis of efficiency by discovering alternate production methods or by allocating resources more efficiently within their firm. This drives companies to create "work alike" drugs or products which are distinct from the patented product, but result in the same medical effect. A successful "work alike" drug will enable the competitor to capture a share of the disputed market and consequently diminish of the monopolist's profits. In some cases, these drugs may be even more effective than the original product and become dominant within the market. Lichtenberg and Philipson term this "between-patent competition," distinguishing it from "within-patent competition" which occurs once the patent has expired and the monopolist now competes with essentially identical products, i.e.

---

11 *Id.* at 10.

12 Michele Boldrin & David K. Levine, *The Economics of Ideas and Intellectual Property*, 102 PROCEEDINGS NAT'L ACAD. SCI. 1252, 1255 (2005).

name brand competition with generic products.[13] Between-patent competition creates two contradictory effects relevant to the question of patent effect on innovation. First, it provides a direct incentive for firms to innovate in competition to patent monopolists, since they are able to gain access to the market and a share of profits from lucrative products. Second, it reduces initial incentive to innovate by decreasing the potential profits a patent holder can gain.[14]

The reduction of monopoly profits has an especially important role in reducing the ability of patents to encourage innovation. Between-patent competition can result in as much as twice the reduction in monopoly profits compared to the effect of introducing generic copies of the product when the patent expires.[15] In addition, this reduction can happen far earlier because it does not require the patent to expire. This means that the losses compound over the expected time the drug is on the market. The actual outcome of these two effects will depend on the quality of the initial product and whether the competitors' ability to innovate is restricted by any other factors. Regardless of whether the original monopolist maintains dominant market share or competitors effectively claim the market, competition will be less efficient than in unhampered markets since competitors are still blocked from finding more effective means to produce the original drug.

---

13 Frank Lichtenberg & Thomas J. Philipson, *The Dual Effects of Intellectual Property Regulation: Within- and Between-Patent Competition in the U.S. Pharmaceuticals Industry* 644 (Nat'l Bureau of Econ. Research, Working Paper No. 9303, 2002).

14 *Id.* at 645.

15 *Id.* at 663.

Even with full consideration of the incentives created by intellectual property protections, one cannot come to a determination of patents' net effect without considering the incentive structures that exist in their absence. In some respects, the incentives against innovation intensify without patent protections such as through the reduction of profits from innovation when other firms are able to reverse engineer a product. Yet, many incentives still exist that render it necessary for entrepreneurs to innovate if they wish to stay competitive.[16]

The firm that develops a new drug enjoys an immediate competitive advantage from the fact that they are the only company capable of producing the new product for a period of time until some other firm is able to reverse engineer the product and mass produce it. Assuming a new product is something valued by consumers, temporary technological monopoly guarantees significant profits for the patent holder and provides a means for regaining research and development costs.[17] The principle benefit of a technological monopoly rather than a legal one is that other firms in the industry may displace the monopolist by finding a cheaper or more efficient means or producing the drug, encouraging further innovation. Yet, in the unhampered market this innovation will only be pursued if it is societally beneficial and an efficient use of resources.[18] If the monopolist is not generating substantial inefficiencies by overpricing their good or artificially lowering sup-

16 S. REP. NO. 15 at 80 (1958).

17 Boldrin & Levine, *supra* note 12, at 1252.

18 MURRAY ROTHBARD, MAN, ECONOMY, AND STATE WITH POWER AND MARKET 750 (Ludwig von Mises Institute, 2009).

ply, factors the monopolist uses for innovative competition may be used more efficiently elsewhere. Therefore, without artificial monopoly and monopoly profits created by patents, innovation is more likely to be conducted in an efficient manner to maximize the valued use of scarce resources.

Temporary technological monopoly is not the only benefit for an original innovator. The first firm to enter a market gains a significant first-mover advantage from being able to capture the market through an established reputation. Post-patent competition under the current regime indicates the importance of the first-mover advantage in competition. A 1991 study found that prices for the original drug were not highly responsive to the entry of generic competition, even though generic brands were priced far below the original drug. The brand-name drug's price fell just 4.5 percent for the mean number of generic drugs entering the market, even though the generic drugs may be priced as low as 17 percent of the brand-name drug's price.[19] Another study found that generic drugs never capture greater than 50 percent of a given market, despite being priced far below their name-brand competition.[20] This is admittedly an imperfect situation, since patent protection gives firms a substantially longer time to establish their reputation and therefore likely results in a stronger first-mover effect than would exist without government intervention. However, the striking results indicate that there is a positive and significant advan-

19 Richard E. Caves et al., *Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry*, 1991 BROOKINGS PAPERS ON ECON. ACTIVITY. MICROECON. 1, 44-45 (1991).

20 Boldrin & Levine. *supra* note 12, at 1254.

tage to being the first firm to enter a field. Since this advantage persists despite price disparities between brand-name and generic competition, the historical evidence indicates that without patent protection, innovators would be able to recoup their research costs and maintain a positive incentive for innovation.

In the absence of intellectual property protections, barriers to sequential innovation would be significantly lower. As technology becomes more complex and dependent on specific inputs, the costs of patent restrictions in terms of foregone opportunities rise rapidly. Without patent protections, all firms would be free to use past innovations as the basis of new technologies, products, or services. This dramatically lowers the cost of bringing new innovation to the market. In the computer, software, and semiconductor industries, which are similar to the pharmaceutical industry in that most innovation is both sequential and complementary, these industries experienced high rates of innovation despite historically weak patent protections. When a series of court cases strengthened intellectual property protections, contrary to expectations at the time, research and development spending either remained steady or declined across the industry.[21] This is consistent with what one would expect in an industry that is as dependent on prior innovation as the computer or pharmaceutical industries. Any increased incentive to innovate is countered by decreased opportunity and increased cost as a result of restricted market access.

This analysis is broadly consistent with historical cases of patent reform in the United States where strengthened intel-

21 Bessin & Maskin, *supra* note 5, at 19.

lectual property protections did not lead to substantially greater innovation. In 1980, the Bayh-Dole Act enabled federally funded research institutions such as universities to patent their research and to grant licenses for these patents to other parties.[22] Prior to the act, there were relatively few intellectual property protections afforded to these kinds of institutions. Given the importance of the research university to medical and pharmaceutical innovation in the United States, one would expect the effect on these institutions to be broadly consistent with the effect on the industry as a whole. Coinciding with the implementation of Bayh-Dole was a dramatic increase in patent filings by U.S. universities and efforts to license these patents and a disproportionate share of these were biomedical inventions.[23] However, the increase in patenting and marketing efforts began before the act. This indicates the strengthened intellectual property regime is unlikely to dramatically increase innovation at U.S. research universities, and the change in the composition of university research can be traced to other factors.[24]

While the relationship between innovation and intellectual property rights is necessarily complex and will likely vary with the nature of a given country's research environment, the effect of intellectual property protections is negative given the current state of the U.S. pharmaceutical industry. Patent competition and the overall effect of cooling the research environment through increased innovation cost and restricted market access undermines

22 David C. Mowery & Arvids A. Ziedonis, *Numbers, Quality, and Entry: How Has the Bayh-Dole Act Affected U.S. University Patenting and Licensing?*, 1 INNOVATION POL'Y & ECON. 187, 191 (2000).

23 *Id.* at 193.

24 *Id.* at 214.

much of the positive impact on innovation one would expect from the protection of monopoly profits. In contrast, while a system without patent protection would still face barriers to innovation such as the high costs of pharmaceutical research, existing market phenomena like technological monopoly and first-mover advantage would allow innovators to retain a profit from their invention. The unhampered market would also be able to gain these benefits without distortions created by allowing monopoly profits. Possibly the most important factor in the relationship between patents and innovation is the highly sequential nature of pharmaceutical research. When firms have the ability and incentive to block potential competitors from innovating in all downstream technologies, the results are dramatic and often detrimental. For this reason, strengthening intellectual property protections in industries like pharmaceuticals frequently fails to create positive change in innovative activity. Overall, in the pharmaceutical industry intellectual property protections work in opposition to their intended purpose, deterring research on net and skewing innovation that does occur away from the most efficient use of resources.