



# Perverse Results from Pharmaceutical Patents in the United States

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**Abstract** In the United States, pharmaceutical patents have had a number of perverse and anticompetitive effects on the development and marketing of prescription drugs. Although some of these effects are unique to the United States, others have implications for patent policy across the world. Among the negative effects of drug patents are: (1) examples of misguided, anti-social, and anticompetitive promotion of patented drugs; (2) misguided incentives that push drug firms toward too much or too little research and development in critical areas; and (3) cartel-facilitating conduct linked to patent licenses or settlements of litigation involving drug patents. Some of these issues can be addressed directly through reforms in patent and competition law policy. There is, however, a need for a broader study of the role of patents in promoting drug research. That study should consider alternatives to the patent system, such as a prize system structured to supplement or partially replace patent rewards for pharmaceutical R&D.

**Keywords** Pharmaceutical patents · Patent policy · Competition law policy

## 1 Introduction

Patents are widely used in the pharmaceutical industry. This paper explores the reasons for this wide use and some of the perverse and anticompetitive consequences that often result. The analysis focuses on the United States, where a patchwork of healthcare, advertising and other laws contribute to anticompetitive results. While some of the concerns explored here are unique to the United States, others have relevance to pharmaceutical patents internationally.

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The reasons pharmaceutical firms rely heavily on patents have been explored elsewhere.<sup>1</sup> Higher profits afforded by patents can provide an incentive for a firm to enter and aggressively compete in this vital industry. A higher revenue flow can be used to finance R&D. As is the case with the chemical industry, pharmaceuticals can often be easily reverse-engineered. Trade secret law is unlikely to provide meaningful protection from copying most medications. Some form of exclusivity can offset the high expenses of developing a new drug, testing it to ensure its efficacy and safety, and obtaining regulatory approval. In many cases, this process can last for years and generate very substantial costs.

Once a drug has obtained regulatory approval, the marginal cost of its production and distribution is often quite low, allowing a firm to more easily capture its R&D costs. In many countries, however, price regulation on patented drugs may limit a firm's ability to recoup its R&D costs. In the United States, where there is relatively little price regulation, pharmaceutical firms may set prices that vastly exceed the cost of production and distribution, arguing that these high margins are needed to offset R&D costs. Legislative efforts to reign in high U.S. drug prices are typically met with industry objections that regulation of prices would lead to less cutting-edge research.

There is no question that some of the patent-generated revenues that pharma firms earn are reinvested in R&D for new drugs. Critics point out, however, that R&D expenses are a small fraction of what firms earn. A recent study shows that pharmaceutical firms earn significantly higher profits than a sample of non-drug firms, albeit not out of line with high tech firms generally.<sup>2</sup>

High profits suggest lack of competitive discipline. The large high tech firms (including Microsoft, Google and Facebook) have faced, or are facing, substantial challenges under the competition laws of the United States, the European Union, and other nations. Drug firms that hold substantial patents are supposed to be rewarded with high returns that provide an incentive and financial backing for R&D. A well-designed patent system, however, would result in a high percentage of those returns being directed to R&D. Indeed, this is the standard industry argument for why high prices for patented drugs are justified. In fact, drug companies spend large amounts on R&D, but also spend very substantial amounts, sometimes more than is spent on R&D, on advertising and promoting patented drugs.<sup>3</sup>

The benefit/detriment balance on pharmaceutical patents should include recognition of the general costs of a patent system.<sup>4</sup> At a minimum those costs will include: (1) the costs of administering a patent system (fees for applying for a patent

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<sup>1</sup> Kyle (2016) (describing unique features of the pharmaceutical industry that explain high R&D costs and the wide use of patents).

<sup>2</sup> Big pharma companies earn more profits than most other industries, study suggests, Newsweek (March 4, 2020), available at: [www.newsweek.com/big-pharma-companies-profits-industries-study-1490407](http://www.newsweek.com/big-pharma-companies-profits-industries-study-1490407).

<sup>3</sup> According to one source, firms such as Sanofi and AstraZeneca spend more on promotion than they do on R&D, while others such as Pfizer spend almost as much on promotion as is spent on R&D. RF, Do biopharma companies really spend more on marketing than R&D?, available at: <https://www.raps.org/news-and-articles/news-articles/2019/7/do-biopharma-companies-really-spend-more-on-market>.

<sup>4</sup> Report of the Federal Trade Commission, To promote innovation: The proper balance of competition and patent law policy (2003), available at: [www.ftc.gov/os/2003/10/innovationrpt.pdf](http://www.ftc.gov/os/2003/10/innovationrpt.pdf).

and the cost of running the U.S. Patent and Trademark Office); (2) litigation costs associated with determining the validity and reach of a contested patent; (3) costly attempts of rivals to invent around an existing patent; (4) costs linked to the patent monopoly, including reduced output and wealth transfer effects; (5) rent-seeking conduct to maintain or extend exclusivity; (6) misallocation of resources when the patent rewards result in research that is excessive in some areas and inadequate in others; and (7) cartel-facilitating conduct associated with patent licensing or patent litigation settlements

For pharmaceutical patents, there are reasons to believe that these concerns are substantial, particularly for the last three factors: costs associated with attempts to maintain or extend a patent monopoly, with misallocated resources, and with facilitation of cartel conduct. I address each of these topics in turn.

## 2 Perverse Exploitation of the Patent Monopoly

Any patent holder has an incentive to gain a maximum return during the period of exclusivity granted by the patent. This involves a range of decisions about how to produce, how to price, whether and how to license, and how to advertise and market. Competition law places restraints on some of these decisions. For example, selling a patented product tied to non-patented products can give rise to antitrust liability. In the United States, venerable case law provides at least some guidance on the limits of such tying activity.<sup>5</sup>

In this section, I address some areas in which competition law has not provided clearly delineated guidance that discourages unwarranted exploitation of a drug patent. These include rent-seeking behavior, such as heavy expenses on lobbying, evergreening (the practice of extending the life of patent protection by obtaining new patents on slightly modified versions of a drug); promotion and advertising that favor patented over non-patented products, and invidious price discrimination linked to high prices. All of these practices are intended to increase the profitability of a patented drug but can generate substantial anticompetitive consequences.

### 2.1 Rent-Seeking Conduct

The pharmaceutical industry has consistently been number one in lobbying expenses in the United States. According to one source, for the first three quarters of 2019, pharma had spent \$228 million on lobbying activity in the United States. This amount was nearly twice as much as the industry in second place – electronics manufacturing and equipment.<sup>6</sup> It seems likely that the pharma industry directs substantial portions of this lobbying money to forestall legislative and regulatory initiatives to limit pricing on patented drugs.

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<sup>5</sup> Sullivan et al. (2016) (describing U.S. law governing tying arrangements).

<sup>6</sup> Open secrets, industry lobbying spending (2018–2019), available at: <https://opensecrets.org/news/2019/10/big-pharma-continues-to-top-lobbying-spending>.

## 2.2 Evergreening

Higher profitability for a patented drug is detrimental to sound patent policy only if it increases patent rewards beyond the point that is needed to promote the proper amount of innovation. Determining at what point patent protection is excessive may be impossible. On the other hand, one market-based restraint on exploitation of patents is that the reward should be commensurate with the value of an innovation for society. Another guide is whether a patent monopoly is exploited in a manner that leads to substantial perverse social consequences. To the extent that patent exploitation loosens the link between societal value and patent profitability, or to the extent that these practices disproportionately generate socially undesirable consequences, they will be seen as inconsistent with the legislative intent underlying the patent system.

A recent study of the 12 highest revenue-generating patent drugs for the year 2017 found that, on average, firms had obtained 38 years of patent protection (the range was from 31 to 48 years).<sup>7</sup> The same study concluded that an average of 71 patents had been issued for each of the 12 drugs. By itself, the study does not prove that profits from this extended patent protection were excessive. The study does document, however, that pharmaceutical firms are devoting substantial resources to extending patent protection beyond the base period of exclusivity.

With an average of 71 patents for each of the top-selling drugs, the pharma firms are pursuing a strategy similar to that of patent acquisition entities (patent trolls). These entities do no R&D and typically sell no products. They amass a large number of low-value patents and use them to threaten or extort payments from firms that produce products that may infringe on one or more of their patents. The effectiveness of this strategy rests not with the value of a single low-value patent, but with the collective effect of a large number of low-value patents. The drug firms should not be equated with patent trolls, but their strategy of amassing a large number of low-value patents is similar and probably very effective in deterring a potential generic manufacturer from entering a market, even after the original patent has expired. Of course, not all improvement patents should be viewed as rent-seeking behavior to extend the life of a patent. Improvements in the drugs can make them more effective, easier to administer, or less likely to have harmful side effects. The market could separate meaningful from inconsequential improvements by ensuring that, after expiration of the base period of patent protection, a generic version of the drug is offered pursuant to its original patented formula. Access to the original drug in generic form should discipline prices and give doctors and their patients a choice in deciding whether the improved patented formulas are worth the extra cost. Evergreening undermines the ability of a generic producer to enter and produce a drug pursuant to its original patent formula.

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<sup>7</sup> I-Mak, Overpatented, overpriced: how excessive pharmaceutical patenting is extending monopolies and driving up drug prices, available at: <https://i-mak.org/wp-content/>.

### 2.3 Promotion of Patented Drugs

Evergreening not only extends the period of exclusivity for a drug, it also extends the incentive for firms to focus their advertising and promotion efforts on such drugs. The incentive for pharma firms is to assign promotion resources most intensely to those drugs that are most profitable – inevitably those drugs that enjoy patent protection. Pharma firms devote substantial resources to this end.

Patented hypertension drugs were widely prescribed for high blood pressure until a 2002 study showed that non-patented diuretics were equally effective and performed better in addressing some of high blood pressure's complications.<sup>8</sup> Until that study came out, many doctors, responding to promotion from drug companies' marketing campaigns, assumed that the newly available hypertension drugs were superior. Drug company representatives had little incentive to promote diuretics because those non-patented medications were less profitable.

An even more striking example of misguided promotion was the marketing of patented opioid pain killers that killed tens of thousands of Americans in the last decade.<sup>9</sup> Firms such as Purdue Pharma promoted their patented opioids (such as Purdue's Oxycontin) without adequate warnings about the high risk of addiction and with little or no control over distribution that raised alarm about access for drug addicts. Purdue was criminally prosecuted and ultimately reached a settlement with the U.S. Justice Department requiring it to pay \$8.3 billion to counter some of the effects of drug addiction.<sup>10</sup>

The problem of promoting expensive patented drugs over equally or more effective non-patented drugs will occur in any country where firm representatives have access to the doctors who prescribe. The problem is more acute in a country such as the United States where laws permit the advertising of patented drugs to the general public. Television ads promote a particular medication for treatment of an ailment, with no attempt to provide the public with an assessment of alternative, less expensive medications. After showing videos of happy and active actors endorsing the patented medication, the ads typically end by urging patients to "ask your doctor about this medication."

Advertisements are profitable to firms if they increase sales and profits. Advertisements to the public could increase sales of a patented drug for two evident reasons: (1) physicians who could prescribe the patented drug may be insufficiently familiar with its benefits, a knowledge vacuum that might be addressed by the public advertisements; or (2) the patient pressures an informed physician, based on the advertisements, to prescribe a patented medication that the doctor would otherwise not have prescribed. If the drug firm's goal is to increase physician knowledge, the more direct and efficient way of doing so would be to target promotion efforts directly toward doctors. The advertisements to the general public

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<sup>8</sup> Angell (2004).

<sup>9</sup> NIH, Overdose death rates, available at: <https://www.drugabuse.gov/drug-topics/trends-statistics/overdose-death-rates>.

<sup>10</sup> National Public Radio, Federal Judge approves landmark \$8.3 billion Purdue Pharma opioid settlement, available at: <https://www.npr.org/2020/11/17/936022386/federal-judge-approves-landmark-8-3-billion-purdue-pharma-opioid-settlement>.

seem better suited to increase patient pressure on the physician. Not all physicians will yield to patient pressure, particularly if a principled doctor has doubts about the wisdom of prescribing a particular medication. On the other hand, some doctors anxious to please may yield to the pressure, ensuring that the consumer ads lead to increased profits for the drug firm.

## 2.4 Invidious Price Discrimination

Studies of prices of patented medications in the United States show rapid increases in prices over the past several decades. Price increases are typically linked to a system of price discrimination that charges uninsured patients the highest prices. This sort of invidious price discrimination that targets the most vulnerable members of society is aptly illustrated by the pricing of rapid-acting insulin in the United States.<sup>11</sup>

Three large pharmaceutical firms dominate the rapid-acting insulin market. Rapid-acting insulin is essential for millions of diabetes patients. Each of the three firms rapidly increased U.S. prices during the two decades following introduction of their product.<sup>12</sup> Of course, not all U.S. patients had to pay the extremely high list price. Those with adequate health insurance, and patients covered under certain government health insurance plans, paid far less. In addition, the drug companies themselves launched programs to provide free insulin for those demonstrating financial need. Even with these adjustments, that still left millions of diabetes patients with no insurance, or inadequate insurance, facing crippling costs to afford their rapid-acting insulin. Many responded by travelling to Canada or Mexico to purchase the same insulin at roughly 10% of what they would have paid in the United States.<sup>13</sup>

The pricing scheme followed by the three insulin manufacturers was relatively straight forward. Set a very high list price, but allow for discounts to powerful health insurance companies or government purchasers. Health insurance companies sought assistance from prescription benefit managers (PBMs) in negotiating prices. A PBM's leverage is enhanced because of its ability to include or exclude a particular medication from a list of approved drugs covered under a health insurance policy.<sup>14</sup>

Health insurance firms in the United States pay PBMs by giving them a percentage of the savings the PBMs negotiate (savings are measured by the amount of discount off the list price of a pharmaceutical). This gave PBMs a perverse incentive to support a high list price for a medication in order to claim a higher fee from health insurance companies. The key point is that uninsured or under-insured patients were the most vulnerable group and it was they who would be stuck with paying the high list price. As a matter of social policy, this is a decidedly perverse

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<sup>11</sup> See Warren Grimes, Invidious price discrimination in the sale of rapid-acting insulin: is there an antitrust remedy? [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3433305#](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3433305#).

<sup>12</sup> *Id.*, at 3–4.

<sup>13</sup> *Id.*, at 5–6.

<sup>14</sup> *Id.*

result. Similar invidious price discrimination achieved through tying conduct has been condemned under the Sherman Antitrust Act.<sup>15</sup>

### 3 Misallocation of Research and Development Resources

Pharmaceutical patents provide a substantial incentive for R&D, but that incentive operates most strongly for medications that must be taken frequently. Palliative drugs, for example pain killers, address the symptoms of a medical condition without curing it. Statin drugs are another example. Widely prescribed in the United States to reduce the amount of harmful cholesterol in the blood, these drugs do not address the underlying conditions that lead to high levels of harmful cholesterol, only its symptoms. As a result, a patient with high cholesterol levels may end up taking the drug for the rest of their life. Not surprisingly, drug firms have devoted substantial resources to develop new statin drugs.

This level of research on cholesterol-reducing drugs may or may not be appropriate. What is clear is that the patent system gives drug firms a much reduced incentive to invest in research for preventive drugs (such as vaccines) or curative drugs (such as antibiotics) that are administered far less frequently. As a matter of social policy, this is not a desired result. Medications that prevent disease or cure disease could produce a more socially desired result than medications that are merely palliative.

The international response to Covid-19 provides a further example of the limitations of a patent reward system. Governments or educational institutions have stepped in to subsidize vaccine development. The U.S. Government has pledged \$2.5 billion to finance Moderna's vaccine.<sup>16</sup> Pfizer, through its partner BioNTech SE, received \$454 million from the German government to finance its vaccine.<sup>17</sup> AstraZeneca developed its vaccine with Oxford University, and with the help of \$1 billion from the U.S. Government.<sup>18</sup> Many of these subsidies were given in return for a commitment to supply minimum numbers of discounted vaccine doses to the pledging government.

Of course, the firms developing these vaccines expected to receive exclusive rights through the patent system. Patent protection by itself, however, would not likely have provided a sufficient incentive for the firms, on an accelerated basis, to devote extensive resources to develop, test, and obtain regulatory approval of the Covid-19 vaccines. Instead, the major incentive came in the form of direct subsidies or advance payments from governments. The taxpayers who are burdened with these huge government expenditures may, once the discounted quantities are gone,

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<sup>15</sup> *Id.*, at 7.

<sup>16</sup> Early data show Moderna's Coronavirus vaccine is 94.5% effective, NY Times, Nov. 16, 2020, available at: [www.nytimes.com/2020/11/16/Covid-moderna-vaccine](http://www.nytimes.com/2020/11/16/Covid-moderna-vaccine).

<sup>17</sup> Germany funded the development of Pfizer's Covid vaccine – not U.S.'s Operation Warp Speed, available at: <https://Fortune.com/2020/11/09/Pfizer-vaccine-funding-warp-speed-germany/>.

<sup>18</sup> AstraZeneca receives \$1 billion in U.S. funding for Oxford University corona virus vaccine, available at: [www.cnbc.com/2020/05/21/coronavirus-us-gives-astazeneca-1-billion-for-oxford-vaccine](http://www.cnbc.com/2020/05/21/coronavirus-us-gives-astazeneca-1-billion-for-oxford-vaccine).

end up paying a higher price for the vaccines. One might legitimately question whether vaccines substantially subsidized by governments should result in grants of patent exclusivity to the developing firms. Developing countries lack the resources to pay the high prices demanded by the vaccine developers, provoking requests to the WTO to waive intellectual property protection for the patented vaccines.<sup>19</sup> While these developing nations paid little or nothing to aid in the development of the vaccines, their well-being is ultimately connected to the rest of the world through travel and trade.

#### 4 Cartel-Facilitating Behavior

Cartel conduct has a long history in the patent world. For drugs, the incentive for cartelization is strongest when there is chemical identity between products, as is likely to be the case with generic substitutes for patented drugs. In addition, there has long been the risk of cartelization in connection with cross-licensing among drug firms.

As a general matter, patent licensing need not raise antitrust issues. A non-exclusive license to manufacture and sell a drug, with no restrictions on quantity or price, is unlikely to trigger antitrust scrutiny. More complex licenses that restrict quantity and pricing can, at least in some cases, be problematic. Many of the highest risk licensing practices involve cross-licensing among actual or potential rivals.

Cross-licenses can be an essential part of a procompetitive standardization agreement, or can also be part of a resolution of patent litigation. They can be problematic, however, when they result in a reduction of competition among horizontal rivals, or when they diminish incentives for future research.<sup>20</sup> In the pharmaceutical industry, a focal point has been the use of settlements in litigation to resolve patent disputes. In particular, weak patents that have been challenged by rivals have resulted in reverse payment settlements: the challenging firms are in effect paid by the holder of a weak patent to stay out of the market for a period of years. In *FTC v. Actavis*,<sup>21</sup> the U.S. Supreme Court held that the FTC could pursue a reverse payment settlement which resulted in a patent holder paying generic rivals to stay out of the market during a period slightly shorter than the period of patent exclusivity. In return, the generic rivals would be given cash or non-cash benefits.

This arrangement, if it were allowed, would open the door to pharmaceutical firms choosing to file even a very weak patent, effectively inviting rival firms to challenge the patent in court, and using a settlement as an excuse for orchestrating a cartel. The incentive for this conduct is large because generic producers are often manufacturing a chemically identical drug that cannot easily be distinguished through brand marketing. Although litigation concerning the reach of *Actavis*

<sup>19</sup> Vaccine race could leave all nations behind, LA Times, A1 col. 4, Dec. 27, 2020 (disclosing that India and South Africa have asked the WTO to waive intellectual property protection for the Covid-19 vaccines).

<sup>20</sup> US Department of Justice and Federal Trade Commission (1995).

<sup>21</sup> 570 U.S. 136 (2013). See *Impax Laboratories, Inc. v. FTC*, F.3, 2021 WL 1376984 (5th Cir. 2021) (applying *Actavis*).



continues, the Supreme Court's decision allows enforcers a tool for blocking blatant cartelization conduct under the guise of a patent litigation settlement.

## 5 Conclusion

Some of the anticompetitive consequences flowing from patent use in the pharmaceutical industry are unique to the United States. Invidious price discrimination associated with patented drugs can be addressed by allowing a government-sponsored or controlled health provider to negotiate non-discriminatory drug prices on behalf of all citizens. The use of television or other public advertisements to pressure physicians to prescribe a patented drug can be addressed by a prohibition on such advertisements. Other problems with patent use may be more difficult to address and have international ramifications.

For example, evergreening practices that extend patent life beyond the base protection period are not limited to the United States. Pharmaceutical firms worldwide are likely to promote the use of profitable patented drugs (over non-patented alternatives) through their sales representatives who work directly with doctors. A more substantial question is whether the patent system is adequately rewarding the right kind of drug research.

Patents generate a substantial incentive for drug firms to invest in palliative drugs that must be taken repeatedly to address symptoms, but a far less robust incentive to invest in preventative or curative drugs. Governments have implicitly recognized this shortcoming. The massive expenditures by wealthy governments in Covid-19 vaccine R&D are a powerful example of the inadequacy of patent rewards in generating needed vaccines in a health crisis. This raises a number of questions that deserve further attention. Should a vaccine that is developed primarily at government expense still result in full patent protection for the developing firm? In a world in which diseases do not respect national boundaries, should patent-holding drug firms be permitted to charge discriminatory high prices to nations lacking the resources to subsidize drug research?

The Covid-19 pandemic points to a generalized weakness in the patent system as it relates to pharmaceuticals. Most patent systems invite bipolar results: either a patent is valid, or it is not valid. The period of patent protection is fixed and cannot be adjusted based on the value of the invention for society. Methods of exploiting the patent tend to be predetermined by existing statutory or case law. There is little room for a more flexible or nuanced system of rewarding valuable R&D.

When it comes to promoting drug research, governments have already moved away from exclusive reliance on the patent system. In the United States, the National Institutes of Health, a government agency, subsidizes certain medical research. These schemes, however, have been somewhat haphazard. Designing an overall system for rewarding medical R&D deserves more serious reflection and analysis. It is time to consider alternative ways of rewarding valuable R&D, such as a prize system, perhaps funded by nation states or by the WHO.<sup>22</sup> Disinterested

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<sup>22</sup> Nicholas (2014) (suggesting the possibility of a prize system to reward socially valuable research).

scientists or academics could be charged with awarding the prize funds for worthwhile research. Such a system might partially replace the patent system or be supplementary to it.

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