THE ECONOMIC EFFECTS OF PATENTS IN THE PHARMACEUTICAL FIELD

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Abstract: *In economic and political circles, discussion about patents has reached an all-time high. Despite this academic development, many businessowners and policymakers seem to feel the necessity of more effective policies concerning the matter. This paper will discuss several prominent arguments regarding patents in the pharmaceutical industry, inside and outside of the academic field. Economic theory and empirical evidence will explain where the arguments presented are incorrect or misrepresentative. This analysis will provide a basis for the claim that pharmaceutical patents are ineffective at best and, at worst, harmful to innovation.*

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Section 1A: Introduction to Patent Law

Professionals in the medical field often argue that in order to sustain and promote economic innovation in the pharmaceutical industry, governing bodies must protect patents across the market. For instance, Advil PM, a common drug classified as a "[n]onsteroidal anti-inflammatory drug," is protected by three patents and owned by GlaxoSmithKline. Before discussing this claim's validity, some clarification is required. The U.S. Code defines the exact nature of a patent:

> A right granted to the inventor of a (1) process, machine, article of manufacture, or composition of matter, (2) that is new, useful, and non-obvious. A patent is the right to exclude others from using a new technology. Specifically, it is the right to exclude others from making, using, selling, offering for sale, importing, inducing others to infringe, and/or offering a product specially adapted for practice of the patent.[1]

This paper particularly concerns itself with patents as government grants of monopoly privilege over the production of pharmaceuticals. One claim commonly made in the medical profession is that medical innovation requires

1 Content and Term of Patent: Provisional Rights, 35 U.S.C. § 154 (a) (2013).

the granting and enforcement of monopoly privileges. While patents increase profits for pharmaceutical innovators, they establish perverse incentives for innovation in the medical field overall. The evidence and economic theory are clear: patents, unnecessary to spur initial investment into research, halt future innovation and drive misallocation through pervasive rent-seeking behavior.

Section 1B: Common Arguments for Patents

There are two key arguments for the existence of and need for patents in the medical field. The first asserts that intellectual property rights should be protected like any other property rights, such as from theft of a house or car. This argument appears in the United Nations' *Universal Declaration of Human Rights,* which states, "[e]veryone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author."[2] Though significant, this argument's normative considerations exceed the scope of this paper.

Proponents of another argument for patents reason

2 G.A. Res. 27 (II), A Universal Declaration of Human Rights (Dec. 10, 1948).

that "without patent protection and regulatory exclusivity… innovators would be unlikely to make the substantial investments required to bring new drugs to market."[3] This claim assumes that, without patents protection for new medicines, the opportunity cost of developing a new drug is higher than the relevant alternatives. Additionally, some argue that capital assets could better be allocated elsewhere in a free market. Proponents of this view believe that, after the costs of investment into the technology of a new drug have sunk, the risks of competing with others are too high. They argue that whoever funded research and development would have to price their version of the drug substantially higher than competitors who were able to avoid those costs. Consequently, the original developers would not be able to make a profit. As a result, innovators would lack the proper incentives to invest in research and development for potentially life-saving drugs. Thus, proponents of patents conclude that these monopoly grants are necessary to ensure that people who are capable of creating these drugs will

3 Iain Cockburn, *The Importance of Patents to Innovation: Updated Cross-Industry Comparisons with Biopharmaceuticals,* 25 Expert Opinions On Therapeutic Patents, 739-742 (2015).

engage in development.

Section 2A: Patent's Effect on Future Innovation

Pro-patent groups often err in their assumptions about the amount of innovation occurring once the patent process is completed. Patents remove the incentive to innovate beyond the current point of development. Furthermore, the law prevents continuing research and development on the patented medicine. In a truly free market, alternatives drive innovation. If people demanding a certain cancer-curing drug may buy from multiple suppliers, then they will choose to purchase the least expensive option. One way a company can raise their price is by creating a superior drug, which differentiates their product from other cancer-curing medicines.

Section 2B: Innovation from Patent Holders

If a cancer-curing drug is patented, then there is little incentive for the supplier to create a superior product as no direct alternative to the drug exists. Since no new drug may enter the market, the opportunity cost for further innovation rises. Michele Boldrin and David Levine, in their paper *Against Intellectual Monopoly,* explain this phenomenon,

arguing that

> new drugs are also extremely costly to develop. Hansen, Grabowski and Lasagna, in 1991, provide the following estimates of the cost in millions of dollars of bringing a 'new chemical entity' to market, assuming a success rate of 23% for patented drugs.[4]

Bringing a new drug to market poses a high risk accompanied by potentially little reward. When an entrepreneur holds a patent, the cost of development significantly outweighs the potential increase in price from new drug innovation. Because those entrepreneurs do not have to account for potential competitors, they can already charge a high price for the good. Thus, the benefit they would gain from the small price increase of a new good is negligible. In a market without patents, however, the incentive to differentiate your product lowers the opportunity cost of the risk. The entrepreneur must innovate, providing higher quality drugs, in order to profit.

Section 2C: Innovation from Non-Patent Holders

As the situation stands, nothing incentivizes an

4 Michele Boldrin & David Levine, Against Intellectual Monopoly, 2 (2005).

innovator to make a better drug. However, granting patents causes other issues. Under current patent law, only the initial producer may lawfully invest in further research and development for a given drug.[5] This law prohibits potential researchers from further developing a patented drug. Thus, if a patent holder is unwilling to innovate their product, then little to no innovation will occur.

Section 2D: Patent Enforcement Effect on Italy

If the pro-patent position is correct, then countries with patent protection on pharmaceutical drugs should develop further and outperform the countries that do not protect these developments. Analysis of Italy from 1961-1983 suggests that the opposite is true. Up until 1978, Italy had prohibited pharmaceutical patents and the enforcement of foreign claims. Before this change, Italy was the fifth largest producer of pharmaceuticals, having discovered 9.28% of the world's new active chemical compounds. From 1980 to 1983, following Italy's adoption of patents, their discovery of chemical compounds dropped to 7.50%

5 Content and Term of Patent: Provisional Rights, 35 U.S.C. § 154 (a) (2013).

of the world's discovery.[6] Given the large quantity of new active chemical compounds discovered each year, 2% is a considerable decrease. This data shows the negative impact patent protection can have on the pharmaceutical industry.

Section 3A: Patent Necessity for Pharmaceutical Innovation

Thus far, this paper has assumed that patents are necessary to encourage the initial innovation of pharmaceuticals. These assumptions, however, must be tested. As mentioned previously, some claim that the costs of research and development for new drugs are so high that no innovation would be possible without the protection of cost recuperation.

When arguing for patents, some commentators assume that an entrepreneur only engages in a venture if they profit more than the other companies in the market—but this is not the case. Entrepreneurs pursue ventures when they expect to receive benefits of greater value than their own relative alternatives. They base their actions in the market upon a cost-benefit analysis that weighs their own options

6 BOLDRIN, *supra* note 1, at 8.

and opportunity costs, not whether they will make more profit than others will. If entrepreneurs truly based their actions on the latter method, then the market would not—as it does—include a multitude of different brands spanning so many industries.

Some claim that the high costs associated with new drug research would prevent innovators from making up the necessary costs and covering their expenses because their competitors would not face the same investment requirements. Advocates of patents often point out that, in the early 2000s, the average cost of research for the development of a new drug was approximately $1.2 billion.[7] This sum of money, while large, does not necessarily preclude the possibility of entrepreneurial profit.

The price of entry into a new market and the risks of expensive research investments are simply components of the cost structure. By default, an entrepreneur must consider a number of expenses, such as property taxes, material costs, and labor costs. When an entrepreneur enters a market,

7 Berry Werth, *A Tale of Two Drugs,* MIT Technology Review, (Dec. 2019) https://www.technologyreview.com/s/520441/a-tale-of-two-drugs/.

they expect to pay those costs and allocate their resources accordingly. The argument for patents claims that because fixed costs differ between an entrepreneur who invests in research and development and a competitor who does not, the government should insulate entrepreneurs from competition. However, this line of argumentation could apply to any fixed costs, such as property taxes or salary wages. By this logic, if one entrepreneur were to pay a lower price for their property than a competitor, then the government ought to protect the competitor with the higher fixed costs. Obviously, the government does not protect competitors in such cases. The responsibility rests on the entrepreneur to plan for costs associated with property.

Section 3B: Research and Development in Other High-Cost Fields

While the costs of research and development may be high, entrepreneurs are capable of accounting for them. For instance, though not protected from competitors, Tesla Motors, Inc. nevertheless invests a great deal of capital in innovation. In the year of 2018 alone, Tesla spent approximately $1.5 billion on research and development.

The costs do not appear to have overwhelmed the company, considering its global status as the most successful and best-known electric car manufacturer.[8] Furthermore, Tesla, and other companies owned by Tesla CEO Elon Musk have vowed not to restrict the usage of any of their previously patented ideas or initiate patent lawsuits against persons using their ideas. In 2014, Musk stated,

> "If we clear a path to the creation of compelling electric vehicles, but then lay intellectual property landmines behind us to inhibit others, we are acting in a manner contrary to that goal. Tesla will not initiate patent lawsuits against anyone who, in good faith, wants to use our technology."[9]

Despite this lack of protection from competitors, Tesla still managed to make a net profit around $440 million in the last two quarters of the 2018 fiscal year.[10] While Tesla did receive government subsidies that same year, the money

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8 I. Wagner, *Tesla's Research and Development Expenses from FY 2010 to FY 2018,* STATISTA.COM, (Aug. 23, 2019) https://www.statista.com/statistics/314863/research-and-development-expenses-of-tesla/.

9 Elon Musk, *All Our Patents Are Belong To You,* TESLA MOTORS INC. (June 12, 2014) https://www.tesla.com/blog/all-our-patent-are-belong-you.

10 Sean O'Kean, *Tesla Posts Back-to-Back Profits for the First Time,* THE VERGE (Jan 30, 2019) https://www.theverge.com/2019/1/30/18203886/tesla-earnings-q1-revenue-profit-record-model-3.

did not confer an advantage over their direct competition. In 2018, Tesla received around $4,918,326 in government subsidies, while General Motors received $494,035,990.[11] While proving that Tesla does not operate in a truly free market, these subsidies do not discount the evidence that entrepreneurs who invest in their own research and development can profit, even without patent protection.

These profits contradict the argument that patents are necessary to spur initial innovation. Costs of research and development for a new medicine are about $1.2 billion over the whole period of research. By contrast, in a single year, Tesla sunk $1.5 billion in research and development. High research and development costs and a lack of protection from competition did not prevent Tesla from innovating. The risks associated with innovation are simply another type of fixed cost that entrepreneurs must consider, in the motor industry or the pharmaceutical field.

Section 4A: Rent-Seeking Behavior with Patents

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11 *Parent Company Name General Motors: Subsidy Tracker Parent Company Summary,* GOOD JOBS FIRST,(last visited April 2020) https://subsidytracker.goodjobsfirst.org/prog.php?parent=general-motors; *Parent Company Name Tesla Inc: Subsidy Tracker Parent Company Summary,* GOOD JOBS FIRST,(last visited April 2020) https://subsidytracker.goodjobsfirst.org/prog.php?parent=tesla-inc.

In addition to being unnecessary for initial innovation, the patent institution is rife with rent-seeking behavior and perverse incentives. These problems further hinder the effectiveness of patents in the pharmaceutical field. Rent-seeking, as defined by Michele Boldrin, occurs when "abundant skills and resources are invested in keeping the competitive advantage by turning the innovation into a monopoly…through various forms of legal exclusion."[12] Rent-seeking behavior misallocates resources and draws them from more-productive sectors in order to secure future profits. The use by an entrepreneur of legal means, such as patents, to prevent competitors from using their discoveries and competing with their product exemplifies rent-seeking. By definition, then, patents are a form of rent-seeking. They also bring about future misallocation when patent-holders attempt to further abuse the process.

The rationale of patents is that they protect the innovator from competition for a time so that they can recoup their higher cost of investment. Currently, within

12 Michele Boldrin, *Rent-Seeking and Innovation,* FEDERAL RESERVE BANK OF MINNEAPOLIS STAFF REPORT 347, (Oct. 1 2004) https://www.minneapolisfed.org/research/sr/sr347.pdf.

the pharmaceutical field, most countries allow innovators to hold the monopoly for twenty years. However, if certain conditions are met, then innovators may extend this period by five years.[13] Unsurprisingly, patent-holders often find ways to extend this time period past its due, expending resources in the process. This tactic falls under the classification of evergreening, which refers broadly to any means taken by an entrepreneur to extend the duration of their patent, thus prolonging their monopoly privilege.

Section 4B: Rent-Seeking by AstraZeneca

In the pharmaceutical industry, evergreening often takes the form of re-patenting existing drugs. From 1989-2000, only 23% of all drugs approved by the FDA contained new active ingredients and offered significant clinical benefits relative to their existing pharmaceutical alternatives.[14] The rest of the drugs approved in this period were simply re-patented versions of existing drugs, submitted to extend their patent period by another twenty years. This process was costly, using resources that might have contributed to

13 *How Long Does a Drug Patent Last?,* Upcounsel, (accessed Dec. 2019) https://www.upcounsel.com/how-long-does-a-drug-patent-last.

14 Boldrin, *supra* note 4, at 10.

the innovation of a more efficient drug. Instead, the resources were spent extending patent periods and re-monopolizing products. This re-classification process clearly misallocates resources and misuses the patent system in order to secure future transfers. Clarinex and Claritin, which are both produced by Schering-Plough, and Nexium and Prilosec, both produced by AstraZeneca, all used re-patenting:

> If the report doesn't convince you, just turn on your television and note which drugs are being marketed most aggressively. Ads for Celebrex may imply that it will enable arthritics to jump rope, but the drug actually relives pain no better than basic ibuprofen; its principal supposed benefit is causing fewer ulcers, but the FDA recently rejected even that claim. Clarinex is a differently packaged version of Claritin, which is of questionable efficacy in the first place and is sold over the counter abroad for vastly less. Promoted as though it must be some sort of elixir, the ubiquitous "purple pill," Nexium, is essentially AstraZeneca's old heartburn drug Prilosec with a minor chemical twist that allowed the company to extend its patent. (Perhaps not coincidentally, researchers have found that purple is a particularly good pill color for inducing placebo effects.)[15]

15 *Id.*

Well-known companies—not just little-known companies selling rare drugs—engage in this pervasive rent-seeking activity. The patenting process itself incentivizes behavior that extends monopoly privileges by legislative means. A monopoly is a powerful tool for producers, and the incentive to extend that government-granted power is proportionally powerful.

Section 5: Conclusion

The patent process fails in multiple regards. Even if patents are necessary for initial innovation in the pharmaceutical industry, the process itself halts any future development. The process removes producer incentives to make further innovations and forbids competitors from doing their own research and possibly improving the existing drug. More importantly, patents are not necessary to spur innovation in the first place. Entrepreneurs already put the risk of researching a drug into their cost structure and calculate accordingly. The patent structure incentivizes companies to use their capital resources to keep a monopoly rather than to innovate and push ahead of competitors. Those desiring to encourage innovation, develop new cures, and

improve existing drugs should not expect pharmaceutical patent policy to advance these goals.