Patent Protection in the Pharmaceutical Industry: Blessing or Curse?

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Adrienne C. Eaton

Matrikel-Nr. 532035
Klopstockstraße 17, 10557 Berlin aeaton63@gmail.com
(0163)729-7370

Prüfer: Prof. Dr. Christian Schade

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Abstract

This thesis examines and summarizes a number of empirical studies addressing patent protection in the pharmaceutical industry and its effects on innovation in the last few decades of the 20th century in the U.S. and Europe. Based upon the results of the studies we come to the conclusion that increases in the strength of patent protection have little or no influence on innovative activity in the pharmaceutical industry.

In dieser Arbeit wird eine Reihe von empirischen Studien behandelt und zusammengefasst, die sich mit dem Patentschutz in der pharmazeutischen Industrie und deren Auswirkungen auf Innovation in den letzten Jahrzehnten des 20. Jahrhunderts in den USA und Europa befassen. Basierend auf den Ergebnissen der Studien kommen wir zu dem Schluss, dass Erhöhungen der Stärke des Patentschutzes wenig oder keinen Einfluss auf die Innovationstätigkeit der Pharmaindustrie haben.

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List of Abbreviations

FDA	Food and Drug Administration
IMD	Incrementally Modified Drug
NME	New Molecular Entity
PhRMA	Pharmaceutical Research and Manufacturers of America
R&D	Research and Development
U.K.	United Kingdom
U.S.	United States of America

Patent Protection in the Pharmaceutical Industry

1. Introduction

"Drug patents are good for our health," proclaims the website for the Pharmaceutical Research and Manufacturers of America, or PhRMA, the trade group for the U.S. pharmaceutical industry (PhRMA 2012a). According to the group, patent protection is absolutely necessary to fuel the fire of innovation that brings life-saving drugs to the world market. In fact, they argue that any threat to existing level of patent protection would be "in no one's interest."

The idea that patents promote innovation is widespread and generally accepted. By extension, it is often assumed that strengthening patent protection will produce more innovative activity, or likewise that weakening protection will threaten innovation, as argued by PhRMA. Why should patents foster innovative activity? The research and development, or R&D, necessary to produce an innovation can be time-consuming, expensive and risky. Some type of incentive is necessary to convince innovators to take on these risks and costs and to give them surety that the results of their efforts will bring them reward. That an innovation can be sold profitably is usually not incentive enough, as it could be copied and sold by someone else at a lower price. Patents solve this problem by granting an exclusive right to the sale and use of innovative output. An innovator can therefore be more assured of profit resulting from his efforts and should be more likely to undertake such efforts in the first place.

According to the pharmaceutical industry, the "average" new drug costs over $1 billion to create.[1] In addition, ten to fifteen years of development and testing are required before a typical drug arrives on the market (PhRMA 2012b). Pharmaceutical companies are therefore very interested in

[1] These costs are hotly contested and could be far lower (Angell 2004, p. 42-46; Light and Warburton 2011)

protecting the profits they expect to gain from their extensive investments. As shown by the statements of its trade group, the industry views patent protection as absolutely necessary for protecting these profits and ensuring continued innovative activity.

This view is unsurprising, as the pharmaceutical industry has had consistently high profits to protect. In fact it had much higher profits as percent of revenue than other fortune 500 firms for all of the latter half of the 20th century (NIHCM 2000). The existence of these impressive profits has lead many critics of the industry to point out that pharmaceutical patent protection is too strong. They argue that drugs under patent are typically sold for prices far higher than the costs of manufacturing them, thus raising healthcare costs and making life-saving drugs unavailable to those who need them. They also make the case that the industry is using the profits gained from strong patent protection not on developing innovative new drugs, but instead on aggressively marketing existing drugs with the hopes of turning them into "blockbusters" with billion dollar sales.

Critics also argue that despite having plenty of incentive in the form of strong patents and steady profits, the pharmaceutical industry is becoming less innovative. A common critique is that pharmaceutical companies are producing a great number of so-called "me-too" drugs. These are drugs considered to be very similar to existing drugs, offering no new breakthroughs or greatly improved therapies and therefore being a waste of R&D resources that could be used for discovering a wider range of therapies. It is also argued that pharmaceutical firms are taking advantage of patent regulations to protect minor improvements on existing drugs, thereby extending the protection on old innovations without creating new ones (see Angell and Relman 2002, NIHCM 2002a). In other words, critics make the case that strong patent protection has not created an incentive to produce innovative new drugs, but instead is hindering innovative activity in the pharmaceutical industry.

This paper evaluates the role of patent protection on innovation and competition in the pharmaceutical industry in the latter half of the 20th century in the U.S. and Europe. We will discuss a number of empirical studies that shed light on some of the fundamental questions regarding the issue. First, we look at the nature and purpose of patent protection and how it shapes pharmaceutical competition. Next, we examine these types of competition, defined as generic and therapeutic, in more detail and look at some of the factors determining their extent, such as pricing policy and marketing. We also examine the "me-too" phenomenon closely and analyze racing behavior in the industry. We then investigate the effectiveness of patents, their actual use in manufacturing industries, and their importance to the pharmaceutical industry. Finally, we look for evidence of any effect of strengthened patent protection on innovation in industry in general and pharmaceuticals in particular.

In conclusion, we do not find that increases in the strength of patent protection have a positive effect on innovation in the pharmaceutical industry. While there may be a minimum level of patent protection needed, it is in no way apparent that further increases in patent strength would lead to the production of more innovative drugs. A complex combination of forces acts upon competition in pharmaceuticals, of which patent protection is only one part. For this reason, pharmaceutical companies rely on a number of other means to protect their profits. We find that patent protection is not the only means of maintaining incentive in the industry, and conclude that any lack of innovation in pharmaceuticals is not due to a lack of incentive to create it.

2. Patents and Competition in Pharmaceuticals

Before beginning an objective discussion of the implications of patent protection on pharmaceutical innovation, it is first necessary to look at the motivation behind patent protection in general, as well as at the nature of patents and their effect on the pharmaceutical industry in particular.

When a new technology is protected by a patent, that patent grants to its holder the exclusive right to the use and sale of the respective technology for a set period of time. In other words, a patent gives its holder a monopoly on the sale and use of his innovations. Therefore, a patent-holder selling an innovative product can charge higher prices than would be possible in a competitive market and enjoy the increased profits for the duration of the patent (Cabral 2000, p. 303).

Governments grant patents with the intention that the potential profits will provide incentive for innovators to create valuable new technologies in order to make them available to the public through sale or licensing. This idea rests on the assumption that if an innovator believes others will copy and profit from his innovation, he might have no incentive to create it. Patent protection should counter this disincentive.

Patents also offer an additional social benefit: the disclosure of the patented technology. The patent approval process requires that the protected technology be published in such a manner that anyone "skilled in the art" or, more precisely, any typical specialist in the industry, could reasonably reproduce it. This disclosure requirement is intended to spur further innovation, as the new technology is then available for others to build upon.

There is, however, a negative side effect to patent protection: higher prices mean that fewer consumers have access to the patented technology. In economic terms, these lost sales are called *deadweight loss* (Scotchmer 2004, p. 36). From an economist's perspective they reflect a market distortion, an aberration from perfect competition resulting from the patent monopoly, which has the sound of a neat theoretical problem.

But in the context of the pharmaceutical industry monopoly power and deadweight loss are not simply signals of market distortion, but instead represent an ethical problem: if there is no incentive to discover new drugs, lives will not be saved, yet if new discoveries exist but are not available to

those who need them, lives will still not be saved! The role of patent protection in the pharmaceutical industry is hotly debated for this reason. The debate involves two opposing views: the pharmaceutical industry claims that strong patent protection leads to greater returns on innovations and therefore greater incentive to create innovative drugs, while public health advocates claim that strong protection leads to reductions in access to medications as well as to high public and private costs (see NIHCM 2000).

Since the debate centers around the strength of patent protection, it is necessary to have a means of describing and measuring such strength. Typically this is seen as a two-dimensional problem, where the protection is described by the length and breadth of the patent (Scotchmer 2004, p. 103). The first dimension, patent length (or duration), is easily quantified and described: it is typically measured in years and describes the length of time that an innovation has legal protection from imitation. Because it is so well defined and can be determined beforehand, making changes to patent length is a favorite mechanism of policymakers when they wish to adjust the strength of patent protection.

The second dimension, patent breadth (or scope), is more difficult to measure and to describe. Breadth can be generally defined as the degree to which similar technologies would be considered infringements upon a patented technology. Although it can be partially determined by a patent office when a patent is approved, a patent's breadth is in practice only fixed after the fact, when a court rules in favor of or against a potential infringer. For this reason it is difficult for policy makers to regulate patent breadth, and even more difficult for researchers to measure changes in it (see Lerner 2009, p. 343).

This two dimensional nature of patent protection determines the nature of competition experienced by a marketed drug, and allows the competition to be classified as either *generic* or *therapeutic*.

Generic competition occurs only after the expiration of the drug's patent and is thus greatly affected by patent length. Generic drugs are essentially copies of already existing brand name drugs. This means that they are close enough in formulation that they would infringe upon the brand name drug's patent if it had not already expired. The longer the patent length, the longer the brand name drug enjoys freedom from generic competition.

Therapeutic competition is the competition between drugs belonging to the same *therapeutic class*. A therapeutic class is a collection of drugs that treat a specific disease or condition in a similar way. For example, the group of cholesterol-lowering drugs called statins is a therapeutic class. Drugs within the same therapeutic class are dissimilar enough to warrant their own patents, yet are similar enough that they are often considered competitors in the same market. The extent of this type of competition is influenced by patent breadth, and just as patent breadth is difficult to describe and to measure, so is therapeutic competition (Caves, Whinston and Hurwitz 1991, p. 20). Drugs within the same class can sometimes be substitutable and sometimes not, nor must one therapeutic class be exactly congruent with one market. As we will see, the ambiguities inherent in therapeutic competition fuel the debates surrounding pharmaceutical innovation and differentiation between drugs.

In order to better understand the intended and actual effects of patent policy on the pharmaceutical industry, an examination of the nature of both types of competition is useful. We now discuss the two in turn, focusing on several empirical studies devoted to each topic.

3. Generic Competition

The study of generic competition can give clues about the effects of patent protection through direct observation of what happens when that protection is removed. Also, because generic competition is strongly affected by policies governing patent length, pricing, and substitution, its study further clarifies the role of policy measures in shaping pharmaceutical competition.

A generic drug is allowed to enter the market only after the patent for the brand name, or original, drug has expired. Ideally, a generic drug will replicate the therapeutic effects of the original drug as closely as possible. In the U.S. and Europe, generic producers must prove that their drug is "bioequivalent" to the original drug before approval for sale as a substitute. A rating of bioequivalence confirms that a generic has active ingredients identical to the original, and that these ingredients act upon the body in the same way (NIHCM 2002b p. 10). Because a generic producer need not actually develop the drug but instead simply manufacture it, generics can be offered at a significantly reduced price over the original. Thus it would be expected that generic drugs should quickly take over the market or at least drive down prices after the patent on the original drug expires. After all, they are an exact substitute at a lower price. But as we will see, other forces are at work here, and generic competition contains some surprising complexities.

3.1 Study: Magazzini, Pammolli and Riccaboni (2004)

A 2004 study by Magazzini et al. examines generic competition in the U.S., the U.K., Germany and France. It aims to analyze the effects of differing regulatory regimes on generic prices and market share in the four countries using sales data for drugs whose patents expired between 1986 and 1996. The represented countries regulate the price and sale of drugs in different ways and for different purposes.

Background: Patterns of Regulation in the U.S. and Europe

Because many European countries have nationalized health care systems, they have implemented various regulatory measures intended to minimize government expenditures for reimbursing patients' health care costs. Many of these cost-containing measures have the indirect effect of reducing drug prices, even if they are not outright price controls on pharmaceutical products.

In Germany and the U.K., pharmaceutical companies are free to set prices as they like. In Germany, however, a reference price system is used by insurance funds for determining reimbursements for drug purchases. This system has had a powerful downward effect on prices, as has a ceiling on total pharmaceutical expenditures (Huttin 2002, p. 86) The U.K. has implemented a fund-holding scheme to help reduce drug reimbursements, where doctors are given a fixed budget from which drug expenditures are to be paid. This has had the effect of making doctors more price conscious when prescribing drugs (Huttin 2002, p. 82). Both Germany and the U.K. have a "black list" of drugs that are not eligible for reimbursement due to their low therapeutic value. France also has a national ceiling on drug expenditure, but more importantly, it regulates drug prices directly (Huttin 2002, p. 81). Of the four countries in the study, France is the only country that implements direct price controls on the output of the pharmaceutical industry, thus imposing lower prices on all drugs.

In the U.S., generic drugs are used specifically to introduce price competition after patent expiration or, in other words, to eliminate the deadweight loss. This mechanism is considered necessary as the U.S. has no price regulations for drugs, and the lack of a national health care system limits the power of existing drug reimbursement systems to affect overall prices. In 1984 the Hatch-Waxman Act was passed by Congress with the specific aim of reducing barriers to generic competition. Before the bill was passed, generic drugs were required to undergo the same stringent clinical trials as brand name drugs in order to receive approval from the Food and Drug Administration (FDA), the regulatory body approving new drugs in the U.S.. A potential generic substitute could not be developed or tested while an original drug was still under patent, meaning that it usually took another few years after patent expiration for a generic to arrive on the market. After Hatch-Waxman, generic companies could file special applications to the FDA that would allow their drugs to forego full clinical tests if the drug was shown to be bioequivalent to the original. Generic companies were also allowed to make copies of brand name drugs for use in

development and testing before patent expiration. As a result, the length of time between patent expiration and generic entry has been much reduced. In exchange, the bill extended the length of patent protection for original drugs, giving brand name drugs up to five more years of protection (NIHCM 2000, pp. 4-5; Scherer 2009, p. 197).

Results of the Study

What effects do these differing regulations have on generic competition? The Magazzini et al. study shows, in agreement with previous studies, that strong price regulation discourages generic entry, while weak regulation promotes generic competition. As might be expected, generic penetration is highest and happens most quickly in the U.S., where regulation is weakest, yet it is also rather strong in Germany. In all four countries market penetration for generics steadily increases after patent expiration, excepting France, where regulation is strongest.

The study also examines why regulation would have such effects on generic competition. The findings are not unexpected: high margins and large markets attract generics. If the original drug prices are high, and if the market is big enough, generic companies have incentive to enter. In a country such as France, where the prices are kept low, and the market is relatively small, there is little to attract generic competitors.

But what effect does all of this competition have on the prices of the original drugs in the four countries? The result is somewhat surprising. The study shows that in Germany and the U.K., as expected, original drug prices steadily decrease after generic entry, eventually converging with generic prices. In France, original drug prices decline before patent expiration and then hold steady thereafter, presumably because they are facing little generic competition. In the U.S., however, prices for original drugs steadily *increase* after patent expiration, entirely against expectations. This surprising phenomenon has been observed in a number of similar studies (U.S. Congressional Budget Office 1998, pp. 29-31). In addition, although generic penetration in the U.S. advances more quickly than in other

countries, it still takes around eight years for a brand name drug to lose half of its market share.

We see then that pricing policy has a strong effect on how much market share a drug will lose after its patent expires, and that original drugs can continue to produce revenue for their firms despite having no patent protection. Yet why would U.S. consumers continue to purchase increasingly expensive brand name drugs despite the fact that rigorously approved exact copies are available for a reduced price? A 1991 study by Caves et al. sheds some light on the mystery.

3.2 Study: Caves, Whinston and Hurwitz (1991)

With the suspicion that brand loyalty or promotional activities on the part of the pharmaceutical companies may be affecting demand after patent expiration, Caves, Whinston and Hurwitz examined prices, market shares, quantities sold, and advertising for thirty drugs in the U.S. Market that lost patent protection over the years 1976-87. The study looked for patterns that give clues to the types of forces affecting generic competition.

Background: Demand and Marketing for U.S. Pharmaceuticals

Caves et al. point out that demand in the pharmaceutical industry is heavily influenced by the behavior of medical professionals and pharmacists. They note that physicians in the U.S. are unlikely to be as sensitive to prices as the consumer and often have little information on drug prices. Fund-holding and expenditure ceilings were specifically designed to alleviate this problem in Europe, but no comparable measures exist in the U.S. due to the lack of a nationalized health care system. The authors do note that increased pressure from third-party payers, such as state reimbursement programs and private insurance, has lead to a steady increase in substitution by generics during the period studied. The authors also describe the extensive sales promotion activities undertaken by the industry, many of which involve direct visits to health-care professionals to inform them of new drugs and induce brand loyalty.

Results of the Study

The study finds that generic drugs in the U.S. were sold on average at roughly 60% of the original price from 1976-87. This is a significant discount and an indication of the high margins at which brand name drugs are sold. Yet brand name market share lost to generic drugs was low given this discount, with the overall generic penetration averaging at 36% in 1987. The study also finds that the entry of additional generic drugs to a market affects the prices of existing generic drugs much more strongly than it does the price of the original brand name drug. These results point to a very strong differentiation between brand name and generic drugs despite their therapeutic equivalence. To determine if sales promotion activities play a role in creating this differentiation, the study analyzes advertising expenditures before and after patent expiration.

The results show that advertising expenditures for brand name drugs begin to decline about two years before patent expiration and then decline more rapidly after generic entry. This suggests that brand name companies use advertising to expand the overall market for their drugs. The arrival of generic competition then reduces the incentive to further expand the market, as any gains would be shared with the new entrants. The study finds that this hypothesis is confirmed by the fact that advertising expenditures tend to decline more in large markets, where anticipated generic competition will be greater, than in small markets where less competition is expected.

If high prices do in fact make drugs unavailable to potential customers, it would be expected that the availability of cheaper generic substitutes would increase the overall size of the market for a particular drug when it becomes affordable to a greater number of people. Contrary to this expectation, the study finds that in the year before patent expiration, sales of brand name drugs decline by roughly 20% and then continue to decline until generic competition begins; once generic entry occurs, the total quantity of the drug sold, including generic and brand name versions, increases by at most 3% and then declines thereafter.

These results confirm that brand name producers use advertising activity to increase the market for their drugs. The declines in market size correspond to the declines in advertising expenditures preceding patent expiration. The authors believe that the resulting loss of sales from declining advertising expenditures counteracts any increase in overall sales resulting from the lower generic prices.

The authors conclude that brand allegiance and the goodwill created by intensive marketing to medical professionals maintains the differentiation between brand name and generic drugs well beyond generic entry. This helps to explain the baffling rise in prices for brand name drugs that was seen in other studies. As shown in the Magazzini et al. study, in European countries such as Germany and the U.K., where doctors are forced to consider pricing in their decisions, we do not see such behavior. But in the U.S., where doctors are more likely to write prescriptions based on habit and brand loyalty, without consideration or even knowledge of price, brand name manufacturers can continue to raise prices despite the existence of lower-priced competition, thus mitigating the effect of lost market share on profits.

The fact that market size does not appreciably increase after generic entry challenges many of the basic assumptions about the effects of patent protection on welfare and deadweight loss. If, as the authors claim, the effects of declining advertising expenditures are strong enough to counteract new sales resulting from lower prices, there is a strong implication that drugs are being marketed and sold to those who do not really need them.

That these price increases can occur beyond patent expiration raises questions about the necessity of longer patent protection; after all, patents are certainly not the only means that a pharmaceutical company has to protect its profits, and this study shows that marketing is a very effective way to achieve the same ends.

4. Therapeutic Competition and "Me-Too" Drugs

Therapeutic competition describes the competition between drugs within a therapeutic class, meaning drugs that use similar mechanisms to treat the same condition. Because drugs within a class are very similar, this type of competition is affected by the breadth of pharmaceutical patents. A drug with a very broad patent could make up an entire therapeutic class by itself, while narrower patents would allow for multiple drugs within one class. Most therapeutic classes in the U.S. and Europe contain at least a few different drugs created by rival companies (Danzon and Chao 2000, pp. 330-331; DiMasi and Faden 2011, p. 23). These drugs are based on molecules that are different enough to warrant their own patents, yet in many cases they are substitutable as treatments for the same disease. In the discussion below, the first drug to enter a class will be called "first in class," drugs that enter the class thereafter will be referred to as later entering drugs, and drugs proven to be most effective in their class will be called "best in class."

4.1 Study: DiMasi and Faden (2011)

Background: "Me-Too" Drugs

Critics of the pharmaceutical industry argue that for many therapeutic classes, many or most of the drugs in the class are basically substitutable, but thanks to large expenditures on marketing and the manipulation of clinical trials they have an appearance of being differentiated, or complementary, products (Angell and Relman 2002, p. 109). These are the much-derided "me-too" drugs, and their existence is given as evidence of the lack of innovation in the industry, as each of the major pharmaceutical firms make an entry into the most popular therapeutic classes with drugs that are difficult to distinguish from those already existing (Angell and Relman 2002, p. 106). In order to analyze therapeutic competition and its effects on innovation, it will be necessary to examine the "me-too" phenomenon.

Unfortunately, the term "me-too" is often applied rather indiscriminately. The term can be used to refer to similar drugs within a therapeutic class, all drugs in a therapeutic class, drugs competing in the same market, line extensions of existing drugs, drugs given a standard rating by the FDA, generic versions of brand name drugs, or all of the above. This proliferation of definitions is evidence of an underlying confusion about the nature of competition in the pharmaceutical industry. The ambiguities involved in describing therapeutic competition are clearly at work here, as is a lack of distinction between generic and therapeutic competition. (It is worth mentioning that because generic drugs are by definition non-innovative and typically produced by companies specifically devoted to their manufacture, it is not logical to include them when making judgments on the overall innovation within the industry.)

Underlying many of the critiques of "me-too" drugs is the assumption that pharmaceutical companies first observe the market success of a rival company's first-in-class drug and then rush to copy that success by creating their own similar drug.

A 2011 study by DiMasi and Faden looks more closely at the "me-too" phenomenon, with the aim of determining whether the appearance of late-entry drugs in a class is the effect of copying behavior. The study analyses the dates of clinical trials and patent filings for drugs in 94 therapeutic classes between 1960 and 2003 under the assumption that firms showing copying behavior would only begin to develop a drug after observing a successful first-in-class drug.

Results of the Study

The study finds, however, that most later-entering drugs in a class were already in development *before* the first-in-class drug came to market. For example, since the early 1990s, patents were already filed on 91% of later-entering drugs before the first-in-class drug was approved. These late entering firms would not have had a chance to observe market success for

the first-in-class drug before they began developing their own similar drug. The authors conclude that this behavior is much better explained as a "race to market" than as low-risk imitation or copying behavior. Instead of copying observed market success, a number of firms may all be aware of the potential of a new discovery and then race to be the first to develop a usable drug based on the discovery. The appearance of "me-too" drugs is then the observable outcome of this race: the first-in-class drug is the drug that simply arrived at the finish line first, while the others appeared on the market only after they finished running the same course of development, testing and approval.

The study finds not only that these races exist, but also that they have been getting tighter. The average number of years that a first-in-class drug enjoys without competition from later entrants has been steadily shrinking: from 13.5 years in the 60s to 2.7 years in the 1990s. This means that most drugs encounter therapeutic competition long before their patents expire. Whether this competition actually leads to lower prices is an important question that is not addressed by the study.

In addition, the authors note that not all first-in-class drugs are necessarily the best in class. The FDA rates drugs to be approved as either "standard" or "priority". Priority ratings are assigned only to drugs offering a significant improvement over existing therapies. Therefore, it can be assumed that if a late-entering drug receives a priority rating, it is more effective than the first drug in its class. According to the study, one-third of the late-entering drugs received a priority rating from the FDA, implying that late-entering drugs can be qualitatively better than those already existing in a class. That drugs within a therapeutic class can have qualitative differences is not always acknowledged when they are critiqued as "me-too" drugs.

Example: The Development of Statins

The racing phenomenon described in the study is well illustrated by the emergence of statins, a widely prescribed class of cholesterol-lowering drugs. In 1987 Merck brought the first statin, called Mevacor, to the market. Like all of the statins to follow, its development was based on previous research undertaken by a small Japanese pharmaceutical company named Sankyo. Four years later Sankyo, now with Bristol-Myers Squibb as a partner, brought its own statin, Pravachol, to the U.S. market. In the same year Merck released its second and more potent statin, Zocor. In 1994, three years following, Novartis entered with Lescol. Then in 1997, ten years later and with four statins already on the market, Pfizer made an entry with a statin that proved more effective than the ones preceding it. Under the name Lipitor, this statin would become the best-selling drug in history. Again yet a year after that, Bayer entered the market with Baycol, which was later withdrawn as it was far more likely than the other statins to cause severe muscle failure, resulting in at least 52 deaths (Simons 2003, Cable News Network 2001).

In this example we see that all of these drugs appeared within a few years of each other. Moreover, all were based on the same initial research. Lipitor, the best in class drug, was already in the development stages when Mevacor, the first in class drug, was approved, but Lipitor needed another ten years to reach the market-entry stage (Simons 2003). Since Lipitor is more effective at lower doses, while Baycol is more likely to cause fatal side effects, we see that not all drugs in a class need be considered equivalent. Indeed, some statins react differently than others when taken in combination with other drugs and different statins have differing effects for different patient populations (Chong et al. 2001).

From this discussion we are led to conclude that the appearance of “me-too” drugs is in fact a result of innovative activity, and that these drugs do have their own important benefits. But what is the nature of the racing behavior that produces them?

4.2 Study: Cockburn and Henderson (1994)

Background: Racing Behavior

Racing behavior is also the subject of criticism, mainly in regards to the wasteful duplication of effort implied by most models used to describe it (Scotchmer 2004, pp. 98-100). In the context of pharmaceutical research, the criticism concerns the waste of collective resources to produce a narrow range of drugs within a few popular therapeutic classes, a subtler critique of the "me-too" drugs.

According to game-theoretical models of racing behavior, races can lead to inefficiencies as firms over-invest in their efforts to be the first to market or the first to file a patent on a promising technology. However, these theories generally rest on some assumptions. One assumption is that payoffs are negatively correlated, or in other words that there is a single winner-takes-all "prize" for the first firm to make it to the market, i.e. total market share, while the other competitors are left with nothing but the loss of their investments. Implied here is another assumption that competing projects are completely substitutable. If the technology created by any firm is substitutable for that of another, the first to market gains the total market as there would be no reason for a customer to prefer the technology of a later entrant, it being no different from the first. Yet another assumption is that there is no transfer of information, or *knowledge spillover*, between the competing firms. Each firm is researching alone, keeping all of its gained knowledge secret. This would lead to duplicative effort, as each firm must learn everything on its own.

These assumptions are challenged by a 1994 study by Cockburn and Henderson, which was conducted to test theoretical models of racing behavior using empirical data from the pharmaceutical industry. The authors used detailed data on R&D investments and outcomes from ten American and European pharmaceutical firms for a period of seventeen years. The

study focuses on drug discovery, the process of identifying and discovering potential new drugs, and not on drug development, the process of creating a finished drug with clinically proven success. The authors use both quantitative and qualitative tools to measure the extent to which the existing theories of racing behavior actually describe industrial R&D processes.

Results of the Study

The results of the quantitative study show that R&D inputs at the project level are not correlated: this means that firms are not making R&D investment decisions solely as reactions to observed investments from competing firms, or based on what theorists call "tit-for-tat" behavior. Instead, R&D inputs are most heavily influenced by a firm's previous investment decisions. This result agrees with evidence from the qualitative study, in which managers cited the capabilities of their researchers, the size of the potential market and the scientific potential of a field as the main criteria for determining R&D investment. They also indicated that they tried to avoid "racing," as it is inherently unproductive and noted that outcomes are uncertain, as novel discoveries can appear where they are not expected. These findings agree with the DiMasi and Faden (2011) study: firms are not trying to copy the actions of their competitors, but instead are responding to the strengths of their research teams and to the appearance of promising research that could bring success in a large market.

The quantitative study also finds that the outputs for firms, which in this study are "important" patents resulting from research activity, are positively correlated, not negatively correlated as assumed by the racing theories. (Important patents are defined in the study as patents granted in two or more major jurisdictions.) This implies that there is no single winner-takes-all "prize" at the end of the race, but, instead, that multiple firms can be seen as "winners," each producing complementary research outcomes. The example of statins works well here: if there were truly a winner-takes-all prize, then Merck's Mevacor would be the only statin on the market. But as we have seen, statins are not perfect substitutes and even a later entrant, Lipitor, was

able to gain a large share of the statin market. The quantitative study also allows for the possibility of significant knowledge spillover in the industry, which again is not assumed by the theories, and as evidence of its existence the authors cite case publication and disclosure norms in the industry.

4.3 Some Caveats

There is a caveat to these results worth mentioning: the authors were studying R&D in the drug *discovery* phase, not in the *development* phase, where the final marketable drug is created. One can easily imagine that in the early exploratory stage of drug discovery complementary outcomes and knowledge sharing would be prevalent, but the high-stakes drug development process could well be a different story. In fact, critics of the industry have argued that the outcomes of many development races are nearly entirely substitutable: in other words, that the "me-too" drugs have few differences, and that we see so many successful drugs within some therapeutic classes only as a result of aggressive marketing and manipulation of regulatory agencies by the pharmaceutical firms (see Angell 2004).

The example of statins can again be used to argue this point. For treating the vast majority of patients, it could be argued that all of the existing statins are substitutable, excepting perhaps the more dangerous Baycol. The great success of Lipitor could be mainly attributed to effective pricing on the part of Pfizer and aggressive marketing to medical professionals (Simons 2003). In other words, the appearance of complementary outcomes in the drug development phase could be interpreted as an illusion of difference between substitutable products. Given the powerful effects of marketing and promotion shown by the Caves et al. study, this could be a real possibility. However, because there are so few "head-to-head" studies testing drugs within a therapeutic class against each other (Angell 2004, pp. 75-76), these criticisms are difficult to prove. Yet even if the critics are right in stating that the industry is creating wasteful and non-innovative products, if the entry of more competing drugs within a class has the effect of lowering

prices for all drugs in the class, their appearance would still bring some benefit to society.

A 1998 study by Lu and Comanor shows that competition within a class does have some effect on drug prices (Lu and Comanor 1998). Drugs that are less advanced, giving similar effects or little improvement over existing drugs, tend to enter the market at lower prices, while drugs that are more advanced, being significantly different or showing important therapeutic gains, can command much higher prices. However, the high prices of advanced drugs drop only slightly in real terms over time, while the lower prices of less advanced drugs tend to rise in real terms after entry. Yet entry prices and subsequent increases are lower when there are more competing drugs already on the market.

These results indicate that there are definite first-mover advantages in the industry, and also that there is some price competition, however weak. Again we see that patent protection is not the only force at work affecting profits. If drugs are different enough to be approved for their own patents, yet similar enough that they are competing as substitutes, it is clear that the existing patent protection alone is not enough to entirely shield a new drug from experiencing competition.

Pharmaceutical patents could be broadened to the point where this competition is eliminated, in the hopes of creating greater incentive to innovate. Yet theoretical models show that broader patents are likely to exacerbate the problems with racing behavior, such as inefficient use of resources and lack of knowledge exchange, and increase deadweight loss in addition. (Scotchmer 2004, pp. 112-114). In fact, strengthening patents could have unintended consequences in regards to the way that patents are actually used.

5. The Use of Patents in Manufacturing and Pharmaceuticals

As we have seen from the discussion of competition in pharmaceuticals, patent protection is not the only means by which a brand name drug is able to maintain market share and high prices. Advertising and first-mover advantages also have a powerful effect on profits and demand. If the promise of protected profits is the actual incentive for innovative activity, then perhaps patents are not the only means of achieving that end? And if patents are not enough to protect a drug from therapeutic competition, how much incentive do they actually provide? How does the industry actually use patents, and how are they really protecting innovative profits?

5.1 Study: Cohen, Nelson and Walsh (2000)

Background: Appropriation and Patent Strength

A series of studies dating back to 1959 have shown that managers in manufacturing industries consistently rate patents as relatively unimportant or ineffective when considering the merits of different mechanisms for *appropriation*, the protection of profits resulting from innovation (Scherer 2009, pp. 171-176). A 2000 work by Cohen et al. aimed to update and improve upon these studies. Using data taken from a 1994 survey containing questions for R&D managers representing 34 industries in the U.S. manufacturing sector, the authors' goals were to determine how firms actually use patents and to look for evidence of changes in reliance on methods of appropriation compared to an earlier 1983 survey. There was reason to expect such changes, as a major shift in the handling of U.S. patent cases had occurred near the time of the earlier survey.

Before 1982, patent cases in the U. S. were handled by local courts, which led to subjectivity in the rulings. A company wanting to prove that its patent

had been infringed would purposefully bring a case to a jurisdiction tending to judge in favor of the patent holder, while a company wanting to prove its rival's patent invalid would bring its case to a jurisdiction with the opposite tendency (Jaffe and Lerner 2004, pp. 98-104). In 1982 a special Court of Appeals was created for the sole purpose of deciding U.S. patent cases. The Court was created mainly to bring consistency to patent rulings, but it had another effect: since its creation a higher percentage of patents have been ruled as both infringed and valid. In other words, U.S. patent cases are much more likely to be judged in favor of the patent holder, resulting in an effectual strengthening of patents (Scherer 2009 pp. 192-194, Jaffe and Lerner 2004 pp. 104-107).

Results of the Study

Considering that after the court reform a firm's patents were less likely to be infringed upon and more likely to be considered valid in court, one would expect that managers would consider patents more effective as a means of appropriation than they had in the previous study. But this 1994 survey showed, like those before it, that in most industries patents were still considered less effective for protecting profits than other mechanisms. Instead, the favored means of appropriation were secrecy and lead-time, or securing a first-mover advantage. The study shows that secrecy had grown to be far more important to managers, going from being considered the least effective mechanism in 1983 to the most effective in 1994. The prevalence of secrecy can be partially explained by the reasons that managers gave for *not* patenting an innovation: the ease with which a competitor could invent around a patented invention, as well as the disclosure of information required when filing for a patent.

The authors note, however, an incredible increase in patenting activity during this time, as the number of patents granted to U.S. corporations had grown by 72% between 1983 and 1995. How could this increase in patenting be reconciled with the increasing reliance on secrecy shown in the study? Could an explanation be that firms were increasingly using patents

for other purposes? To answer this question, Cohen et al. looked at the uses for patents cited by managers. They found that firms were relying on patents to block rivals, prevent legal suits, and as leverage when negotiating, irrespective of how ineffective managers considered patents as a means of protecting innovative profit. This finding lends weight to the theory that enhanced patent strength has an unintended side effect: it allows patents to be used as legal weapons (see Jaffe and Lerner 2004).

5.2 Pharmaceutical Reliance on Patents

Importantly, however, the pharmaceutical industry was shown to be an exception not only in the Cohen et al. study, but also in the series of similar studies (Cohen et al. 2000 p. 9; see Scherer 2009). Pharmaceutical R&D managers consistently rate patents higher in terms of effectiveness than do managers from other manufacturing industries. In the Cohen study, for example, pharmaceutical managers rate patents to be effective for protecting the profits of more than 50% of product innovations, second only to medical equipment producers. Why is this the case? The study does not answer this question, but it is possible to identify some good reasons.

For one, the cost of actually manufacturing a drug is low when compared to the costs for researching and developing the chemical formula. Once a chemical compound is isolated, it can be reproduced rather quickly and easily, as evidenced by the low prices of generic drugs. This means that competitors with access to a chemical formula can quickly enter the market, making copying a greater threat for pharmaceuticals when compared to other, more complex manufacturing industries (Scherer 2007, pp. 27-28). Secondly, a large market for copied drugs can be easily found, especially if they are offered at reduced prices. The incredible proliferation of counterfeit drugs attests to this fact (World Health Organization 2012). Finally, the regulatory approval process for most drugs requires disclosure of many aspects of a drug's composition, development and therapeutic effects (Kesselheim and Mello 2007). Secrecy is therefore less effective, and

pharmaceutical firms may be more likely to rely on patents to protect technologies that would have to be disclosed eventually anyway.

This suggests that some basic level of patent protection is necessary and relied upon by the pharmaceutical industry. But how strong should this protection be? Would increasing the existing strength of patent protection actually create additional incentive and promote more innovation? Or would it instead simply increase the use of patents as strategic weapons?

6. Patent Protection and Innovation

If it were possible to empirically show a correlation between increases in strength of patent protection and innovation in industry in general, then the argument for stronger pharmaceutical patents would receive a significant boost. Several studies have attempted to overcome the inherent obstacles involved in this type of analysis, such as the difficulties of measuring innovation and of determining changes in patent breadth. An interesting and much-cited study by Sakakibara and Branstetter used some unusual aspects of the Japanese patent system to overcome these obstacles and look for evidence of changes in innovation as a response to changes in patent strength.

6.1 Study: Sakakibara and Branstetter (2001)

Background: The Japanese Patent System

Before 1988, the Japanese patent system only allowed for one claim per patent, so that only one novel aspect of a new technology could be protected per patent. Japanese patents therefore offered very narrow protection, and companies were obliged to file a number of patents to protect any single new technological advance. As a result, the fees for filing and the costs of litigation were quite high, yet the protection obtained was rather weak.

Competing companies could easily "invent around" the existing patents, simply by making small adjustments to the patented technology.

As a response to pressure from the U.S., Japan enacted a reform allowing for coverage of multiple independent claims in one patent. The reform also included an increase in patent duration for pharmaceutical products. The new system made it easier not only for patents to be granted, but also for infringement to be proved and prosecuted. Therefore, the length and breadth of patent protection was expanded, and in a way that was easy to prove and describe. That this occurred in a modern, industrialized nation as a result of exogenous forces made for an ideal set-up for studying the effects of patent reform.

Results of the Study

The Sakakibara and Branstetter study took advantage of this situation to see if any effects on innovative output from Japanese industry could be seen to result from the reforms. The authors combined interviews with executives in a number of industries with analysis of R&D expenditure and various measures of innovative output to examine the effects of the reforms on Japanese industries.

The authors assumed that if companies receive new incentives to create innovative products, an increased investment in R&D should be observable. A rise in R&D expenditures found after the reforms would be an indication that increased patent protection leads to innovative activity. The study found that while R&D expenditures had been rising steadily in Japan for some years before the reforms, they showed a very slight decrease after the reforms and then continued to rise at the same rate as before. Thus, there was no evidence of increased spending that could be attributed in any way to the patent reforms. The study also looked specifically for effects on R&D in the pharmaceutical industry, as pharmaceuticals enjoyed increased length of protection and would perhaps be more sensitive to changes in patent strength, but again found no effect.

Next the study looked at the number of Japanese patent applications. As would be expected, there was a general decrease in the number of patent applications and an increase in the number of claims per patent as firms took advantage of the new system. However, because increased patenting activity is not a reliable indicator of increased innovative output, the authors looked for indications of changes in patent quality by using a method that substitutes the number of technological areas, or classes, contained in the patent for the breadth of the patent. Using this method they found no evidence of changes in patent quality. Assuming then that a more reliable indicator of increase in innovative output might be the number and quality of patents applied for overseas, the study also looked at patenting activity by Japanese firms in the U.S., measuring again quantity and also quality, this time by using a "citations function" and by measuring the number of claims per patent. A citations function measures the degree to which a patent is cited by later patents, thus giving some idea of how many important new ideas were contained in the patent. Again, they found no evidence of an increase in either quantity or quality of patents that could be attributable to the reforms.

The only effects of the reforms that the study found were the expected increase in claims per patent, as well as an increase in patent-related lawsuits. The increase in lawsuits implies that the reforms did increase the use of patents as legal weapons, just as described in the Cohen et al. (2000) study (see also Jaffe and Lerner 2004). No evidence of increased innovation or its effects was found.

The authors conclude that there is little evidence that broader patent protection provides further incentives for innovation. They are careful to note that the Japanese patent reforms are not a perfect experiment, and that further study would be needed to prove that there were no effects on innovation (the study does not look at effects on profits, and there could be effects from idiosyncrasies particular to Japanese companies, for example). However, there have been a few studies showing similar results. A 2009

study by Lerner, for example, looks for effects from changes in patent law in a number of countries by analyzing changes in quantity and quality of foreign patents filed in the U.K. This study also finds no evidence of any effects on innovation after patent reforms (Lerner 2009).

But perhaps it is possible to observe the pharmaceutical industry more directly. We know that the extension of pharmaceutical length granted by the Hatch-Waxman act and the creation of the Court of Appeals were both considered to strengthen pharmaceutical patents in the U.S. Also, the U.S. has the largest market for pharmaceuticals in the world. One would then expect that the promise of this large market, combined with increased strength of protection, would certainly be great incentive for world pharmaceutical companies to bring ever more innovative drugs to the U.S. market. Can evidence of such an effect be found?

In order to look for such effects, some means of determining the degree to which a drug can be considered innovative is necessary. As we have already seen the difficulty in determining the degree of differentiation between drugs within their therapeutic class, we can imagine that assessing their level of innovation will be at least as difficult. In general, measuring innovation is problematic and a topic upon which much ink has been spilled (see Jaffe and Trajtenberg 2002). However, it turns out that it is possible first to roughly classify new drugs as being more or less innovative based on criteria used by the FDA for approvals and second to look at changes in the levels of innovation over time.

6.2 Study: NIHCM 2002

A 2002 study by the National Institute for Health Care Management (NIHCM), a non-profit foundation devoted to researching the U.S. health care system, does just this by examining drugs approved for sale on the U.S. Market between 1989 and 2000.

Background: FDA Classifications for New Drugs

When a drug company applies to the FDA for approval of a new drug, the FDA classifies the drug based both on the nature of its composition and its therapeutic potential. When considering chemical composition, the FDA classifies as a "new molecular entity" (NME) any compound that has never yet been approved for sale on the U.S. market. (New drugs in an existing class, such as the later-entering "me-too" drugs, would also be considered NMEs, as their molecules differ somewhat from others in the class.) The FDA also approves many drugs that are based on compounds that already exist on the market, yet are offered in a different form such as a different dosage or method of administration. In the NIHCM study these are grouped together and labeled as "incrementally modified drugs" (IMDs). Finally, the FDA also approves drugs that are identical in form and composition to those already on the market, usually because a different manufacturer is producing them. The NIHCM study groups these as "other" drugs.

As NMEs are truly new to the market, they are considered by the study to be the most innovative type of drugs, while IMDs, being merely modifications of existing drugs are considered less innovative, and "other" drugs necessarily the least innovative, being identical to existing drugs.

Also, as mentioned in the DiMasi and Faden (2011) study, the FDA classifies drugs not only according to type of compound, but also according to therapeutic potential. Drugs showing only a minor improvement over existing therapies are classified as "standard", whereas drugs that offer major advances in treatment, or that provide a treatment where one does not yet exist, are classified as "priority" and given a faster review by the agency. Both NMEs and IMDs can receive either a priority or a standard rating, as it is possible not only for modified drugs to create a greater therapeutic potential than has previously existed, but also for a new drug to offer no improvement over those already existing on the market. The NIHCM therefore classifies the newly approved drugs on a continuum; with priority

NMEs rated as the most innovative drugs and standard IMDs and other drugs as least innovative.

Results of the Study

The NIHCM (2002) study finds that most of the new drugs approved by the FDA from 1989-2000 were IMDs or other drugs, with only 35% being the more innovative NMEs. Of these NMEs, 42% were given priority review. Of the total approved drugs during the period, only 15% were the most innovative, or priority NMEs. In addition, the study found that this number is declining. In order to check for trends, the study period was divided into two periods: 1989-1994 and 1995-2000. The percentage of priority NMEs dropped from 17% in the first period to 13% in the second, with the percentage of standard IMDs rising from 39% in the first period to 50% in the second, showing a decline in the creation of the most innovative drugs and an increase in the development of the less innovative modifications on existing drugs.

The study argues that some of the rise in IMDs can be attributed directly to strengthened intellectual property protection. A provision of the Hatch-Waxman act allows a drug to receive three years of market exclusivity, meaning that no generic version the drug is allowed to enter as a competitor, if the FDA approves a "new use" of the drug. Therefore by creating new uses for existing drugs, pharmaceutical companies can in effect extend their patents by another three years.

The study concludes that while there was in fact innovation in the pharmaceutical industry during the period studied, the industry was producing a large and growing number of drugs that could not be considered innovative. This is despite the fact that the study considers a period after a strengthening of pharmaceutical patents, just following the 1984 passage of the Hatch-Waxman act and the 1982 creation of the Court of Appeals.

It is generally acknowledged that fewer NMEs are being produced by pharmaceutical companies, even by those who would like to argue that the industry remains very innovative (see Grabowski and Wang 2006). In fact, the major pharmaceutical companies have few promising new drugs in development stages, or in the "pipeline." This is increasingly a source of concern for the industry (see Wilson 2011). As few new blockbuster drugs are likely to appear, pharmaceutical companies are attempting to extend the franchise of the older drugs for as long as possible, as evidenced by the increasing number of IMDs based on existing molecules.

7. Discussion

We conclude that there is little to no evidence that increases in the strength of patent protection have any positive effect on innovation in the pharmaceutical industry. As we have seen, a complex combination of forces affects competition, prices and demand in the industry. Government regulation, advertising, market size, firm capabilities and the vagaries of scientific discovery all have powerful impacts on the outputs and success of pharmaceutical firms. While the promise of profit is certainly an incentive to innovate, managers admit that patents alone cannot guarantee that that promise will be fulfilled. The industry therefore uses other means of protecting its profits and ensuring the commercial success of their products. Advertising, timing, firm reputation and competitive pricing being just some of the other instruments that pharmaceutical companies rely upon to affect profits. Governments, on the other hand, can use regulations or the purchasing power of reimbursement programs to influence pricing and competition, while customary prescribing practices or the availability of insurance can have strong effects on demand. The complexities of these interactions could mean that adjustment of patent strength itself has little impact on innovation.

In addition, we see that patents are increasingly being used for a variety of purposes beyond those for which they were originally intended. They are

used to block rivals, as leverage in negotiations or as reflections of company value. These uses may reflect the evolving needs of large companies engaged in long-term research programs, but there is no evidence that these applications of patent protection would affect innovation in a positive way. On the contrary, the use of patents as blocking instruments could have negative effects on innovation in the industry as a whole.

Given the complexities mentioned above it is hardly surprising that little evidence can be found for positive effects of strong patent policy on innovation. While a minimum amount of protection is necessary to shield drug producers from outright copying, it is unclear that any increase in the existing protection in the U.S. and Europe would have any positive impact. There is, in fact, some empirical evidence that there may be an optimum level of patent protection for developed nations, beyond which the effects on innovation would be negative (see Qian 2007).

Because of the ever-increasing costs of health care in the U.S. and growing scrutiny of the industry as a result of the ongoing healthcare crisis, it seems highly unreasonable that U.S. policy makers would want to increase patent protection for the pharmaceutical industry any time soon. This is problematic for the pharmaceutical companies, as the patents on many of their blockbuster drugs are expiring, yet there are currently few drugs in development likely to have such phenomenal sales as those in the previous decades (Wilson 2011).

We already see this phenomenon occurring. In the fall of 2011 the patent for Pfizer's blockbuster statin, Lipitor, expired. In recent years Pfizer has not introduced a new drug with the promise of market success anything like that of Lipitor, and as a consequence the company is suffering. By the spring of 2012 Pfizer's earnings had dropped considerably. The company is now planning on reducing R&D spending by 30%, ending many development projects and selling off most of its non-essential units (Thomas 2012).

But why is it not possible for Pfizer, or the other large pharmaceutical firms, to reproduce the success of their previous blockbuster drugs? Industry executives were certainly aware of the eventuality of the loss of returns from their older drugs and must have known that new blockbusters were needed in order to maintain the high profits to which the industry was accustomed. These profits were certainly incentive enough to create more blockbusters, yet so far they have been unable to repeat the past successes. Hence, it seems improbable that the lack of new blockbuster drugs is attributable to a lack of incentive to create them.

Instead, it is likely that there are other underlying causes for the lack of promising drugs in the pipeline. It may be that the structure of the large pharmaceutical firms is no longer advantageous to the discovery and development of innovative therapies. Or perhaps the current exploratory research has not yielded the types of discoveries suitable for blockbuster drug development. Gene therapies, for instance, cannot be sold indiscriminately to a broad population (see Drews and Ryser 1997). Whatever the cause, it is clear that incentive itself is not enough to create innovation.

8: Conclusion

In conclusion, we find that there is little to no evidence that increases in the strength of patent protection have a positive effect on innovation in the pharmaceutical industry. By offering basic protection from copying, patents are a necessary incentive mechanism in the pharmaceutical industry. However, they are not the only means the industry uses to protect profits, nor do they offer complete protection from competition. In addition, while incentive may be necessary for innovative activity, it is not sufficient to produce it. Many other factors affect the likelihood that innovative outputs will occur.

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Declaration of Authorship

Herewith I, Adrienne Eaton, state that I created the present work alone, only using the mentioned sources and tools. I am aware of the examination regulations. Until now, I did not hand in a bachelor/master thesis in my field of studies and did not fail permanently.

Adrienne Eaton

Berlin, 16.06.2012