Patent Law in the Pharmaceutical Industry
The Changing Times

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Abstract

With recent changes to the patent laws in the United States, it is important to consider how these developments affect not only the pharmaceutical industry, but also the generic brand companies, the American consumers, and the world as a whole. Recent court cases like *FTC v. Actavis*, new legislation like the America Invents Act, and the recent or impending expiration of the patents of well-known drugs such as Pfizer’s Lipitor or Astra Zeneca’s Nexium, have all created a need to consider the future of pharmaceutical patents. This paper strives to take a holistic approach to analyzing the future of patents within the pharmaceutical industry. First, the recent changes to patent law will be analyzed by discussing the consequences and overall impacts to both generic and brand name pharmaceutical companies. Then, examples of these consequences will be examined to see if these changes will have negative impacts either for the pharmaceutical industry or the consumer. Finally, solutions will be proposed and possible outcomes will be evaluated.
I Introduction

In the simplest sense, a patent is complete exclusivity to any profits gained through commercialization of the object patented, granted by the government to the inventor of a product or design.¹ The concept of patents and patent law dates back to the founding of the nation and the writing of Article One Section Eight of the US Constitution which states, “The Congress shall have the power to … promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.” George Washington himself signed the Act of April 10, 1790 that creates the modern patent system, and Secretary of State Thomas Jefferson was the first to grant a utility patent to an inventor in July of the same year.²

The reason for the creation of the American patent system was twofold. Prior to patents, the rights of inventors depended upon the wills of the monarch or legislature of the country.³ If an inventor knew his or her design or concept could be reverse engineered as soon as it was sold and produced by competitors, there would be no incentive to invent anything new. By providing the inventor the exclusive right to produce and distribute a product over a period of time, patents guarantee inventors’ rights and thus, spur innovation. The second reason for establishing a patent system is to create transparency and full disclosure of products and designs. In applying for patent protection, an inventor must submit all design concepts, ideas and data. The patent examiner reviews all detailed descriptions and sketches. In essence, the inventor discloses to the public exactly how to reproduce the invention in exchange for an exclusivity period of 20 years. Once that time frame expires, anyone who has the capacity to produce the product can do so. This system deters inventors from keeping what otherwise would be trade secrets and provides the general public with information about the product they purchase and use.
Although the concept of the patent law system remains constant, the specifics are ever changing. For the pharmaceutical industry in particular, patents are an essential aspect throughout the entire process from research and development in the laboratory all the way to the purchase made by the consumer at the pharmacy counter. With respect to recent changes of the patent laws in the United States, it is important to consider how these developments affect, not only the pharmaceutical industry, but also the generic brand companies, and the American consumers. In fact, interactions between these parties can be likened to a triangle. When a patent is first granted, and a pharmaceutical company receives Food and Drug Administration (FDA) approval to go to market with the product, a link is established between the brand name company and the consumers (through the consumers’ health insurance providers and physicians). This link allows the company to sell its product to the customer and in turn receive a profit (Figure 1).

Figure 1- Once FDA approved and patented, a drug can be sold from a brand name company to the consumer.
As long as the product remains on the market, the link between the company and the consumer remains. However, when a new player is introduced, the scenario changes. While a brand name company is gaining profit from consumers, a generic company is working to recreate the drug that is being sold. As soon as a generic company files an Abbreviated New Drug Application (ANDA) and subsequently receives FDA approval, that company can start selling the product. The only thing prohibiting the generic company from entering the market is the patent protection held by the brand name company (Figure 2).

**Figure 2-** Even though a generic company may have FDA approval to sell a drug to consumers, they are denied from doing so because of the patent protection afforded to the brand name company

That patent protection can be removed either through expiration of the original patent, a lawsuit challenging the patent, intentional patent infringement, or an agreement reached between the two parties. Regardless of the method, once the patent protection is removed, the generic company now also becomes a player in the market and can sell to consumers. Thus, another line of the triangle is drawn (Figure 3).
This significantly reduces the share that the brand name has of the market, not only because there is now competition in the once monopoly, but because consumers’ insurance companies often only cover generic drugs, if there is one available. Therefore, a generic company entering the marketplace is a game-changer for the pharmaceutical company. However, there have been increasing incentives for generic companies to challenge patents earlier and earlier from the patent’s expiration date. This leads to more dialogues between generic and brand name companies and can often result in settlement agreements that are subjected to antitrust laws, such as the one in the most recently decided Supreme Court case *FTC v. Actavis*. All the consequences of this line connecting the generic companies to the brand name companies (Figure 4) have yet to be discovered.

**Figure 3-** Once the generic company gets rid of the patent roadblock, it can sell to consumers. This reduces the brand name company's share of the market.
This paper will shed some light onto how these connections affect both the pharmaceutical industry as a whole and the third player, the consumer. First, the history behind the patent laws will be discussed so you will be able to place these laws into context. Then, specific examples and case studies pertaining to patent laws will be analyzed. Finally, the future of patents within the pharmaceutical industry will be conjectured. At the conclusion of this paper, various possible outcomes for the pharmaceutical industry will have been evaluated and I will predict the future of patents within the pharmaceutical industry.

Patents are granted based upon three criteria: the novelty, the usefulness, and the subject matter. Patents cannot be granted twice, so the invention must not have already been patented. The invention must have utility that is, “specific, substantial and credible” in order to be granted a utility patent. Pertaining to subject matter, patent applications must fall into one of four categories: process, machine, manufacture, or composition of matter. For example, a new drug that treats cancer would fall into the composition of matter category. Regardless of what category in which a patent is granted, all utility patents have a lifespan of 20 years from the date of first filing. This general rule creates a great impact.

Realizing this, large pharmaceutical companies must make a majority of their profits from “blockbuster drugs” that monopolize the marketplace for a lengthy period of time. For example, before it went off patent in 2011, Pfizer’s Lipitor® topped the charts with total sales of
over $7.6 billion dollars. The next closest seller was Bristol-Myers Squibb’s Plavix® at $6.8 billion.\textsuperscript{vi} In the fourth quarter of 2012, the first quarter after Lipitor® went off patent, sales for the drug dropped remarkably and decreased a total of 71\% from the previous year.\textsuperscript{vii} Once the patent expired, generic companies such as India’s Ranbaxy had the ability to produce and market atorvastatin, the generic version of Lipitor®, thus becoming direct competition for Pfizer.\textsuperscript{lviii} This demonstrates that pharmaceutical companies view patents as necessary tools to protect drug exclusivity and create a profit. Therefore, pharmaceutical companies deem it very necessary to fight against alleged patent infringers.

The difference between generic drug companies and brand-name pharmaceutical companies is that the latter invests billions of dollars into research and development whereas the former merely recreates already invented products at a drastically lower cost. Generic companies can view patents as a roadblock to making a profit (Figure 2). Once they gain Food and Drug Administration (FDA) approval to make a generic version of a drug they bide their time, waiting until they win a patent suit or until the patent expires. Generic companies, especially overseas, are often not well regulated and many cut corners on safety or sanitation in order to lower costs. For example, on May 13, 2013, “Ranbaxy plead guilty to seven federal criminal counts of selling adulterated drugs with intent to defraud, failing to report that its drug didn’t meet specification, and making intentionally false statements to the government.”\textsuperscript{ix} Ranbaxy faced $500 million in fines, the most a generic drug company has ever had to pay, due to the undercover work of a whistleblower.

For generic companies such as Ranbaxy, there is great incentive for generic drug companies to lower costs and obtain a share of the drug market as soon as possible. Under the Hatch-Waxman Act, officially known as the Drug Price Competition and Patent Term Restoration Act of 1984, a generic drug company does not need FDA approval to begin bringing a patent challenge against a brand-name company.\textsuperscript{x} A generic company can file an ANDA immediately after the brand-name company lists its New Drug Application (NDA) in what is referred to as the “Orange Book” (officially the Approved Drug Products with Therapeutic Equivalence Evaluations).\textsuperscript{xi} Before the generic company even has the capability to make or market the drug, they can challenge the patent. If they are successful, they may be able to enter the marketplace much earlier than the pharmaceutical company anticipated. In fact, there is even incentive to be the first to file an ANDA, a 180 day head-start before any other generic company can enter the marketplace, essentially creating a six-month duopoly of competition. When a generic company enters the marketplace prior to the official expiration of a patent, the product can be purchased at a low cost to consumers, thus driving down the overall cost of healthcare.

Healthcare in the United States of America has been a very controversial topic within recent years. Since the passing of the Patient Protection and Affordable Care Act (ObamaCare),

\textsuperscript{1} Actually, due to the patent challenge Pfizer entered into a negotiated agreement with Ranbaxy and went off patent with Lipitor earlier than was expected.
US citizens have been concerned about healthcare costs and funding for the healthcare industry. Many Americans rely on expensive medication such as Sutent® for cancer or Cinryze® that treats hereditary angioedema. These necessary drugs can cost upwards from $40,000 a year per patient, thus driving up the cost of healthcare as well as families’ medical bills. If a consumer can purchase a life-saving drug at a generic price, he or she will most likely do so. In fact, according to the FDA, eight out of ten prescriptions are filled for generic drugs. Additionally, some consumers have health insurance that only covers certain types of prescription drugs and may only cover generic versions, when available. This means that even if the customer specifically wants the brand name version of the drug, he or she will not be able to have it covered under his or her insurance policy. Since generic drugs are required to have exactly the same label as their brand-name counterparts, many consumers do not even realize that they are not receiving the brand name version of the medicine. Consumers don’t often think about the world of intellectual property or the patents that protect the pharmaceutical companies, but maybe they should. Without patents, brand-name companies would not have incentives to continue research and development and then new innovative and lifesaving products would never be created. This could have potentially devastating consequences for overall health of Americans. The links created between brand name and generic pharmaceutical companies and between those companies and the consumers they sell to, may perhaps be the most important deciding factor in the fate of the pharmaceutical industry.
II Background

Determining the fate of patents within the pharmaceutical industry requires a deep knowledge of the laws governing this niche of legal study. In this section, I will introduce three laws pertaining to these topics. First, we will discuss the Hatch-Waxman Act and how it revolutionized patent law in the pharmaceutical industry. Then, I will introduce the America Invents Act and the incentives it provides inventors to file patents as quickly as possible. Finally, I will analyze the Supreme Court decision of Federal Trade Commission v. Actavis and provide an explanation of what it means for pharmaceutical companies.

IIA. The Hatch-Waxman Act

IIA.1 History

Before discussing the consequences of patent law in the pharmaceutical industry, it is important to understand where these laws came from and what they say. The history of patent reformation within the pharmaceutical industry is relatively new. Prior to 1984, there were no specific rules governing patents within the pharmaceutical industry. When a pharmaceutical company developed a new drug they would seek approval from the FDA for safety only, not efficacy. That is to say, the FDA would approve the drug on the basis of whether or not it would harm the user and not necessarily on whether or not it would improve the patient’s condition. Then in 1962, the Federal Food, Drug and Cosmetic Act was amended so for a drug company to gain FDA approval of a drug both the safety and effectiveness must be proven. Therefore, there was more incentive given to the Research and Development teams to create drugs that improved patients’ conditions. This also led to difficulties for generic drugs to come to market because the process was the same, a lengthy expensive process consisting of clinical trials to prove both safety and efficacy and their own NDA filings that many generic companies felt was not worth the effort and expense. Since, “USPTO issuance of a patent and FDA marketing consent are distinct events that depend upon different criteria,” just because a drug was patented didn’t mean it could go straight to market.

In fact, after the changes made in 1962, congressional testimony stated that there were 150 drugs whose patents had expired but no generic company had started to produce due to the expensive and time-consuming process of filing a NDA. President Jimmy Carter first started to alleviate this issue by realizing that improving industrial innovation would include striking a balance between the need to obtain FDA approval for a drug and the ticking clock of a patent. President Ronald Reagan also agreed with this vision and his Secretary of Commerce set up an intellectual property committee to address these issues and more. The bill that we now refer to as the Hatch-Waxman Act, came from that committee, passed the Senate through the efforts of its sponsor Orin Hatch from Utah and then was sent to the House of Representatives. The bill did not pass by the necessary two-thirds majority in the House for immediate enactment and therefore was sent to the House Rules Committee. There, it was reviewed and changed by one of the strong proponents of the bill, Representative Henry A. Waxman from California. Finally, the
bill passed both branches of Congress and was signed into law by President Reagan on September 24, 1984\textsuperscript{xviii}.

\textit{IIA.2 Provisions}

Although the history surrounding the passage of the bill is not really monumental, the Hatch-Waxman Act has revolutionized the way pharmaceutical patents are viewed by both companies and consumers. There have been slight changes to the Act from 1984 until today but the main provisions remain the same. The first significant provision is the creation of the Abbreviated New Drug Application (ANDA). This allows generic companies to speed up the FDA approval process when they wish to market a drug that has the same active ingredient as an already patented product. Instead of having to conduct their own clinical trials, generic companies can rely on the research of the patent filers to prove the safety and efficacy requirements of the FDA. This saves the generic company both time and money and therefore as soon as the original patent expires, many generic companies can place their product on the market immediately. \textsuperscript{xix} This gives generic companies more incentive to file an ANDA quickly, which leads to the second provision.

Through the ANDA, more incentive is given for the generic company to challenge the validity of the patent holder’s patent. The first to challenge an existing patent on validity, infringement, or enforceability receives an exclusive 180-day period on the market once the patent expires or found invalid.\textsuperscript{xx} This means that for 180-days there are ideally only two companies allowed to sell the drug, the original patent holder and the first challenger. This provision of the law is crucial to incentivizing generic companies to challenge pharmaceutical patents.

Another provision of the Hatch-Waxman Act states the ways that generic companies can challenge pharmaceutical patents. When a patent is granted for a particular drug, the patent holder must list the patents pertaining to the specific drug in an FDA document commonly referred to as the “Orange Book.” Once the patent holder does this, generic companies seeking to challenge one or more of the patents listed that prohibit it from selling a pharmaceutical can file the ANDA and with that, claim one of four different reasons about why manufacturing the generic drug does not infringe the patents pertaining to that particular drug. \textsuperscript{xxi} These reasons include: (1) That the patent has not been listed, (2) that the patent has already expired, (3) that the generic company will not sell the drug until the patent has expired, and (4) that the patent is invalid or the particular patent will not be infringed by the generic company producing and selling a drug. This last provision commonly referred to, as “paragraph IV certification” is from which most patent lawsuits arise.

If a generic company filing an ANDA claims paragraph IV certification, then it must inform the patent holder of this claim. Then the patent holder has 45 days to file a patent infringement claim against the generic company. If this happens, the FDA will place a hold on
approval of the ANDA until one of three events happens: (1) the court finds the drug either not infringed or invalid, (2) the court finds the patent infringed and after passage of time the patent expires, (3) thirty months from filing the ANDA when no decision has been reached by the court. This third provision attempts to guarantee a speedy litigation because the plaintiff will not want the thirty-month time period to elapse without a ruling from a judge.

However, this thirty-month provision is unique to the pharmaceutical industry because many times the ruling of the judge will not affect its outcome. For example, let’s say company A obtains a patent for and produces a drug and company B decides to file an ANDA and bring a lawsuit under paragraph IV certification. They go through court proceedings that last over three years and at the culmination company B is found to have infringed company A’s patent. However, throughout this process thirty months have passed and the ANDA filed by company B was approved by the FDA under the thirty-month provision. At this point, since no decision had been reached in the litigation proceedings, company B starts producing and selling its generic version of the drug, diminishing company A’s profit. Once company B is found to have infringed the patent, it may have to pay for the profit that company A lost, and may also be ordered to take the offending drug off the market. However, since the generic drug had already been on the market for over six months, it may be highly improbable or even impossible to completely remove it from the distributors. On the other hand, if company B was found not to have infringed company A’s patent or the patent was found to be invalid. Company A had, “already [thirty] months of exclusive marketing without penalty.” Thus, this thirty-month provision is often considered controversial with ANDA filings and paragraph IV certification claims.

IIA.3 Implications

Although the majority of the Hatch-Waxman Act appears to provide easier ways for generic companies to challenge patent holders, it does include a provision that is beneficial to the brand name drug companies. Traditionally, a drug company filing for a patent does so during the development or clinical testing phases and not after the drug is approved by the FDA. This means that a patent would be granted and the drug would still go through three or more years of testing before it is approved by the FDA and can be sold. Since patent rights only last for 20 years since the time of filing, the patent holder therefore loses out on three or more years of market exclusivity and the revenue that results from that. If the inventor waits to file a patent until the FDA approves the drug, the company runs the risk of a competitor filing for the patent first. The Hatch-Waxman Act seeks to remedy this discrepancy by allowing for patent extensions. The extension granted is equal to the time, “between the effective date of the investigational new drug application and the submission of the NDA, plus the entire time lost during FDA approval of the NDA.” The patent holder must file for extension within 60 days of obtaining FDA approval. The maximum time that the patent can be extended is equivalent to five years, and once the FDA approves the patent, the time that the patent is enforceable with the extension cannot exceed fourteen years.
For example, company A creates a drug and files for a patent on January 1, 2010. Company A then goes through clinical trials and Phase I through III testing for a fourteen year period and the drug finally receives approval to go to market on January 1, 2024. At this point there are only six years remaining on the patent. Company A files for a patent extension on January 30, 2024. The patent is extended for the maximum of five years, extending the expiration date of the patent until January 1, 2035. This also falls within fourteen years of the FDA approval since from 2024 to 2035 only eleven years have passed. If, however, the clinical trials only take ten years and the drug is approved by the FDA on January 1, 2020, the patent will have ten years of validity remaining. A five-year extension would mean that from the FDA approval until the patent expiration in 2035, fifteen years had passed. This is not allowed under Hatch-Waxman and therefore only a four-year extension would be granted, taking the expiration date to January 1, 2034. This means that even if the clinical testing lasts over five years, the extension granted could be less than that, resulting in a maximum of fourteen years of market exclusivity after FDA approval. Those six years of patent exclusivity will always be lost.\textsuperscript{xxvi}

The Hatch-Waxman Act is unique in that it creates laws that are specific only to patents within the pharmaceutical industry. The Hatch-Waxman Act contains benefits for both brand name companies and generic companies, but the primary result of the implementation of this Act has been an increase in generic drugs on the marketplace as an outcome of more patent challenges. In fact, “[t]he robust generic drug industry owes its very existence to the Act, and patent term extensions or restorations are very important to the research-based pharmaceutical industry.”\textsuperscript{xxvii} This is important because as will be explored later, the existence of the generic drug industry and the dynamics between the generic companies and the brand name companies are what drive a majority of the conflicts within the pharmaceutical industry today.

\textit{IIB. The America Invents Act}

\textit{IIB.1 History}

Although the Hatch-Waxman Act can be considered overall beneficial to generic drug manufacturers, a separate piece of legislation, the America Invents Act, could be considered a win for inventors and those who invest in research and development. The Leahy-Smith America Invents Act (AIA) has been characterized as some of the most revolutionary changes to United States patent laws since 1952.\textsuperscript{xxviii} The largest component of the AIA switches the United States from a “first-to-invent” country to a “first-to-file” country. This essentially means that if two competitors invent a product on a particular day, the inventor who first files the patent with the USPTO will be granted patent protection. No longer will investigators have to comb through lab notebooks to determine at what exact moment the product was invented; now the only time stamp that matters is when the first person reaches the patent office.

The history behind this Act is unique in that it demonstrates rare Congressional agreement and rapid movement through the branches of government. Senator Patrick Leahy of
Vermont introduced the bill in the Senate on January 25, 2011 and it passed with an overwhelming 95-5 majority on March 8, 2011. In the House of Representatives, House Judiciary Committee Chairman Lamar Smith of Texas introduced the bill on March 30, 2011, and it passed June 23, 2011 with a vote of 304-117. President Barak Obama signed the final bill into law on September 16, 2011. Thus, within nine months this sweeping patent reform bill solidly passed both branches of government necessary for it to become law. One of the reason this was the case is because the AIA was the first major patent reform in nearly 60 years and our elected officials felt as if it were time for a change.

IIB.2 Provisions

There are many different provisions contained within the AIA, but a few of them affect the pharmaceutical industry and thus are crucial to this discussion. The AIA, “implements a first-inventor-to-file standard for patent approval, creates a post-grant review system to weed out bad patents, and helps the Patent and Trademark Office (PTO) address the backlog of patent applications.” This plans to result in legal reform, job creation, and USPTO reform. The actual text of the Act is complex, consisting of many amendments to Title 35 of the US Code, the federal laws dealing with patents, but the Act essentially changes three distinct ways that the US views patents.

The most substantial change the AIA creates is a first to file system in the United States. This means that patent applicants will no longer have to “prove” that their inventions were created prior to inventions from any challengers. During patent litigation, this saves all parties both time and money throughout the discovery process because priority for a patent will go to the entity that had their paperwork in order. Additionally, inventors do not have to wait until the day the final product is finished to establish patent rights. The US Code allows inventors to file provisional patent applications; that is, a shorter version of a patent that includes only a description of the invention, the manner and process of making and using it, and a drawing. Under the AIA, this provisional application can count as providing the inventor with patent rights under the first to file system and former Attorney General calls this both “constitutional and wise.” Currently, all nations on the globe operate under a first to file system, and the United States was the last one to adopt this methodology. The first to file system essentially places the ball in the hands of the inventor and says if he wants to score a patent he must pass to the USPTO as quickly as possible. This demonstrates the power of the patent system in the United States.

The second important, although not as revolutionary, provision of the AIA is the creation of a system that allows for post-grant review of the patent. This means that even once the USPTO grants a patent, an outside party can challenge the validity of the patent. Although, similar to the “paragraph IV” challenges that can be brought through the Hatch-Waxman Act, this provision is different because it does not necessarily lead to a litigation. Once a patent is filed, the post-grant review provision allows for a challenger to petition for a post-grant review
within nine months of the granting of the patent. The petitioner will ask to cancel one or more provisions of the patent in question on the grounds that it is invalid because it does not meet the requirements for patentability (the invention is novel, useful, and non-obvious) or that it is invalid because the description of the invention and the manner and process of making it was not disclosed in the clear and concise terms required by subsection 112 of the United States Code Section 35. If a patent is reissued, due to rejection in part or in whole of the original patent, in some cases, the reissued patent can also be challenged under the post-grant review provision.

Once a challenger files a post-grant review petition, the patent holder will have the ability to respond and argue why a post-grant review should not occur. Additionally, if the challenger also takes civil litigation action to challenge the validity of a patent, the post-grant review will not be granted. However, if the review is granted, then the Patent Trial and Appeal Board will review the patent in question. They will come to a decision on the validity of the patent and, “issue a final written decision with respect to the patentability of any patent claim challenged by the petitioner.” The Patent Trial and Appeal Board’s decision will be upheld in replace of a civil litigation suit; however, the patent holder has the right to appeal this decision to the Patent Trial and Appeal Board and, if necessary, the United States Court of Appeals for the Federal Circuit.

This provision of the AIA helps saves on costs by offering challengers an alternative to litigation in order to determine the validity of a patent. The cost for a post-grant review by the Patent Trial and Appeal Board is a one-time fee that is affordable for almost all businesses, whereas patent litigation is both very time consuming and costly and may not be a feasible option for many who may wish to challenge a patent. Therefore, this provision of the AIA will allow for many more challengers to patents, and reduce the instances of frivolous litigations.

A third provision of the AIA, seeks to reform the method in which patents are granted and help the USPTO, “address the backlog of patent applications” and this can reduce the costs involved with filing a patent. Prior to the AIA, obtaining a patent and litigating to keep those rights could cost upwards of $400,000. Most small business owners do not have the kind of money necessary to obtain and defend a patent. Additionally, a company loses money through delays involved in granting patent rights. Prior to the passage of the AIA, in July 2010, there were 1.2 million patent applications waiting for final approval. 700,000 of these applications had not even gone through the first review by a patent examiner. While pharmaceutical companies wait for their patents to be approved, they are finishing up clinical testing and waiting for FDA approval. However, if they do not receive patent approval by the time their product is ready to launch, they risk losing millions of dollars in lost profit by not launching, or a costly and timely litigation if they launch “at risk” with patent approval pending. Neither of these scenarios is ideal and that is why the AIA is crucial in addressing the backlog of patents waiting to be approved. The AIA contains provisions allowing the USPTO to hire new patent examiners and other support staff. These extra resources are made possible through a 15% surcharge on certain patent fees such as filing fees, reissue fees, and requests for oral hearings. By raising prices to
obtain a patent by a couple hundred dollars, the AIA saves companies millions of dollars in potential litigation and lost profits, and ultimately the US economy billions of dollars annually in “forgone innovation.” xlix

The result of this third provision has reduced the number of patents waiting for approval significantly. 1 Due to the hiring of additional patent examiners, the USPTO has been able to decrease the time an inventor has to wait to receive patent rights. Overall, this will be an incentive for more patent applications to be filed and for more patents to be granted thus allowing more pharmaceuticals to enter the marketplace. This may be a way to stimulate economic growth as more and more companies find it easier to obtain valid patents, save money on litigation costs, and thus are able to invest more into Research and Development.

IIB.3 Implications

Overall, the AIA has created significant patent reform within the United States. By bringing the US up to par with the rest of the world by implementing first to file patent rights, litigation costs can be reduced and more patents can be granted. The post-grant review by the Patent Trial and Appeal Board also reduces litigation costs, and the 15% surcharge on fees allows for the USPTO to hire more patent examiners, thus reducing the backlog of patent applications waiting for approval. All these reforms affect the pharmaceutical industry because they mean that it is easier to obtain a patent by the time a drug is ready to go to market. They also mean that companies (both brand name and generic) can reduce the amount of money they spend on litigating patents and use that money to stimulate innovation by investing more in Research and Development. Both of these also help consumers because new drugs can be created quicker and at a lower cost than prior to the reforms of the AIA.

IIC. FTC v. Actavis

IIC.1 Background

When competition is allowed in a marketplace, it benefits consumers the most. For example, once a patent expires, the brand name drug company can no longer charge extraordinary amounts of money for a particular product, and generics flood the market allowing consumers to purchase necessary drugs at competitive prices. No longer does the patent holder have a monopoly, thus dictating the price, but the consumers’ demand is based upon the equilibrium price of the particular product. Therefore, in order to remain competitive with the generic companies, brand name companies must lower their prices significantly. Some Big Pharma companies even launch a generic version of their brand name product, called an Own Generic (OG), just to stay in the marketplace, because when filling prescriptions pharmacies in some states will always substitute a generic product if it is available. ii This means that both generics companies and consumers have incentives for generic versions of drugs to enter the marketplace as quickly as possible. Under normal circumstances, the generic company
threatening to launch a patent-infringing drug would have to battle in court against the patent holder to determine whether the launch of the generic is legal.

During the court proceedings there is often a bench trial (a judge rules on the case) or in a few cases, a jury determines the validity of the patent and the legality of the generic version of the drug (See section IIIA for an example). Litigating to the very end is costly and time consuming for both the brand name company and the generic company. Many times, to save on litigation costs, the brand name company and the generic company will reach a settlement agreement. Traditionally, this means that the generic company will agree to stay out of the marketplace until the date of patent expiration, or the generic company will pay the brand name company consideration to be allowed to enter the marketplace before the patent expires. In return, the brand name company will agree to not file another infringement suit (See Figure 1). In fact, “public policy favors the settlement of disputes” because time and money is saved thus benefiting the economy as a whole.ii

![Figure 5 - Consideration in traditional settlement](image)

Recently, pharmaceutical companies have reached settlements in patent lawsuits that are not considered the norm. In these settlements, a generic company will agree not to launch the product right away in exchange for a payment from the brand name company. In return, the brand name company will allow the generic to enter the marketplace prior to the expiration of the patent, without contesting the entry in the form of a lawsuit. The generic company may also agree to render some form of services to the brand name, such as promotion of the brand name drug prior to the generic launch. Looking at this settlement on the surface, it seems that the generic company wins; they receive a payment and get to launch early, but this is not necessarily the case. By stopping the generic company from entering the market at that moment, the brand name company gains billions of dollars of profits from a few extra years of market exclusivity (See Figure 2). If the settlement was not reached and the infringement was litigated to the finish, the brand name company has a 50% chance of losing market exclusivity at the culmination of the trial. Therefore, by “buying off” the generic company’s immediate launch and delaying the
generic from entering the marketplace for a few more years, the brand name company is saving not only litigation costs, but potentially lost profits. That is why these settlements are often referred to as “pay-to-delay” settlements.

For example, Company A has the patent for a drug and enjoys a $4 billion per year profit. The patent expires in 2018. Company B files an ANDA and threatens to launch a generic drug in 2013. If this occurred, it would drastically reduce Company A’s profits to just a few million dollars per year. Company A sues Company B and the two parties enter into negotiations. Company A offers to pay Company B $1 billion and allow Company B to enter the market, without contest in 2016, two years before the patent expires. In return Company B agrees not to launch the drug immediately and will promote Company A’s drug to its customers for the next three years. This is a win for Company B because they are $1 billion richer and they did not even manufacture or sell a product. This is also a win for Company A because by paying Company B to delay the launch of the product for three years, Company A gains $11 billion in profits (The $12 billion for three more years of market exclusivity, minus the $1 billion in payment to Company B). Both companies also save on litigation costs. Some would argue that this is also a win for the consumer because if the lawsuit was found in Company A’s favor, the consumer enjoys two extra years of low-priced generic drugs. On the other hand, if the lawsuit was found in Company B’s favor, the consumer loses three years of receiving the inexpensive drugs. Whether this type of settlement helps or hurt consumers is exactly what the Supreme Court discussed in their most recent opinion, Federal Trade Commission v. Actavis.

As reverse payment settlements become more and more popular, the Federal Trade Commission (FTC) grew wary of these methods of settling. The FTC’s job is to protect the competitive marketplace and, “to prevent business practices that are anticompetitive or deceptive or unfair to consumers.” By carrying out this mission the FTC protects the consumers by ensuring they receive a fair price for the goods they consume. From the outside it may seem that market exclusivity due to patents, is an anticompetitive measure, essentially granting the patent-
holding company a monopoly for a period of time. However it has been found that patents are “exception[s] to the general rule against monopolies,” as they grant a temporary monopoly to the patent holder. Additionally, the patent holder has particular rights granted along with the patent. For example, the patent holder can sell the product at a fixed price and even license the technology with an agreement that the competitor will sell at a fixed price. Settlements are also legal as long as the patent holder acts “within the scope of the patent.” The FTC believes, however, that these “pay-to-delay” settlements between generic and brand name pharmaceutical companies are anticompetitive because they ultimately harm the consumer and when the brand name company gives the generic company money, it is essentially paying the generic company to stay out of the marketplace, which is illegal under antitrust laws.

II.C.2 The Supreme Court’s decision

The case of FTC v. Actavis began with just this kind of settlement. In 2000, a product known as AndroGel® (Testosterone Gel) was approved by the FDA. In January 2003, Solvay Pharmaceuticals was granted a patent for some new technology that is used in AndroGel®. Subsequently, in May 2003, both Watson Pharmaceuticals and Paddock Laboratories filed ANDAs seeking paragraph IV certification and challenging the validity of Solvay’s patent. Three months later, Solvay sued for patent infringement. In 2006, the FDA approved Watson’s ANDA and the companies were preparing to launch their generic drugs into the marketplace, thus infringing Solvay’s patent and costing the company approximately $300 million in lost profits. Since AndroGel® still had years of patent protection left, Solvay decided to enter into settlement agreements. It concluded that unless given a form of compensation, Watson and Paddock would insist on a much earlier entry date than the date of 2015 that Solvay wanted. Weighing the economic costs of settling vs. continuing to litigate, Solvay decided to pay approximately $19 to $30 million a year to Watson, for the company to promote AndroGel® until 2015. Additionally, Solvay paid a total of $2 million a year to Paddock to serve as an alternative supplier of the product. In exchange, both Watson and Paddock agreed not to enter the marketplace as generic manufacturers until 2015.

The FTC filed a lawsuit under Section 5 of the Federal Trade Commission Act, which states that unfair methods of competition are unlawful. The customary court proceedings followed. The 11th circuit district court dismissed the FTC’s lawsuit on the basis that the settlement reached by the parties did not exceed the scope of Solvay’s patent rights, and the court of appeals affirmed that decision. On October 4, 2012 a petition for a writ of certiorari was filed and subsequently granted and the case was argued before the Supreme Court on March 25, 2013 by the Deputy Solicitor General Malcolm L. Stewart and defended by Jeffry I. Weinberger. On June, 19 2013 the Supreme Court released their decision. In a 5-3 decision, the Supreme Court ruled that the “pay-to-delay” settlements are not inherently unlawful, but the FTC is well within their right to challenge these settlements and make the case that they are anticompetitive.
This essentially means that the case the FTC brought against the defendants should not have been dismissed and they should have been allowed to make their case about why the settlement Solvay, Watson, and Paddock entered into was anticompetitive. The Supreme Court states that the “rule of reason,” traditionally applied to antitrust proceedings, needs to be applied to determine if the settlement center around patent protection is anticompetitive. The Supreme Court based their decision on five distinct issues 18:

1. Reverse payment settlements have potential for adverse effects on competition
2. The anticompetitive consequences of these settlements will sometimes be unjustified
3. These settlements give the patent holder power over the competitors and consumers
4. Large reverse payment settlements likely seek to prevent the risk of competition
5. There are other, pro-competitive ways the parties could settle

All of these factors, the Supreme Court says, allow courts to consider the antitrust standard of the rule of reason when deciding whether reverse payment settlements are legal.

The Supreme Court focuses on large unjustified payments that are provided to the generic company for them to stay out of the marketplace. The Court believes that when a patent holder pays the generic company a large amount that is otherwise unjustified the, patent holder, “has serious doubts about patent’s survival,” if the parties were to litigate to conclusion. 19 The Supreme Court states that, “by examining the size of the payment [courts] may well be able to assess its likely anticompetitive effects along with its potential justification without litigating the validity of the patent.” 20 This essentially means that the size of the payment from brand name to generic will help determine the motives of the company. If this large payment is not for a particular service, or if the brand name company receives nothing other than the promise to stay out of the marketplace, then the settlement is subject to FTC antitrust scrutiny.

However, on the matter of how large is too large, the Court remains silent. The Supreme Court does not make a determination in the particular case at hand as to whether a total payment of approximately $30 million a year from Solvay is too large of a payment. The Supreme Court also does not make a ruling as to whether the promotional services that Watson provides to Solvay in return for the payment, justify the sum of money. The Supreme Court also does not mention how the validity of a patent will be determined if it is not necessary for the infringement lawsuit is not litigated to conclusion. The courts will determine these questions, and similar ones, in the coming months and years. Each individual court will be responsible for applying the rule of reason test to each specific reverse payment settlement that is brought before it. 21

IIC.1. Implications

The Supreme Court ruling in FTC v. Actavis has greatly changed the landscape of the settlement negotiations between brand name companies and generic companies. Both critics and proponents of the ruling are unsure as to how this will affect current FTC cases against drug
companies and future potential patent settlements. This will impact both parties’ desire to settle. In fact, the Pharmaceutical Research and Manufacturers of America’s, representing brand name companies, executive vice president and general counsel Mit Spears said, “we are disappointed that the majority failed to provide clear and unambiguous guidance as to how patent settlements could be structured to avoid antitrust exposure short of litigating a patent dispute to the end.”\textsuperscript{lxiv}

The generic companies also echo this opinion.

There are many current FTC cases that are waiting to be tried and some that have been settled (See section IIIB for an example). Speculation has begun as to what the court’s determinations will be in all these cases. The first issue that arises, is that many defendants (drug companies) may argue that if the patent was litigated to conclusion, it would have been upheld and thus the settlement was not anticompetitive but in fact, pro-competitive; the competitor was allowed to enter the marketplace prior to the date of patent expiration. This will result in a patent merits defense, which David F. Sorensen of Berger & Montague PC said at an American Bar Association Section of Antitrust Law said that courts would be disinclined to listen to.\textsuperscript{lxv}

However, the courts will not be able to prevent the patent merits defense argument because, “the Supreme Court's decision opens the door to all sorts of pro-competitive justifications from the drug makers,” said Kaye Scholer LLP antitrust practice group Co-Chairman, Saul P. Morgenstern.\textsuperscript{lxvi} Another, factor that may come into play in future FTC lawsuits is a study performed by the Intercontinental Marketing Services (IMS) that actually found “pay-to-delay” settlements to be pro-competitive.\textsuperscript{lxvii} The results show that, “settlements of ANDA litigation in 33 different drug molecules resulted in a savings to consumers of $25.5 billion from 2005-2012.”\textsuperscript{lxviii} Additionally, about one third ($8.3 billion) of the 2005-2012 total were savings to the Federal government.\textsuperscript{lxix} This report is good news for the defendants in FTC cases who will now have hard evidence to argue their claims. Overall these “pay-to-delay” settlements should be viewed as favorable to consumers because the generic gets to enter the marketplace earlier than if the settlement had never occurred. In fact, Senior Corporate Council Sheila Brodbeck of Pfizer, Inc. said that the term “pay-to-delay” is actually a misnomer because, “we [the brand name companies] let them in early.”\textsuperscript{lxx} Whether the courts agree with this argument will be determined by future rulings (see case studies).

Additionally, the Supreme Court ruling has impacted how drug companies will view future settlements. The reason brand name and generic companies reach settlement agreements in the first place is to avoid the expense of litigating the validity of the patent. Preparing for a lawsuit is time-consuming and expensive with costs for discovery, witness compensation, not to mention lawyer and court fees. If the companies were to enter into a settlement agreement for the purpose of avoiding litigation and then find out that the FTC is suing them for an anticompetitive agreement, then the settlement agreement would have been for nothing. The companies would have been better off by just litigating the patent claims to finality. Therefore, the Supreme Court’s ruling in \textit{FTC v. Actavis} will force both parties to think twice before reaching an agreement. By offering a side-deal (like Solvay did) where the generic company will promote or
distribute the product in exchange for payment, companies may be able to avoid the FTC’s wrath. However, the payment offered must be a “fair value for services,” and companies may have to defend themselves in valuation trials or other hearings.

Another far-reaching consequence of this ruling is deterrence of patent challenges altogether. The irony of this is that the Hatch-Waxman Act was put into place to allow generic companies to challenge patents more easily and with less expense. The Supreme Court’s decision may deter settlements and therefore generic companies would have to litigate a patent challenge to conclusion, risking millions of dollars. If this becomes the case, many generic companies would refrain from filing a paragraph IV certification with their ANDAs. This would completely nullify the intention of the Hatch-Waxman Act as well as the intentions of the FDA and the Federal government to create a competitive environment for pharmaceutical companies. In fact, the Generic Pharmaceutical Association said that, “consumers may have access to few generic options because companies will have to be more careful.” Overall, innovation could also be deterred because the integrity of patent rights is suspended by FTC lawsuits. As John Osborn, former General Counsel for… states, “In the end, the key questions are whether the Supreme Court’s opinion will limit innovation over time, or reduce the number of generic challenges that have exploded since the 1980s under the Hatch-Waxman scheme? In either case, consumers will lose.” This sentiment is imperative to keep in mind when determining the fate of patent law within the pharmaceutical industry.

III Case Studies

In order to fully understand how the laws affect patents within the pharmaceutical industry, examples of the use of these laws must presented and their outcomes evaluated. Three separate cases will be referenced and their overall impacts will be determined. An example of a straightforward patent challenge, patent infringement and the subsequent litigation will be demonstrated in Altana Pharma v. Teva Pharmaceuticals. A current example of the result of the Supreme Court decision in FTC v. Actavis will be discussed in the matter of Teva Pharmaceutical Industries and Cephalon, Inc. Finally, the future of innovation within the pharmaceutical industry will be discussed by analyzing the current “patent cliff” in the United States.

IIIA. Altana v. Teva et. al Re: Protonix

IIIA.1 Infringement

In July of 1988, three years after first filing the application, inventors from Altana AG, a German chemical company, were granted U.S. Patent No. 4,758,579 by patent examiner Jane T. Fan, for a new drug known as pantoprazole sodium. Altana, as the patent holder had the rights to license the technology to create this drug, and Wyeth Pharmaceuticals bought the
exclusive license for pantoprazole sodium. Under that agreement, Wyeth would be the only company who could produce and sell the drug for the lifetime of the patent. On February 2, 2000, Wyeth received approval from the FDA to market the drug. This drug was sold by Wyeth under the name Protonix® and was approved for prescription by physicians as a proton pump inhibitor for gastroesophageal reflux disease, or in other words, to decrease stomach acid. Protonix® was a blockbuster drug and within the first five years on the market, brought in annual net revenue of approximately $1.6 billion. However, since the patent was to expire in 2005, Altana along with its licensee Wyeth filed to extend the term of the patent. Under Section 156 of United States Code 35, a change created by the Hatch-Waxman Act, Altana and Wyeth asked for a patent extension due to the longevity of the approval from the FDA. In 2004, Wyeth and Altana were granted an extension of U.S. Patent No. 4,758,579 for five additional years from the original expiration date. This means that the patent for Protonix® would not expire until July 2010 and Wyeth would recover five years of profits from market exclusivity that they lost due to the FDA approval process. From an outsider’s perspective, the profits of Protonix® looked like they were heading in a positive direction.

Meanwhile, generic companies were rushing to be the first to file an ANDA on the patents Wyeth had listed in the “Orange Book” and thus gain the 180 days of exclusivity when the patent expired or was found invalid. On April 4, 2004, Teva Pharmaceuticals, an Israel-based generic company, was the first to file an ANDA on U.S. Patent No. 4,758,579, seeking FDA approval to sell a generic version of pantoprazole sodium. Teva also claimed paragraph IV certification, stating that Wyeth’s patent was invalid or the ANDA did not infringe the patent in contention. In 2005, Sun Pharmaceuticals, an Indian generic company, also filed an ANDA under paragraph IV certification. Wyeth now knew a patent challenge was commencing, and began preparing to bring patent infringement lawsuits against both these companies to avoid losing billions of dollars in revenue.

In May of 2004 and in April 2005, Wyeth filed complaints for patent infringement against Teva and Sun, respectively, requesting for a permanent injunction against the defendants’, “commercial manufacture, use, offer to sell, or sale within the United States,” until the expiration date for the ‘579 patent. Upon the filing of this patent infringement complaint, due to the Hatch-Waxman laws, the FDA was required to delay approval for the generic drugs for thirty months or until the conclusion of the suit. This means that starting in August 2007, the FDA could approve the generic versions of for Protonix® and Teva and subsequently, Sun could launch their generics “at risk” even if the claims for patent infringement were not decided. In June of 2006, Altana and Wyeth’s cases against Teva and Sun were consolidated into one lawsuit and the case remained somewhat quiet for a year.

Wyeth knew that the thirty month delay of the FDA approval was going to expire in late 2007 so in June of 2007 Wyeth corresponded with both Teva and Sun, asking if they had plans to
launch generic pantoprazole sodium “at risk” without a final decision on the patent infringement claim. Teva told Wyeth that they planned to launch a generic Protonix® “at risk” as soon as the FDA approved their application. Sun told Wyeth that they did not plan to launch the generic product, “but [they would] reconsider [their] decision if Teva prevail[ed] on plaintiffs' preliminary injunction motion and if Teva [did] launch its generic product.” Essentially, Sun would not launch unless Teva launched, and Teva planned to launch, so Wyeth had to prepare for the “at risk” launch of two generic versions of Protonix® at the end of 2007. Altana filed motions for preliminary injunctions against both Teva and Sun on June 22, 2007. This means that Altana and Wyeth asked the court to prohibit Teva and Sun from launching their generic versions of Protonix® “at risk” because Altana and Wyeth believed that they had a high likelihood of success in the patent trial proceedings. On September 6, 2007 Judge Jose L. Linares of the Federal District Court in Newark, New Jersey decided that a preliminary injunction should not be granted and thus Teva and Sun, upon FDA approval, were free to launch their generic versions “at risk.” It should be noted, that Judge Linares did not decide on the final issue, whether the patent was invalid, but merely decided that in this case, the burden for a preliminary injunction was not met, meaning that if the generics launch, Wyeth did not necessarily have a high likelihood of success and would not suffer irreparable harm. However, if Teva and Sun did launch the generic versions and in proceeding litigation they were found to have infringed the Protonix® patent, they would have to pay more in damages than if they did not launch the generic, which is why the launch was deemed “at risk.” After the issuing of Judge Linares’ denial of the preliminary injunction, all parties waited to see what would happen.

Throughout the cold months of December 2007, Wyeth, Teva and Sun tried to settle on a deal that would appease all parties and save them from tedious and costly trial proceedings. During this time, Wyeth also prepared a generic version of Protonix® (called an “Own Generic” or OG) in case Teva and Sun launched their generics. It did this, not because it thought the patent for pantoprazole sodium was invalid, but because if Teva and/or Sun launched the generic version, Wyeth needed to be able to compete with them. Essentially, due to formulary restrictions on health insurance and state laws requiring pharmacies to distribute generic versions of drugs, if one is available, one generic in the marketplace meant that Protonix® would most likely not reach consumers, and Wyeth should try to recoup some of that lost profit by competing directly in the generic marketplace. Due to this strategy, in December 2007 both Teva and Wyeth had generic versions ready to ship. On the Friday before Christmas, Teva started shipping the drug out to distributors. This prompted action from Wyeth who asked Teva to cease further shipment until an agreement could be reached. The parties were able reach an agreement that no shipments of the generic drug would be sent until at least January 2008.
III.A.2 Litigation

On January 29, 2008, in response to the termination of an agreement not to launch by Teva, Wyeth launched its OG followed in suit by Teva and then Sun. Bernard Poussot, CEO of Wyeth, stated that the company did not believe the patent for Protonix® is invalid and cautioned that they would, “continue to seek an injunction against any infringement of this patent, as well as monetary damages, including lost profits.” At this point, it seemed that a trial to determine the validity of Altana’s patent was inevitable.

As time passed, the sales for Protonix® dwindled, and a drug that brought in $1.6 billion in revenue in 2005, netted just shy of $400 million in 2008, due to its generic competitors brought on by the infringement of Teva and Sun.

In April 2010 a jury trial was held in Newark, New Jersey in front of Judge Linares to determine the validity of Altana’s patent. In a more than two week proceeding spanning from April 5 to April 23 a jury picked from the citizens of Newark heard from each of the three parties involved in this case. With evidence and testimony dating back to the first patent approval in 1988 to the filing of the ANDA in 2004 to the launch of the generic drugs in 2008, the jury was able to put together a picture of what occurred behind the scenes throughout the more than twenty year lifespan of the popular drug called Protonix®. Wyeth argued that Teva and Sun infringed the patent they had licensed from Altana. Teva and Sun argued that the patent was invalid because the formula for pantoprazole sodium was obvious. At the conclusion of the trial, the jury deliberated and on April 23 returned with a verdict. The jury found that Teva and Sun did not prove with clear and convincing evidence that the patent for pantoprazole sodium was obvious and thus invalid by double patenting. This verdict was in favor of Altana and Wyeth and Teva and Sun, by launching their generic versions of the drug had infringed upon Altana’s patent. Teva and Sun would owe Wyeth for its lost profits, upwards of $1.5 billion. The win for Altana and Wyeth and the talk of a large payment for damages prompted Howard Hogan, a partner at Gibson, Dunn & Crutcher LLP in Washington, DC to remark, “This should serve as a warning to generics companies about the dangers of at risk launches.”

Now that the patent had been found valid and infringed, preparations were made for a determination of the damages to be awarded to Wyeth. Analysts estimated Wyeth could regain anywhere between $450 million to $3 billion in lost profits. In the meantime, Teva and Sun appealed the verdict to the Third Circuit Appellate Court. The appeal could not be heard until the damages were awarded, and in October of 2010 Teva demanded a second jury trial to determine what was owed to Wyeth.

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2 Pfizer, Inc. bought Wyeth in 2009 and the responsibility for this litigation and all others transferred to Pfizer. For clarity, the remainder of this document will still refer to Wyeth as the plaintiff.
Over two years later, on June 3, 2013, the damages trial was held in front of a jury. The question at hand was not whether Teva and Sun had infringed the patent, but how much Wyeth lost in sales due to that infringement. Different formulas were used to calculate that amount. Wyeth wanted to use the full amount of lost sales without regards to any discounts they provided to insurance companies or the profits they made from selling their OG. Teva wanted to pay as little as possible so they argued that Wyeth would have made much less than they were claiming due to steep discounts given to insurance companies. Sun didn’t want to pay anything, because in their mind, they didn’t infringe the patent. Sun had launched a generic version after both Wyeth and Teva had placed generics on the market. The plaintiffs presented their case for about a week. Then, on June 11, before even placing one witness on the stand, the defense agreed to a settlement deal. In this agreement, the plaintiffs would receive $2.15 billion, $1.6 billion from Teva and $550 million from Sun. Additionally, and probably more importantly, Teva and Sun signed orders stipulating that the patent was infringed and waiving their right to appeal. Why before even launching their case, did the defense admit infringement and settle for much more than they were originally seeking? This is probably due to the uniqueness of this particular case.

**III.A.3 Implications**

The proceedings in *Altana v. Teva et. al* are not vastly different from most drug patent infringement cases. A generic company claims paragraph IV certification, and the companies prepare to fight. Once the thirty-month delay for FDA approval concludes, the generic launches and prices for the drug drop. The brand name company loses profits and tries to settle with the generic to avoid having to go to trial. This case was not much different, except for two notable details.

The first, is that for the damages trial in particular, the defense asked for a jury trial. Jury trials are unusual in patent cases, and even more rare to determine damages. A typical juror will become bored quickly with mundane details about calculations of profits and discounts. When numbers become involved, judges are more likely to make rulings in bench trials rather than a jury comprised of non-mathematicians or accountants. This is a possible reason why Teva and Sun decided to settle. The plaintiff’s case could use pathos. They had a story to tell, about how they had this great product and the defendants came a “stole” it from them and that’s why they deserved a higher payment. Whereas the defendants’ cases were very dry and technical. They wanted the payment to be calculated using discounts, not full prices. Their witnesses consisted of many experts stating why their calculations, not the plaintiff’s were correct. After assessing, the jury’s reaction to the plaintiff’s somewhat less mundane testimony, the defense decided to not waste time and money boring the jury and figured they would probably be safer with a settlement.
The second difference is that in this case there were two defendants, not unusual in patent infringement cases, and those two parties could not come to an agreement on a joint defense strategy. Both parties, Teva and Sun, wanted to pay as little as possible to Wyeth and Altana. Sun, in particular, believed that it should not pay as much as Teva because it was the third to enter the generic marketplace, not the first. Sun also argued that they never would have launched their generic, if Teva hadn’t launched first. This created much animosity between the two parties, which was apparent in the courtroom. Sun and Teva each filed individual motions, had separate counsel sitting apart from each other, and even some of their responses to objections sided with the plaintiffs. Failing to agree upon a mutual defense, shows a weakness in the case to the jury and perhaps the only agreement upon which the two parties were able to concur was the settlement.

Although somewhat different than typical pharmaceutical patent infringement cases, *Altana v. Teva et. al* is a good example of how the Hatch-Waxman laws apply to both generic and brand name companies. This case demonstrates the often-hostile relationship among the generic and brand name companies and establishes that with every premature generic launched, the consumers and generic companies may win but the brand name companies lose.

**III.B. Provigil FTC case**

**III.B.2 History**

In January of 1987 a new drug known as modafinil was filed with the USPTO. Invented by Louis Lafon, the drug, classified as eugeroic, treats narcolepsy and other sleeping disorders by creating wakefulness. The patent was granted in 1990 and received FDA approval in 1998. Through a supply and license agreement, modafinil, sold as Provigil by the company Cephalon, Inc., had sales of $475 million in 2005 and $800 million in 2007. Due to various reissues and extensions, including orphan drug exclusivity and pediatric exclusivity, patents protecting Provigil extended protection until April 6, 2015. As expected, in December of 2002 four different generic companies filed for FDA approval of generic versions of modafinil thus provoking patent infringement lawsuits from Cephalon. By 2006, Cephalon had settled with these generic companies by paying them a total of $200 million “for various licensing agreements, supply agreements and research and development deals” with their agreement that they would not start selling generics until April of 2012. Since these four companies were granted “first to file” rights under the Hatch-Waxman act, they would receive 180 day market exclusivity upon entering the market. Since none of them would enter the market until 2012, this 180 day exclusivity period discouraged any additional generic manufacturer from challenging the patent, and thus Cephalon was safe to sell Provigil unchallenged until 2012. The CEO of Cephalon, Frank Baldino, said about the agreement, “We were able to get six more years of
Trisch 29

This would be a statement that would be repeated over and over by critics in the following years.

Enter the FTC. On February 13, 2008, the FTC sued Cephalon for anticompetitive actions in reaching its settlement with the generic companies. This was a classic case of “pay to delay,” the FTC argued and by paying the competition a sum of money to stay out of the market for approximately six years, Cephalon was creating a monopoly and hurting consumers by denying them generic Provigil®. In a press release, Jeffrey Schmidt director of the FTC Bureau of Competition said, “Cephalon prevented competition to Provigil® by agreeing to share its future monopoly profits with generic drug makers poised to enter the market, in exchange for delayed generic entry. Such conduct is at the core of what the antitrust laws proscribe.”

The FTC knew that sales from Provigil® were the source of over 40% of Cephalon’s sales and believed that by paying off the competition they were protecting their own profits. Cephalon disagreed. They believed that by the settlement, “resulted in generic entry years earlier than patent expiration” in 2015” and thus was actually pro-competitive. Additionally, Cephalon’s ability to settle a patent litigation was well within the scope of their patent. Anti-trust litigation began as the FTC sought a permanent injunction against Cephalon that would allow generic modafinil to be sold prior to 2012 and prohibit the company from entering the same type of settlement in the future.

In April of 2008, the FTC’s case, originally filed in Washington, D.C. was transferred to the Eastern District of Pennsylvania, the court of Cephalon’s headquarters. Additionally, several civil lawsuits were filed against Cephalon as well for delaying generic competition, including suits from CVS and Walgreens. These complaints claimed, “Cephalon is actively working to destroy the market for generic Provigil and the potential benefits to consumers from generic entry.” The cases were consolidated and the plaintiffs argued a total of four complaints against Cephalon including: that the patent was invalid or not infringed, that the 180 day exclusivity period held by the generic companies prevents other companies from attempting to enter and this is not a right that is given to a patent holder, that there was, “a larger antitrust conspiracy” as part of the settlement agreements, and that the agreements prevent sales of generic versions of the drug that were not part of the original patent litigation.

On March 29, 2010, Judge Mitchell S. Goldberg of the US District Court in Eastern Pennsylvania ruled on dismissal of the cases. Judge Goldberg stated that the cases should be analyzed under the scope of the patent test and did not dismiss all the cases, including the FTC’s antitrust case against Cephalon. After receiving denial of their motion to dismiss, Cephalon knew that battling the FTC was going to be a challenge.

As all the parties involved geared up for litigation, across the country judges were ruling on “pay-to-delay” antitrust lawsuits brought by the FTC, including Merck and Solvay, and it seemed as if this issue would gain attention of the Supreme Court justices. In late August 2012, Judge Goldberg placed the case on hold until the US Supreme Court granted writ of certiorari in
December for another reverse payment settlement case; this case was, of course, *FTC v. Actavis*. The Cephalon case was therefore placed on hold until the Supreme Court ruling in June of 2013.

In reference to staying the cases, Judge Goldberg wrote, “the value of such resolution depends upon its finality,” and ruled that it was unproductive to move ahead with the litigation if the standards by which he should rule may be changed by the Supreme Court.\(^{\text{cxx}}\)

A year passed and after the release of the Supreme Court’s decision on June 13, 2013, a hearing to discuss evidence was scheduled for early August. On August 1, 2013 the Chief Financial Officer, Eyal Desheh, of Teva released a statement saying that it had an agreement in principle to settle the lawsuits for $485 million.\(^{\text{cxxi}}\) Desheh said, “The settlement-in-principle is in the best interests of the company given the circumstances of this situation.”\(^{\text{cxxii}}\) Teva’s chief legal counsel, Richard Egosi, said that Teva was settling now because settlement, in light of the Supreme Court decision, “eliminated the uncertainty of the legal standard and brought the sides together.”\(^{\text{cxxiii}}\)

Although Teva has decided to settle, the legal battle is not over. On September 11, 2013 Judge Goldberg decided that Teva had a right to withhold certain documents marked privileged, including board of director meeting minutes. Judge Goldberg stated that Teva only has to turn over one of 54 documents to the FTC.\(^{\text{cxxiv}}\) It was thought that the parties will settle, but the talks fell through, and the FTC has made this case a “a top priority.”\(^{\text{cxxv}}\) The FTC is seeking, “equitable relief designed to prevent recurrence of, and obtain redress for, Cephalon’s violation of law, including monetary equitable remedies.”\(^{\text{cxxvi}}\) It is too soon to tell how this case will end, because “It will … take time for judges to explain how the rule-of-reason test will be applied.”\(^{\text{cxxvii}}\) In fact, as Shashank Upadhye, a partner in the intellectual property practice at Seyfarth Shaw LLP, states, “every case is going to stand on its own merits and the facts.”\(^{\text{cxxviii}}\) Only time will tell how the Supreme Court ruling will be applied to reverse settlement cases.

**IIIB.1. Implications**

Stepping back and looking at the Provigil\(^{\text{®}}\) anti-trust case as a whole presents some interesting concepts. The first is that, when reaching deals that could potentially be considered anticompetitive, companies find critics in both the FTC and private entities such as insurance providers or pharmacies. A settlement to prevent continuation of litigation could result in different litigation with multiple parties. Provigil\(^{\text{®}}\) is not an isolated case. In July of 2013, the New Jersey Public Interest Research Group released a report of 20 drugs that have been affected by pay to delay settlements, including Lipitor and Adderall. These drugs, although allowed to be produced as generics before the official patent expiration date, have been kept off the market for up to 11 years, costing consumers $3.5 billion of additional costs per year, the report claims.\(^{\text{cxxix}}\) This kind of information has prompted response from Congress, including testimony from Mike Russo. He states that there are alternatives to pay to delay settlements that will allow for earlier release of generic versions of patented drugs, including the brand name company withdrawing
the patent infringement suit, agreement between the parties to settle without payment which ideally would lead to the earliest possible entry date, or proceeding to trial without a settlement. The issues with his proposed solutions is that the brand name companies will never agree to the first, and the generic companies would be hard to convince of the second, which leaves continued litigation as the only option. Thus, I predict the future of patent infringement litigation will result in increased trials instead of settlements. However, in the upcoming years precedent will be created in how the courts will approach these types of settlements, and a standard may be reached. Action from Congress is possible as well, and they could pass legislation preventing pay for delay settlements or creating a more desirable alternative route for pharmaceutical companies. Pay to delay settlements and the resulting conflicts surrounding them are just one of the unintended consequences of the Hatch-Waxman Act, and the future of patents within the pharmaceutical industry is greatly affected by them.

IIIC. Future of Innovation

The America Invents Act took effect on March 16, 2013. Recent responses to the Act states that the Act will not deter innovation within the pharmaceutical industry because, “[t]here have been almost no cases in which worthwhile research was held back by existing patent protections.” However, our nation is currently at a turning point within research and development and changes to innovation within the pharmaceutical industry are inevitable. First analyzing the cost to develop a new “blockbuster” drug, then by examining the onset of the patent cliff, then by, finally through discussion of generic companies’ innovation and partnerships, the future of innovation within the pharmaceutical industry will be determined.

Pharmaceutical companies spend billions of dollars in research and development and many of the drugs created never make it to market. In fact, 95% of medicine developed fails to be both efficacious and safe in humans, thus failing to receive FDA approval. An analysis conducted by Forbes found that for every drug that receives market approval, a pharmaceutical company will spend on average $5 billion in research and development, not only on the successful drug, but on the potential development of all the medicines that do not make it to market. For example, over a ten-year period, pharmaceutical giants like AstraZeneca have developed only four new drugs and spent $38.2 billion, which results in a cost of $9.56 billion spent for development for each successful drug. This type of spending is not sustainable says Susan Desmond-Hellmann, the chancellor at University of California San Francisco. It’s no wonder that drug prices are so high because so much money is spent on failed research and development ventures.

Frightened by these numbers, experts dug deeper in search of explanations. The averages found told an interesting story. As a company develops more successful drugs, its spending per drug increases. Companies that only developed one drug over the ten year period spend a median of $351 million for that one drug, but companies that developed eight to thirteen drugs over the ten years, spent a median of $5.46 billion per drug. This leads to the conclusion that in
order to develop more successful drugs, much more money was spent on drugs that failed. Bigger pharmaceutical companies spend more than smaller companies because their rate of return on a successful drug is higher. Additionally companies spend extra money in order to have an international presence and have their drugs approved in multiple countries.

IIIC.1. Possible Solutions

In order to solve this apparent problem, what can be done? Companies could take the approach of Bristol-Myers who had nine drugs approved over the ten years but only spent a total of $3.4 billion per drug, almost half of the average. One way that pharmaceutical companies can spend money wisely is by only following through on projects that have a good chance of success and abandoning those developments whose chance of success has become low. In a world where the goals business and science must be on the same page, it is necessary to “follow the science.” In fact, Roger Perlmutter, head of R&D at Merck said, “Great drugs build great franchises, but great franchises don’t necessarily build great drugs.” Additionally, by focusing on special niches of the drug market, such as rare diseases companies, can spend less on R&D and stand to gain more in the marketplace. For example, “Alexion, the biggest stand-alone orphan drug maker, spent $490 million in R&D in the decade before its drug was approved.” Additionally, through partnerships and research grants from foundations, pharmaceutical companies can cut down the costs on the development of the drug. This type of collaboration may be a major factor in the future of the pharmaceutical industry.

As the cost of developing new drugs skyrockets, the timing is ticking on the market exclusivity of already existing “blockbuster drugs.” In an epidemic known as the “patent cliff” over the past ten years, patent expiries for brand name drugs has contributed to a 30% rise in generic prescriptions. These “blockbuster drugs” include Pfizer’s Lipitor® in 2011, Eli Lily’s Cymbalta® in 2013, and AstraZeneca’s Crestor® in 2016. The patent cliff is expected to continue until 2018, and “companies are taking strategic steps to diversify their portfolios and focus on innovation to ensure long-term viability for the future.” As the number of patents expiring rises, generic companies are presented with opportunities to grow and develop their businesses creating a stronger generic force. The IMS reports that $71.5% of total spending was on branded drugs and generics accounted for $28.5% of total spending. However, generics accounted for 84% of the prescriptions provided in 2012, and is projected to reach 87% by 2017. Additionally, the implementation of the Affordable Healthcare Act will see an increase of consumers vying for lower healthcare costs generic medicines are estimated to save Americans $127 billion in healthcare costs over the next five years. As the patent cliff comes to an end, the industry is calling for the “next big development” in healthcare. The next five years, 2013 through 2018, are expected to see an increase in innovation by generic companies as well as collaboration among pharmaceutical companies and even the government.

The future of innovation within the pharmaceutical industry may not reside solely within the brand name companies that have dominated for so long. Traditionally generic companies,
such as Teva have now become patent holders through both acquisition and innovation. In June of 2013, Teva was involved in two patent litigations, one defending against claims of infringement, and one protecting their patent from infringement by competitors. University of Michigan professor Eric Gordon, states, “Arguing for patent protection in one courtroom and against it in another courtroom is a sign that Teva is no longer just a generics company.” On the flipside, once a patent expires, in order to continue to stay in the competition, brand name companies will market their drug at generic prices to remain on insurance formularies and in the hands of consumers. Eric Gordon reflects on this phenomenon,

Branded pharma companies originally wanted to get into generics in order to provide more stable cash flow and earnings, even if at low margins, to balance the lumpiness of earnings from intermittent on-patent blockbusters. Later, generic manufacturers like Teva started to envy the profit margins of the branded pharma companies and added on-patent products to their portfolios. The two businesses, generics and new drugs, are different in important ways. There is no harm in one company doing both, and there is no great advantage to it.

Since generic companies have decided to play in the “big leagues” against brand name companies they have also worked on expanding their market to include countries from around the world. Areas of the globe such as China, India, North Africa, and the Middle East are attractive for generic manufactures because of their weak patent protections and low manufacturing costs. In undeveloped areas of the world, generic manufacturers actually have an advantage over the local industries because of their high profit margins and large scale manufacturing capabilities. Although generic companies have now become even more of a threat to big pharmaceutical companies, the future of innovation may lie within collaboration instead of competition.

Many big pharmaceutical companies now have partnerships with biotech companies to increase productivity of the research and development process. Additionally, many small companies are able to dedicate time to further develop a drug that had originally been abandoned by a large company. For example, Cubist Pharmaceuticals spent only $220 million in research and development of the drug Cubicin after taking over from Eli Lilly when the company abandoned the development of the drug. Non-profit organizations will invest in pharmaceutical companies to advance their own laudable missions. For example, the Cystic Fibrosis Foundation asked Vertex pharmaceuticals to develop a medication against this disease. Due to their efforts, a drug known as Kalydeco was developed that aids patients who suffer from cystic fibrosis due to a specific genetic mutation. Government agencies such as the National Institute of Health have also called upon pharmaceutical companies to aid in development of new drugs especially in continuing research and development on drugs that had previous been abandoned by the companies.
Partnerships among companies are not uncommon as well. A Business for Social Responsibility conference held in 2012, Claire Dixon of GSK stated that collaboration is essential especially in areas where the problems are complex and challenging. Companies have banded together to research drugs to combat hot button diseases such as AIDS or cancer and universities have been successful in bringing would-be competitors together to collaborate on research. For example, the University of Hong Kong has allied with Pfizer, Eli Lily and Merck to examine the role of Hepatitis B in liver cancer. This focus on research could lead to the development of a new drug to aid treatment of liver cancer.

Overall, the future of innovation within the pharmaceutical industry is at a crossroads. New drugs must be developed in order to end the patent cliff and they must be made affordable for consumers. Companies must figure a way to reduce costs in development of new drugs and the emergence of traditionally generic companies as patent holders will continue to be a factor within the industry. As the effects of the America Invents Act take hold, patents will be filed more quickly, and perhaps collaboration among companies and other entities will allow for true innovation and real solutions to life-threatening diseases.

IV The changing times

Now that we have examined the development of patent laws, and explored some specific cases of these laws, it is now time to predict the future of patent laws in the pharmaceutical industry. We first learned about the Hatch-Waxman act, and later examined a case regarding Pfizer and Teva. From this, we learned the consequences of the 180-day exclusivity period given to the first generic company to file an ANDA. Then we examine the most recent changes in patent law, the results of the Supreme Court case FTC v. Actavis. We looked at a case of “reverse payment” settlement in Altana v. Teva, and realized many of the consequence of the Court’s ruling have yet to be revealed. Finally, we looked at the future of innovation in light of the America Invents Act, and examined multiple cases that demonstrate continued innovation in the industry.

After discussing the issues surrounding patent laws in the pharmaceutical industry and then looking at some specific cases, I think it is necessary to predict the future of the pharmaceutical industry. In order to do this, we need to examine different ways the industry could change. A viable solution will only occur when all three sides of the triangle are balanced. When the consumer, the brand name pharmaceutical companies, and the generic companies are all equally satisfied with a solution that should be the long-term solution. However, in order to find that point of balance, it is necessary to test and analyze different options through policy changes or transformation of viewpoints. I believe a trial and error system will be the way to determine the future of patent laws in the pharmaceutical industry.

Patent protection is needed to encourage innovation within the industry. However, 20 years of patent protection may be too big of an incentive. Would innovation still occur if the
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patent protection of pharmaceuticals was cut to 15 years? What about 10 years? I will examine how these changes could affect the industry.

Let’s imagine patent protection for pharmaceuticals was decreased from 20 years from the first date of filing to 15 years. In this hypothetical situation all grounds for patent extension would be eliminated so this would mean that I file for patent protection on January 1, 2014 my patent will expire on January 1, 2029. Assuming my drug is not entitled to expedited FDA approval, I could take the average of 12 years for my drug to be approved. This means that my drug would be approved in 2026. If I went immediately to market, I would have three years of exclusivity before generics entered the marketplace. Let’s say this drug is a blockbuster and makes approximately $4 billion per year in profits. In those three years, my company would earn $12 billion. However, the cost it took my company to develop the blockbuster drug was approximately $5 billion. This means that my net profit for three years of sales would be $7 billion, a 140% increase from what I would have if I didn’t invest that $5 billion to create the drug in the first place. Would this be a high enough margin to sustain my company? Would it be worth it to continue innovation?

Now let’s take that scenario and cut the patent protection in half down to 10 years. Since the FDA approval process would take approximately 12 years, this would mean that my patent would expire before my drug was even allowed to be sold. In this scenario the patent protection is essentially nullified, and my company would have no incentive to continue to develop new medicines.

Looking at the two cases presented, clearly there is a limit to how short a patent term could be. Reducing patent protection to 12 years or below would nullify the intent of the patent in the first place. I would suggest 15 years as the lowest a patent term could ever be. In this case a drug company would receive approximately three years of monopoly profits before generics entered the marketplace. To me, this seems like enough incentive to continue to be innovative with research and development.

Now let’s examine the other possibility. Suppose patent terms were actually extended. Many companies receive continued patent extensions, often renewing patents on the basis of a new method of delivery or new formulation such as an extended release tablet. These extensions allow companies to extend their market exclusivity past the original 20-year period. What would happen if these individual extensions were eliminated but the patent term was extended overall to 30 years? In this case I file for patent protection on January 1, 2014 and my patent will not expire until January 1, 2044. The FDA approves my drug in 2026 and I go to market, selling a drug as a monopoly for 18 years. I may change the formulation of my drug slightly, but I do not receive a new patent for it or an extension of my existing patent. During those 18 years I will sell my drug for $4 billion per year, making $72 billion, and $67 billion in net profits. This is a remarkable 1340% increase from what I would have if I didn’t create that drug. However, since I do not
receive patent extensions for reformulations of the drug, I don’t have much incentive to improve the quality of the drug.

Using the formulaic method I outlined above, we could find the perfect amount of time a pharmaceutical patent should exist. Let’s say that pharmaceutical companies will not invest money to develop a new drug unless they will make at least triple the amount of money they put into research and development. Additionally, consumers and generic companies will not be happy with a drug that has a monopoly on the market for over 8 years. Taking these things into consideration we set our boundary conditions. Pharmaceutical companies need to make a profit of $20 billion, or $15 billion in net profits. This means they need their drug to be on the market exclusively for at least 5 years. That would be our minimum condition. 8 years of exclusivity would be our maximum. Assuming FDA approval takes 12 years, the right amount of time for a patent to exist would be between 17 to 20 years, leaving us at our current system. If the tipping point for pharmaceutical research increases or generic companies and consumers change their opinion about what is a fair length of time for exclusivity, the correct length of patent protection changes as well. Thus, this is a dynamic system and can be expressed as the below equation.

\[ \text{($invested)A + ($ invested) / ($ made per year) = N_A} \]

Minimum patent term = \(N_A + \text{(Time for FDA approval)}\)

Maximum patent term = \(N_B + \text{(Time for FDA approval)}\)

Where A is defined as a multiplier that pharmaceutical companies believe makes it “worth it” to invest money in drug development, \(N_A\) is the minimum time of market exclusivity desired by the pharmaceutical companies, and \(N_B\) is the maximum time of market exclusivity allowed by the generic companies and consumers. Although this model may be beneficial for analysis the economic effect of patents within the pharmaceutical industry, it is not very practical when applied using only averages.

So what is the solution? I propose that we do not change the time of patent protection and exclusivity but merely take steps to make the pharmaceutical industry fairer for all players. We should eliminate patent extensions, and expedite the FDA approval process.

There are other issues that must be considered when discussing the future of patents within the pharmaceutical industry. Namely, how the three points of the triangle: pharmaceutical companies, generic companies, and the consumers all overlap. Some solutions could include encouraging pharmaceutical companies to sell their own generic versions of drugs and allowing for cooperation between pharmaceutical companies and generic companies.

With the rise of new healthcare solutions, such as the Affordable Care Act, now is more important than ever to discuss the effect of pharmaceutical patents on consumers. For example, pharmaceutical companies now produce their own generics one their patent on a particular drug
expires. In a 2005 US Appeals Court decision, it was decided that Pfizer could sell a generic version of its drug Neurontin, an anti-epilepsy drug. Instead of fighting a patent battle against two generic companies, Pfizer just decided to compete fairly in the marketplace by launching its own generic of the product. This gives the pharmaceutical companies an advantage because although they do not charge as high of a price for their product, they are able to remain on the formulary of the many healthcare providers. Additionally, they avoid legal fees for patent lawsuits, and become viable competitors to the traditionally generic companies.

The launching of an own generic product also helps consumers. Consumers can receive the same quality drug at a lower cost sometimes even before the drug comes off patent. If consumers purchase an own generic, they know they are receiving the same original formula from the same reputable company. On the other hand, launching an own generic creates competition for generic pharmaceutical companies, who rely on the 180-day period granted to them by being the first to file an ANDA. Clearly generic companies view the launch of an own generic as unwanted competition and have tried to take legal action to prevent this. However, I believe selling a generic version of a drug, prior to or after the expiration of a patent will help consumers, and still be fair to pharmaceutical companies. A solution to the problem of pharmaceutical patents may be to offer incentives to pharmaceutical companies who are willing to sell a cheaper generic version of their product prior to the expiration of their patent.

Another factor to consider in the changing times of the pharmaceutical industry is that traditionally generic companies are now launching their own drugs and licensing or applying for their own patents. Generic companies turning toward innovation could lead to some interesting future consequences. For example, well-known generic pharmaceutical company Teva has a patent on a drug that treats multiple sclerosis, Copaxone®, that is set to expire in 2014. At that time, Teva will face competition from other generic pharmaceutical companies. This will be a detriment to Teva as a company because Copaxone® accounts for one-fifth of all Teva’s revenue. This clearly demonstrates a shift from generic companies solely copying preexisting drugs to investing in research and development in order to develop their pipeline. For example, Teva spent $1.4 billion on research and development in 2012. Other traditionally generic pharmaceutical companies such as Ranbaxy and Mylan spent approximately $73 million and $401 million on research and development, respectively. These numbers tell a bigger story, that is that generic companies are interested in developing their own products and willing to invest money in order to do so. Generic companies want to play in the “big leagues,” but will be unable to compete without the necessary tools and infrastructure. In the future this may lead to bigger problems because generic companies may not have enough resources to regulate and control the development of new drugs. This could lead to poor quality or even dangerous side effects. Therefore, as generic companies delve more deeply into research and development ventures it is imperative that regulation of their clinical trials and manufacturing processes is increased to a maximum.
Another possible solution to patents within the pharmaceutical industry comes in the form of joint ventures between a brand name company and a generic company. This can be any of various possibilities but could include research and development, licensing agreements, or “pay to delay” agreements. For example, in 2010 GlaxoSmithKline licensed the brands of Augmentin® and Amoxil®©, oral penicillin, in the United States to generic Indian-based company Dr. Reddy’s Laboratories. This transfer of ownership, allowed Dr. Reddy’s Laboratories to break into the penicillin market, an area where they did not previously have any experience. Though joint ventures such as this, there are two winners, both the brand name company and the generic company. Joint ventures allow these otherwise competitors to cooperate, thus creating more profits across the board. On the other hand, when it comes to joint ventures oftentimes the American consumers are the ones who suffer. For example, in regards to “pay to delay” deals, generic lawyer Matthew Mousely of Duane Morris in Philadelphia said, “reverse payment settlements are awesome, but the government [and the consumers] hate them.” Although joint ventures and settlements may be good for the overall industry and for brand name and generic companies alike, consumers lose out when these types of deals are made. In the future, I expect that generic and brand name companies will reach more and more joint ventures and agreements, and face more government involvement and regulations because of it. Unless new statutes are enacted specifically prohibiting “pay to delay” or similar agreements, pharmaceutical companies will continue to work together at the consumer’s expense.

On the other hand, the consumer is in need of a long-term solution that pleases all. American consumers are finicky beings: they want inexpensive healthcare, but they want lower taxes; they want new medicines to solve all their ailments, but they also want inexpensive drug options. Often laws requiring the use of only generics when available forces the use of generics upon the consumer. They may also have to use a generic version because it is the only one covered by their insurance. Forcing a consumer to use a generic can have harmful consequences. Generics are almost always made overseas where plant conditions and sanitation may be less than standard. This can lead to an increase of side effects. One way to prevent unwanted side effects would be to force generic company to have exactly the same proportions of active and inactive ingredients in a drug. This way, consumers know what they are getting right when they purchase it. If a generic company did wish to stray from the exact formula than it would be necessary for them to conduct clinical trials to determine the safety and any possible side effects of their drug. This regulation and high standards for the generic industry will keep consumers safe, without drastically raising costs or prices.

Since consumers are driving force of pharmaceutical market, they will be responsible for the reforms needed. A viable solution will be reached when agreement can be reached among all three points of the triangle. Keeping the triangle balanced, with each player receiving equal benefits, is the challenged posed to the pharmaceutical industry of the future. Whether the solution includes changing the length of a patent, refusing patent extensions, allowing for more interaction between generic and brand name companies, or providing more inexpensive options
for consumers, the solution needs to take the opinions of all involved parties into consideration. A “perfect” solution that fits all parties’ concerns may never be found, but it is necessary to continue to search for one and whenever possible test out different options. This industry will need to change for better or for worse, before it can ever reach an equilibrium.
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