Research

Intellectual Property Underpinnings of Pharmaceutical Innovation: A Primer

WILL RINEHART | JULY 29, 2014

EXECUTIVE SUMMARY

Companies across the U.S. are meeting health challenges head on by investing in time, talent, and materials. U.S. federal law has long protected these endeavors through the intellectual property (IP) regime. Understanding the process of innovation in both health and medicine requires a basic knowledge of three areas: the legal underpinnings of patent law, the economics of patents, and how the two interact within a company. Today, we cannot forget just how important these laws have been in creating and sustaining the technological sectors, especially those where innovation is especially costly. A basic overview of intellectual property rights (IPR) in innovative industries, particularly in medical treatments, is a beginning point to explore where the regime has gotten things right.

THE BASICS OF PATENTS

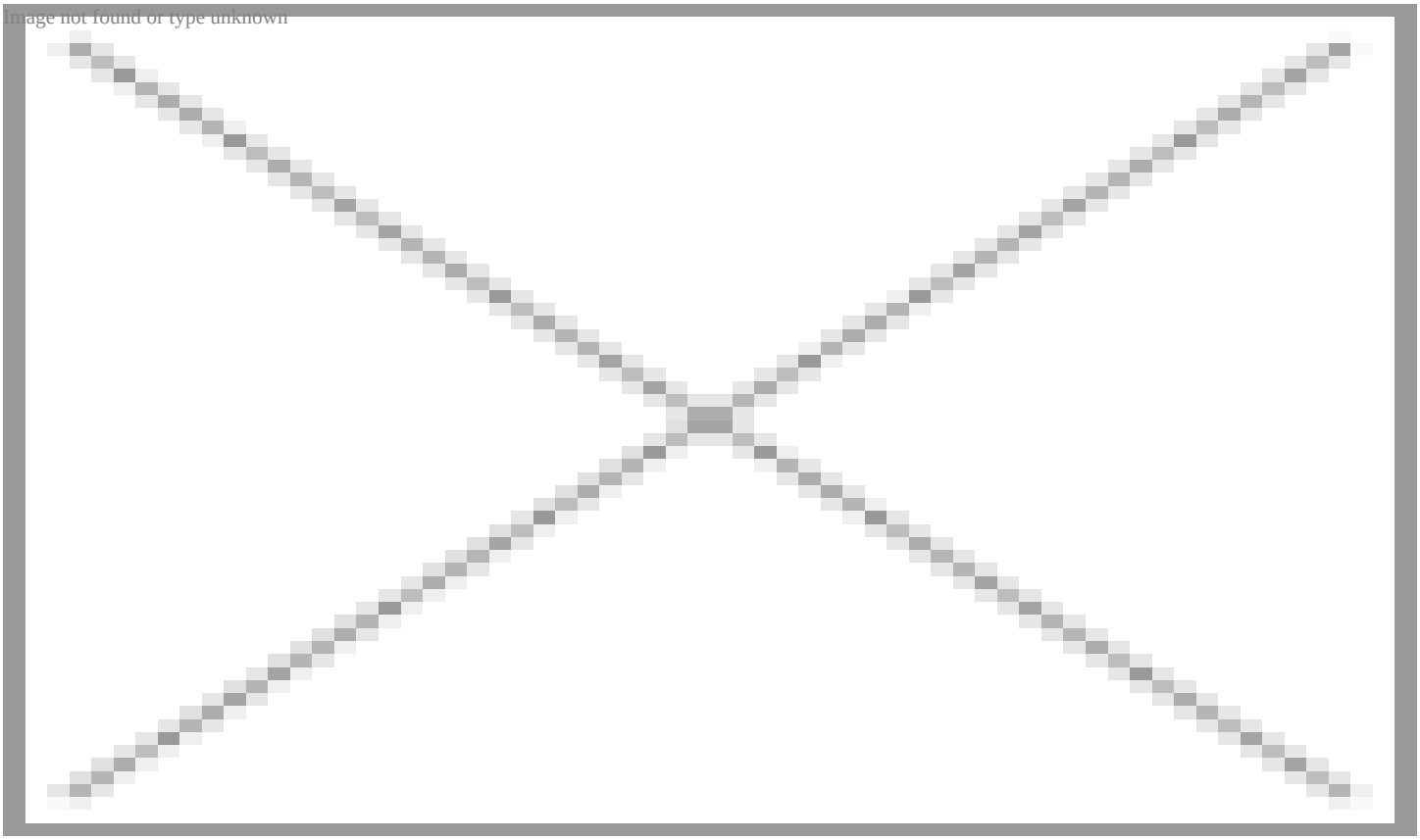
Patents are a government granted right that allows individuals or companies to exclude others from making, using, selling or importing inventions for a set amount of time, typically 20 years. Three types of patents are recognized by law: utility patents, design patents, and plant patents. Utility patents protect original processes, machines, articles of manufacture, or composition of matter. Design patents protect the ornamental design of an object. Lastly, plant patents protect any new variety of plant.

There are three general requirements to receive utility patent protection: usefulness, novelty, and non-obviousness. Typically, usefulness is satisfied if the invention can accomplish at least one of its intended purposes. Given that a patent must do what it says, most pass this first hurdle. A more robust requirement is the need for the patent to be novel or new. Novelty requires that the invention was not publicly known before the patent applicant invented it. In addition to utility and novelty, the third restriction on patentability is non-obviousness. The test for this requirement requires a hypothetical individual within the industry to answer the question, “Would this invention be obvious to an expert in the relevant field?” This last demand has become a fairly contentious issue with software patents. The number of individuals and clarity in the issue of breath has created complications in a number of cases.

The modern patent regime has its basis in reforms undertaken in 1952, which standardized and simplified the patent application process. In 1982, the long standing Court of Customs and Patent Appeals was merged with United States Court of Claims to create the United States Court of Appeals for the Federal Circuit, the only appellate court that adjudicates in a specific legal subject. In 2010, the Leahy-Smith America Invents Act (AIA) was passed, enacting the most sweeping changes to the U.S. patent system in a generation. After countless years of debate, the AIA switched the U.S. patent system from the “first to invent” standard to “first inventor to file.”

Until that point, the U.S. had been the last remaining country still using a first-to-invent system.

Patent applications and grants have increased nearly every year since the government began tracking statistics in the early 1960s. In 2012, the last year for complete information, the Patent and Trademark Office issued 276,788 patents while taking in 576,763 applications. Even though it takes around three years to get a patent, the office still rejects a substantial number of applications every year. The composition of these patents seekers has changed over the years. In 2008, foreign companies garnered a majority of the patents for the first time, with Japan, Germany, and South Korea taking the top countries of origin. As the center of innovation and home to the largest market, the United States is still the place to ensure that your innovation is secure. While patent protection is extremely important for many industries, the vast majority of patents go to large technology companies like Apple, Google and Samsung.



While there has been a domestic discussion as to the exact protections of federal patent law, the IP protections in the United States still ranks amongst the strongest. In many countries, especially where there are rising incomes and government interest to spur on cheap adoption of innovation, IP regimes have not matched domestic and international standards. As is often the case, ineffective enforcement on the ground has effectively nullified mutually agreed upon treaties.

The Office of the United States Trade Representative is tasked with helping to resolve these issues, and thus releases every year the Special 301 Report. For over 25 years, the report has identified trade barriers affecting a wide variety of industries that are involved in IP intensive industries and advances made by governments to settle concerns. Through bilateral talks, the WTO and various international organizations, the Trade Representative has been working to reverse "the deterioration in IPR protection, enforcement, and market

access for persons relying on IPR in a number of trading partners." The same concerns perennially surface. In China, the theft of trade secrets remains a significant concern. Meanwhile in India, patent protection is undermined across a number of industries by using various mechanisms including revocations, rejections, and compulsory licenses. Ultimately, the international concern with patents is part of a much larger issue with effective institutions and the rule of law. As economies become more tightly interconnected, having a uniform legal protection will ensure that innovation continues both domestically and abroad.

THE ECONOMIC BASIS OF PATENTS

Intellectual property encompasses a bevy of related legal grants, including patents, copyrights, trademarks, trade secrets, the protection of name and likeness, and a number of other niche rights. Each of the these distinct legal regimes have tried in various ways to optimize how the grant functions, so one needs to be careful in applying the lessons learned from each legal construct as one cannot necessarily be adopted onto another. Yet what unites all intellectual property is that each provides regulatory institutions to solve inefficient outcomes related to knowledge based innovation.

Through the grant of a property right in knowledge, patents are one means to solve the basic appropriability problem, a key tension in information economics. Since novel information can be easily reproduced, but once it is created, it is difficult to prevent someone who has not paid for it from having access, creators find it challenging to reap benefits from their intellectual advancements. Knowing that the benefits will be relatively minimal, inventors are less likely to pursue research, thereby reducing innovation and undersupplying various creative works. For a set time, the innovator gets specific rights that make the innovation an excludable good. After this time passes, the knowledge becomes part of the intellectual ether to be built upon by others.

There are a number of clear advantages to this system. Patent law incentivizes the creation of new innovations because the creator knows they will receive the benefit of their labor afterwards. The Supreme Court summed up the sentiment in *Mazer v Stein*:

> "The economic philosophy behind the clause empowering Congress to grant patents and copyrights is the conviction that encouragement of individual effort by personal gain is the best way to advance public welfare through the talents of authors and inventors in 'Science and useful Arts.' Sacrificial days devoted to such creative activities deserve rewards commensurate with the services rendered."

The inducement for commercialization also is useful in that patents help to disclose information that might have otherwise been kept secret. Absent patents, inventors would rely on trade secrets to protect their discoveries.

Being that it is an exclusive right to a piece of knowledge, patents are often considered to be a kind of monopoly. Criticism has been heaped upon patents in exactly the way one would expect given this definition. The creation of intellectual property rights creates an allowable exclusivity. Yet, it should be immediately apparent that patents do not automatically confer a monopoly over an industry. For example, a pharmaceutical company that invents a new and improved cancer medicine is still in competition with alternatives from other companies, which ultimately acts as a constraint on their ability to charge prices above a competitive level.

Commercial success is tied to more than just an innovative idea; superior marketing, management, positioning, and other factors are likely to be more important than the patent itself. Moreover, individuals and companies will seek multiple solutions to the same problem, whether that might be in new commercial arrangements or products. By limiting a particular avenue for competitors, patents have the potential effect of promoting further

innovation by encouraging others to develop new products.

PATENTS IN PHARMACEUTICALS

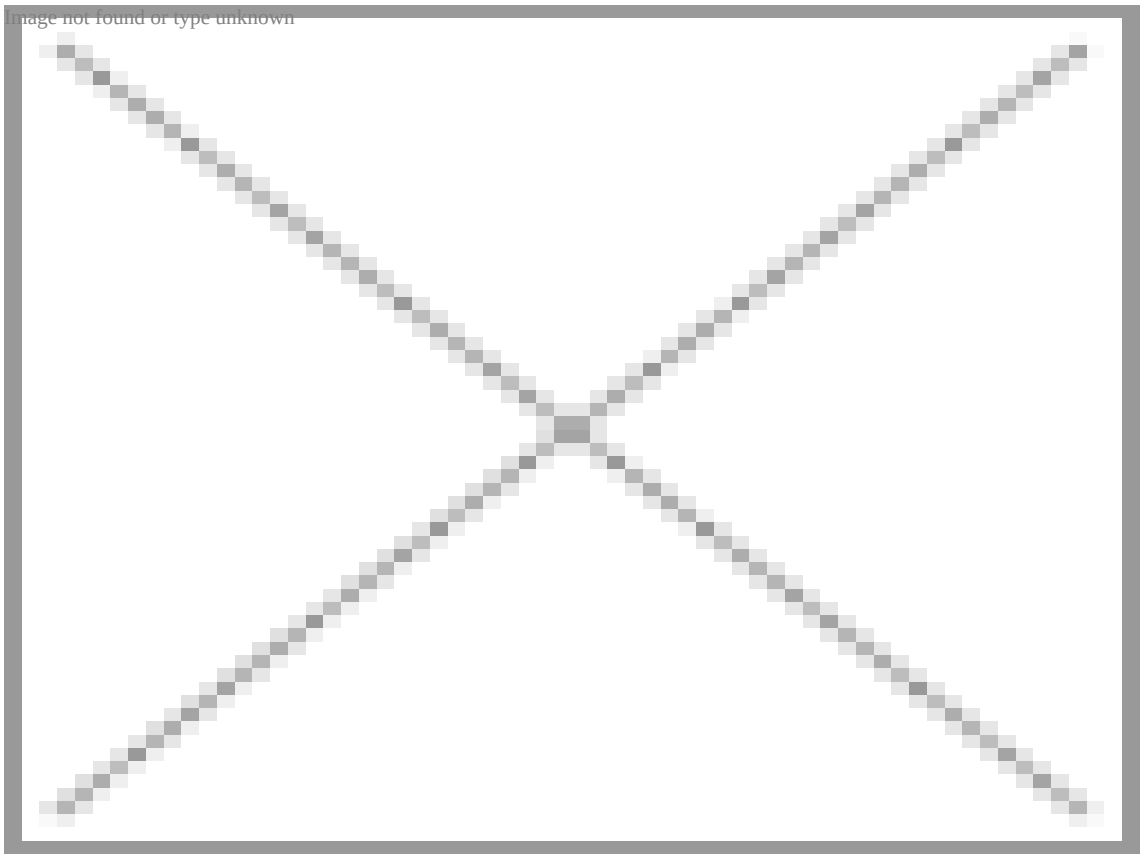
The medical field presents a strong case for patents, and because of its unique features, allows for a better understanding of the current tensions in other areas of patent policy.

The medical field has a lone inventor myth, which is exemplified in the belief of *the* cure for cancer. The truth is that there is unlikely to be any sole cure, but rather through research and applied innovation, effective methods and treatments for dealing with these diseases will be found. Of course, this means that the entire endeavor will be expensive. As with any piece of property, the bounds of intellectual property must be set, which is where we first encounter the variance that can exist between industries under patent protection. Compared to software patents where there is far less clarity in breadth of patents, medical patents tend to be more discreet in their delineation. It is relatively clear what constitutes a new drug and what does not.

Pharmaceutical companies also differ from other industries in their cost structure, including the time and resources needed to bring an innovation to market. Both the research phase and the regulatory approval process are costly and time intensive.

Biopharmaceutical discovery has benefited from a remarkable shift in research and technology. Even in the last 10 years, the methods to innovation have been revolutionized, spurred on by better understandings of genetic relationships. Take for example, Gleevec, a treatment for chronic myeloid leukemia. Before the drug was introduced, less than a third of those diagnosed with chronic myeloid leukemia were alive five years later, but after it became available that figure jumped to 90 percent. The method of research responsible for its development was extremely innovative and as such the total development was costly. Gleevec and the drugs that followed it are part of a new breed of drugs that are far more complex than their predecessors.

Even with biopharmaceutical innovations, estimates place the average cost of bringing a successful new drug to market at around $1.2 billion. After compounds are screened for use to treat a condition, only about 1 out of the 6 that make it to clinical trials will eventually obtain FDA approval. The table below shows that total industry research and development (R&D) has increased in recent years.



The marginal cost of another pill is often miniscule compared to the initial investment cost. Prices for generic drugs are substantially lower than the original brand because these new firms don't have to amortize the initial R&D costs over a drugs patent life. Additionally, pharmaceutical firms face high risks in their ventures as well as high costs of entry compared to other industries.

Clinical trials provide an example of the costs to develop a market ready drug. As the Tufts Group has shown, the average length of a clinical trial increased by 70 percent from 1999 to 2005. In that same time period, the average number of routine procedures per trial increased by 65 percent. To add to that, the average clinical trial staff work burden increased by 67 percent. To top it all off, enrollment criteria and trial protocols resulted in 21 percent fewer volunteers being admitted into trials and 30 percent more enrollees dropping out before completion of the tests.

Overall, the regulatory process of drug approval levies a heavy risk for manufacturers and innovators. For every one drug that passes through the regulatory approval process, manufacturers usually assess 5,000-10,000 substances. This is a time consuming and expensive process where innovators hope to see a return on their investment over the long-term. The FDA aims to strike a balance between access to life-saving treatments and assuring the public with standards of safety in all pharmaceuticals.

The final step in pending drug approval usually involves hundreds to thousands of participants in a blind study of the drug. This part of the process now represents about 40 percent of pharmaceutical companies' R&D expenditures. However, this often-cited statistic actually understates the amount spent. R&D expenditures include all pharmaceutical candidates that a company tests—including hundreds that never reach this trial stage. An analysis conducted by the Manhattan Institute found that for the drugs that are actually approved, these

clinical trials typically represent 90 percent or more of the cost of developing an individual drug all the way from laboratory to pharmacy.

CONCLUSION

Medical treatments are among the best cases where intellectual property law has gotten things right. Patents are an important way to ensure that the benefits of research are captured by the creator. Solving the 21st Century's problems will require complex solutions that will only come about because of intense research and development. Patents ensure that this research takes place. Even though some have criticized aspects of the patent regime, the system itself still serves as a testament to and an enabler of American innovation.