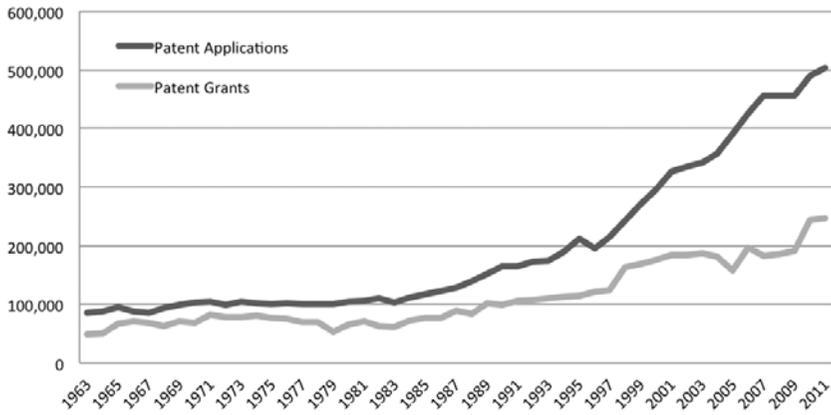


Introduction

As one of the world's most important markets, the United States is a critical space for developing new products and services. Firms that innovate require legal protection to ensure that they capture a return on their investment. In the context of new and useful articles and methods, that protection is largely provided by the US patent system. Intuitively, one may conclude that having a well-functioning patent system in America is essential for a prosperous business environment in the US. In fact, the system has been cited as an important tool for economic growth and jobs creation (Rai, Graham & Doms, 2010). The substantial patenting activity by non-US companies means that the US patent system benefits the global economy as well.

Any modern firm seeking a competitive advantage must therefore understand the nature and functioning of the patent system. First and foremost, patents provide a period of exclusivity for maximizing profits. Additionally, patents can confer a myriad of ancillary advantages for a firm, such as acting as a signaling device or providing a vehicle for accessing competitor technology through licensing. For competitors and society, patents serve as a key conduit of information that fuels broader innovation by disclosing a fully enabled invention even before it is in the public domain. When firms fall on hard times, investors often rest their hopes on patents—often as an important source of remaining value (Mattioli, Spector & Jones, 2012).

Evidence of just how much patents can shape an industry is readily available in the news. For example, on any given day in 2011 or 2012, one was likely to encounter a story about litigation in the mobile communications sector. Nearly all of the major players—including Apple, Google, Microsoft, Samsung and HTC—have been involved in one case or another in a variety of venues across the US. They have played the role of both plaintiff and defendant in cases involving a dizzying array of technologies from touchscreen inputs to software for enhancing messaging. The litigations are high stakes to say the least. In the battle between Apple and Samsung involving cell phones and tablet computing devices, Apple scored a decisive victory in August 2012 when it received a jury verdict of infringement in the amount of nearly \$1.5 billion (*Apple Inc. v. Samsung*



Source: US Patent & Trademark Office, 2012.

Figure 0.1 US Patent Applications and Grants, 1963–2011

Electronic Co., 2012; Wingfield, 2012). The consequences may be a “tax” added onto the price of mobile computing devices that compete with Apple’s (Ante, 2012). One might be tempted to view the mobile communications sector as an outlier; however, just weeks earlier Monsanto won a \$1 billion verdict over Du Pont in the completely unrelated field of genetically modified seed patents (*Monsanto Co. v. E.I. Dupont De Nemours & Co.*, 2012). Clearly, patent rights have a great impact on business.

There is reason to believe that the US patent system will play an even greater role for businesses in the future. After leveling off slightly in the first part of the 21st century, the number of issued patents has exploded, rising to 247,713 in 2011.

As more and more patents issue, firms are increasingly compelled to integrate patent strategy into their business plans. Moreover, patents have extended into industries that are not necessarily perceived as high technology, such as food production and clothing manufacture. It is no longer optional for the business community to care about the patent environment; understanding patents is a baseline requirement.

However, as important as the US patent system is to the global business community, it is not without problems. Concerns have arisen over the years that there is a substantial misalignment between the interests of society and the actual impact of the system. Some believe that patents are too easy to obtain or that the quality of issued patents is poor, clogging the marketplace with blocking property rights and stunting competition (Jaffe & Lerner, 2004; Heller, 2008). Others have argued that patents can limit

follow-on innovation by preventing the sharing of technology necessary to serve as a foundation for others (Murray & Stern, 2007). The rules are often archaic and poorly suited for emerging industries, particularly those related to the Internet. Even when there is a theoretical advantage to the system, the costs of ownership and enforcement may prevent many patent owners from seeing a benefit to pursuing rights. In fact, it has been suggested that patents may not be cost-effective for any industry outside of pharmaceuticals and biotechnology (Bessen & Meurer, 2008).

To address the problems in the patent system, there have been many proposals for change from academics, business leaders and policymakers. While it is not always easy to agree on the specific reforms necessary—divisions exist between industry sectors like pharmaceuticals and electronic communications that experience the system differently—most agree that the system should be improved.

And indeed, much change has come to patent law over the years. The courts in particular have been very active in reinterpreting of the Patent Act of 1952 and articulating common law rules that fill in the spaces. Some of most important changes have come from the US Supreme Court, which until recently appeared to cede most patent issues to the specialized US Court of Appeals for the Federal Circuit. For example, in *eBay Inc. v. MercExchange, LLC* (2006), the Supreme Court curtailed the use of injunctions in patent cases, which weakened the negotiating power of patentees. In *KSR International Co. v. Teleflex Inc.* (2007), the Supreme Court broadened the test of obviousness, retroactively calling into question the enforceability of many issued patents. More recently, in *Mayo Collaborative Services v. Prometheus Laboratories Inc.* (2012), the Supreme Court addressed the scope of patentable subject matter by further defining what activity transformed a method from a law of nature to a protectable invention.

In addition, Congress has been active in patent reform. Typically, the legislative branch is the slowest to change due to the consequences of altering such an important system, not to mention the complexity of the rules and differing interests. However, in 2011 Congress pushed through some of the most significant reforms in decades when it enacted legislation known as the America Invents Act (AIA). The most prominent and controversial of the AIA's changes is shifting the US from a first-to-invent to a first-to-file system, meaning that rights will normally be determined by the first inventor to file an application at the US Patent and Trademark Office (PTO). Other changes include expanding prior user rights, eliminating the best mode requirement and making it nearly impossible to claim a patent on a tax strategy. For businesses, an important but less discussed revision was the elimination of private *qui tam* actions for false patent

marking, which had previously led to significant liability for manufacturers that neglected to remove expired patent numbers.

The PTO has also been very busy in changing the way it operates in response to demands from the business community. The office has dramatically increased the number of examiners to deal with the deluge of patents, created accelerated exam procedures to account for important technology, drafted guidelines for examination of inventions in areas of tenuous patentability, and increased its outreach to the business community. When the PTO's efforts are combined with its collaboration with other patent offices across the globe, it is fair to say that the amount of information available to the business community has never been greater.

Still, many believe that much more is required for the system to function properly so that it optimally encourages innovation while preserving competition. One of the United States' most widely respected scholars and jurists, Judge Richard Posner, issued a strong critique of the patent system after sitting as a trial judge in a case between Apple and Motorola (Posner, 2012). According to Judge Posner, most industries do not benefit from patent rights.

In most [industries], the cost of invention is low; or just being first confers a durable competitive advantage because consumers associate the inventing company's brand name with the product itself; or just being first gives the first company in the market a head start in reducing its costs as it becomes more experienced at producing and marketing the product; or the product will be superseded soon anyway, so there's no point to a patent monopoly that will last 20 years; or some or all of these factors are present. Most industries could get along fine without patent protection.

The problems caused by factors such as patent trolls, defensive patenting and search costs can render the system a burden on industry rather than a catalyst for innovation. Judge Posner suggests that a variety of reforms, such as reduced patent terms and widespread compulsory licenses, are necessary.

The business community is therefore faced with an extremely important patent rights system that can also create barriers and is in a constant state of flux. This book is intended to highlight some of the most important changes in US patent law in recent years and describe their impact on domestic and global businesses. The changing face of US patent law can be broadly categorized in terms of: (1) the forces that impact patent policy; (2) modifications to the patent application process; (3) issues and reform related to patent oppositions and litigation; and (4) rights regimes that supplement protection in industries where patents are less effective.

Individual chapters within this book provide detailed consideration of various issues within these categories.

FORCES THAT INFLUENCE PATENT POLICY

Because the overall functioning of the US system is complex, lawmakers and the courts must keep in mind policies to guide decision-making and provide a measuring stick for success. General principles of course include the creation of incentives for increased invention as well as follow-on innovation. But many other policies could be integrated into the patent system, such as support for green technology, assistance for independent inventors, preference for domestic patent applicants or high standards for the examination of gene sequences. Unfortunately, a well-functioning patent system cannot be all things to all interest groups, so choices must be made. How is this done in the context of a system that has the potential to so dramatically influence the business community? The answer can be found in an understanding of the forces that influence patent policy.

In Chapter 1, Robert Thomas and Cassandra Aceves confront this topic head-on by considering the formation of interest coalitions to effectuate intellectual policy revision. The chapter contrasts the experiences of copyright interest groups with those of patent interest groups in recent years, and assesses how each has fostered change. It considers why some groups appear to be more successful than others in influencing the debate, building on interest-group politics theory and other descriptions in the literature (e.g., Thomas, 2006). The chapter provides a model that identifies variables motivating intellectual property political action and the coalitions that are likely to form based on these factors. It then applies the model to explain the influences on international treaties such as the Trade-Related Aspects of Intellectual Property Agreement (TRIPS, 1994) as well as domestic legislation such as the AIA. The chapter concludes that successful influence occurs when efforts are drawn narrowly and suggests that future coalitions are likely to follow a conservative model. It argues that such a model facilitated passage of the AIA and the lack of such an approach in controversial efforts to expand copyright met with predictable failure.

In Chapter 2, David Orozco considers a narrower venue for influence: the PTO. The chapter explains the underappreciated significance of the PTO in making patent policy in industries such as software, biotechnology and clean technology. It focuses on the PTO's rulemaking authority and argues that, despite court-imposed limitations, the agency engages in substantive policymaking. The chapter refers to such power

as an “administrative policy lever” and states that it can be explained by positive political theory, a construct that examines legal actors’ decisions and motivations in response to larger political forces and frameworks (McCubbins, Noll & Weingast, 1989). It then discusses the trajectory of future administrative patent levers in light of the passage of the AIA. The chapter predicts that the PTO will increase in policy-oriented activities and notes that an attendant risk is a balkanized patent policy.

THE IMPACT OF REVISIONS TO THE PATENT APPLICATION PROCESS

Within the scope of agreed-upon patent policies, change occurs most immediately and directly in the context of the patent application process. To be sure, actions regarding core patentability issues such as allowable subject matter and the means for determining the winner of a contest between inventors with similar claims are extremely important. The failure to design workable rules can disenfranchise a large segment of future patent owners, suppressing innovation. However, even minor modifications to the process can have an impact. Setting workable fee structures, rational examiner workload or incentives, and clear guidelines may determine who is willing to play the patent game. Any revisions to the patent application process must be understood by the business community and integrated into management practices.

In Chapter 3, Robert Bird provides a broad overview of changes imposed by the AIA and then drills down for an in-depth discussion of the new rules relating to inventor determination and erasing the stain of inequitable conduct. The chapter contextualizes the narrower discussion by noting the significance inventor contests and inequitable conduct accusations have had on patentees throughout history. Regarding inventor determination, the chapter explains the rationale for shifting the US from a first-to-invent system to a first-to-file system. It reviews the available evidence on the likely impact of the law such as Abrams and Wagner’s (2012) widely discussed empirical study of Canada’s earlier shift, and finds clear conclusions to be lacking. However, the chapter notes that there may be important advantages to first-to-file in a global system, particularly for domestic filers. Conversely, the chapter argues for caution in the application of the new supplemental exam procedure. Without a careful restraint of this “amnesty,” low-quality patents may proliferate.

In Chapter 4, T. Leigh Anenson and Gideon Mark examine the recent changes to the inequitable conduct doctrine and the possibility that they may ultimately harm the patent system. Inequitable conduct is a defense

that exists when a patentee has violated his or her obligations to be fully forthcoming in the course of an *ex parte* examination. Withholding evidence of prior art may compromise an examiner's ability to determine patentability. This chapter reviews the availability of the inequitable conduct defense as a remedy to this breach of good faith. It considers new rules under both the AIA and the recent decision in *Therasense, Inc. v. Becton, Dickinson & Co.* (2011) that effectively restrict the application of the doctrine. The chapter concludes that these changes go too far in reducing the incentive for patent applicants to make a full disclosure, permitting abuse of the system and endangering its integrity.

The discussion by Wade Chumney, David Baumer and Roby Sawyers in Chapter 5 assesses the impact of the expansive boundaries of patentable subject matter on professions. The chapter considers the possibility that, absent an effective defense, patent owners may end up severely hampering the practice of professions such as accounting. It reviews the history of business method patents and describes the emergence of flexible rules. The chapter then demonstrates how these flexible rules can essentially allow one to patent key aspects of the accounting profession. It provides several examples of patents that appear to offer such a level of control. The chapter then details the policy arguments against the issuance of accounting-related patents, noting that great costs are necessarily imposed. It proposes a "learned profession defense" as a solution, explaining that a similar infringement exemption has been successful in the context of medical methods. The chapter concludes that limits are necessary, or professions will suffer and society will bear much of the burden.

THE CHALLENGES OF A SHIFTING ENFORCEMENT ENVIRONMENT

Obtaining a patent is only part of the equation for a business interested in exploiting its innovative advantage. Similarly, the fact that many patents exist in a technology space does not mean that competitors have no room to maneuver. Businesses must appreciate the critical second step of patent enforcement as an element of the intellectual property environment. Unfortunately, the rules are often in a state of transition due to the delicate balance of preserving the advantages of strong property rights in inventions while maintaining competition whenever possible. For example, invalid patents may be identified as a problem and eliminated after enforcement is threatened, but the procedures must not unduly weaken a patentee's investment expectations. Additionally, what actions constitute enforcement plays an important role in clarifying

infringement risk. Shifting them after the fact undermines confidence in the marketplace. The unanticipated spillover effects of strong patent enforcement that impact the dissemination of health or safety information are a primary concern to businesses and the public. There have been many changes in these patent enforcement principles over the years, and the business community must keep abreast in order to stay competitive.

In Chapter 6, Lynda Oswald addresses the ever more common issue of infringement through the action of multiple parties, or “joint infringement.” With the emergence of patented business methods and software systems with several components, courts are seeing more cases in which no single party infringes all elements of a claim. Courts must fashion a rule that eliminates infringement loopholes while not inappropriately drawing innocent parties into a case. The chapter reviews the Federal Circuit’s recent en banc decision in *Akamai Technologies, Inc. v. Limelight Networks, Inc.* (2012) that significantly changed the joint infringement landscape. Assessing its lack of adherence to conventional tort theory as well as departure from existing precedent, the chapter argues that the Federal Circuit has strayed into patent policymaking. It suggests that the specialized nature of the court has led to overly isolated jurisprudence as predicted by commentators (Nard & Duffy, 2007). The chapter concludes that returning to more traditional legal doctrine would better serve patent law and the business community.

Daniel Cahoy, Joel Gehman and Zhen Lei in Chapter 7 consider the possibility that patents can serve an ancillary purpose as an information containment tool. By design, patents are information disclosure devices, and providing a full and complete understanding of the invention is part of the patent owner’s bargain with society. However, when follow-on use of an invention is necessary to generate information on safety or effectiveness, patents may actually serve as a barrier. This chapter considers the issue as a matter of theory and how the Federal Circuit’s decision in *Madey v. Duke* (2002) eliminated an essential exemption for such use. It then explores its real-life application in the context of natural gas extraction (fracking). It suggests that the application is broader and notes that there are both attendant business strategies and societal concerns that may influence the future development of doctrine. For now, the chapter concludes, there are limited means that society can exploit to avoid the issue of patents as information containment tools.

In Chapter 8, Susan Marsnik considers the issue of post-grant, administrative review of patents. Such review has existed for some time in US law in the form of reexamination, which was considered to be substantially more restrictive than the European Patent Office’s (EPO) opposition system (EPC, 2010, Art. 99). As a result of amendments in the AIA, the

PTO will be the venue for three new or revised post-grant review procedures. This chapter discusses the rationale behind strong post-grant review and why the pre-AIA system was lacking in the US. It details the European system and then explores how the new procedures in the US adopt many of the EPO provisions. The chapter analyzes whether the new US procedures will fulfill the goal of reducing the number of bad patents while preserving innovation incentives. It concludes that limitations related to cost and litigation estoppel will make the US procedures less effective, and render them an unlikely tool for improving patent quality or stemming the tide of litigation.

THE EMERGENCE OF EXCLUSION SYSTEMS BEYOND PATENTS

As important as patents can be in research-intensive industries, they can in some cases actually be too weak to provide a return on investment. This is particularly the case in industries with long product development times and extensive regulatory procedures. In such cases, innovators may need a supplemental protection system that provides many of the same advantages as patents. Congress has responded to this need from time to time by creating specialized information exclusion systems that provide additional value to businesses.

In Chapter 9, Donna Gitter reviews the implications of a supplemental rights regime in the context of the new Food and Drug Administration (FDA) approval pathway for follow-on protein products or biosimilars. In 2010, Congress enacted the Biologics Price Competition and Innovation Act (BPCIA), which allows for generic biologic treatments. Modeled on an existing procedure for generic pharmaceutical drug products, the law is intended to facilitate competition once innovator exclusivity has expired. However, to preserve innovator incentives, the BPCIA includes long data and market exclusivity periods that operate apart from the patent system. The chapter addresses the controversy in the interpretation of the data and market exclusivity provisions, and provides an optimal interpretation of the statute. It examines the academic literature and considers the impact of the new regime on international trade agreements. The chapter concludes that some amendment of the new law may be necessary to increase its clarity and improve its function as a supplemental innovation protection system.

By considering the many changes US patent law has undergone over the years, one can appreciate the dynamic nature of the system and take full advantage of it. This book provides an overview of many of the most

important changes that impact businesses. Its comprehensive treatment can serve as a tool for firms and aid policymakers in generating ideas for future revision.

REFERENCES

- Abrams, D. & Wagner, R.P. (2012). Poisoning the Next Apple: How the America Invents Act Harms Inventors. *Stanford Law Review*, **65**. Retrieved from <http://ssrn.com/abstract=1883821>.
- Akamai Technologies, Inc. v. Limelight Networks, Inc.*, 2012 U.S. App. LEXIS 7531 (Fed. Cir. Aug. 31, 2012).
- America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011).
- Ante, S.E. (2012, Sept. 28). The Apple Tax. *Wall Street Journal Online*. Retrieved from <http://online.wsj.com/article/SB10000872396390444270404577610013613551038.html>.
- Apple Inc. v. Samsung Electronic Co.*, No. 11-CV-01846 (N.D. Cal., Aug. 24, 2012) (jury verdict). Retrieved from <http://www.patentlyo.com/files/juryverdictapplesamsung.pdf>.
- Bessen, J. & Meurer, M. (2008). *Patent Failure: How Judges, Bureaucrats, and Lawyers Put Innovators at Risk*. Princeton, NJ: Princeton University Press.
- Biologics Price Competition and Innovation Act of 2009 (BPCIA), 42 U.S.C. § 262 (2010).
- Convention on the Grant of European Patents (EPC), Oct. 5, 1973, as revised Nov. 29, 2000. (2010). *The European Patent Convention* (14th ed.), Munich, Germany: European Patent Office.
- eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006).
- Heller, M. (2008). *Patent Gridlock*. New York: Perseus Books.
- Jaffe, A.B. & Lerner, J. (2004). *Innovation and its Discontents*. Princeton, NJ: Princeton University Press.
- KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007).
- Madey v. Duke*, 307 F.3d 1351 (Fed. Cir. 2002).
- Mattioli, D., Spector, M. & Jones, A. (2012, Aug. 10). Kodak Patent Bidding is Tame. *Wall Street Journal*, B1.
- Mayo Collaborative Services v. Prometheus Laboratories Inc.*, ___ U.S. ___, 132 S. Ct. 1298 (2012).
- McCubbins, M.D., Noll, R.G. & Weingast, B.R. (1989). Structure and Process, Politics and Policy: Administrative Arrangements and the Political Control of Agencies. *Virginia Law Review*, **75**(2), 431–82.
- McCubbins, M.D. & Schwartz, T. (1984). Congressional Oversight Overlooked: Police Patrols versus Fire Alarms. *American Journal of Political Science*, **28**(1), 165–79.
- Monsanto Co. v. E.I. Dupont De Nemours & Co.*, No. 09-CV-00686 (E.D. Mo., Aug. 2, 2012) (jury verdict).
- Murray, F. & Stern, S. (2007). Do Formal Intellectual Property Rights Hinder the Free Flow of Scientific Knowledge? An Empirical Test of the Anti-Commons Hypothesis. *Journal of Economic Behavior & Organization*, **63**(4), 648–87.
- Nard, C. & Duffy, J. (2007). Rethinking Patent Law's Uniformity Principle. *Northwestern University Law Review*, **101**(4), 1619–76.

- Posner, R.A. (2012, July 12). Why There are Too Many Patents in America. *The Atlantic*.
- Rai, A., Graham, S. & Doms, M. (2010). *Patent Reform: Unleashing Innovation, Promoting Economic Growth & Producing High Paying Jobs*. Washington, D.C.: US Department of Commerce. Retrieved from www.commerce.gov/sites/default/files/.../Patent_Reform-paper.pdf
- Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276 (Fed. Cir. 2011) (en banc).
- Thomas, R.E. (2006). Vanquishing Copyright Pirates and Patent Trolls: The Divergent Evolution of Copyright and Patent Laws. *American Business Law Journal*, 43(4), 689–739.
- Trade-Related Aspects of Intellectual Property Rights Agreement, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 (1994).
- United States Patent & Trademark Office (2012, May 22). *U.S. Patent Statistics Report*. Retrieved from http://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm.
- Wingfield, N. (2012, Aug. 24). Jury Awards \$1 Billion to Apple in Samsung Patent Case. *New York Times*, A1.

