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Patents to the Rescue - Disasters and Patent Law

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PATENTS TO THE RESCUE - DISASTERS AND PATENT LAW

*Dr. Andrew W. Torrance**

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INTRODUCTION

At first glance, patent law and disasters seem unlikely bedfellows. It is true that the United States Patent and Trademark Office (hereafter “USPTO”) is no stranger to disaster, having suffered its own “Great Patent Fire of 1836.”¹ However, disasters such as the September 11, 2001 (“9/11”) terrorist attacks, the Southeast Asian Tsunami of 2004, and Hurricane Katrina do not immediately evoke images of the patent system. When members of the armed forces, police, firefighters, medical workers, relief workers, and other emergency response personnel rush to the aid of disaster survivors, one does not expect them to be joined by teams of emergency patent personnel. Nevertheless, the patent system does play a pivotal role in allowing

¹ See, e.g., United States Patent and Trademark Office, Kids’ Pages, <http://www.uspto.gov/web/offices/ac/ahrpa/opa/kids/special/1836fire.htm> (last visited Jan. 28, 2007).

society to prepare for, react to, mitigate, learn from, and even prevent disasters.²

The patent system is useful in disasters in a number of very different ways. At the most fundamental level, the economic incentive provided to inventors by the prospect of patent protection greatly spurs innovation that can enhance the general technological capacity of society. But for the availability of patent protection, the baseline level of technology available to society would be much lower. A lower level of technological capacity tends to lower the ability of society to deal effectively with disasters. The patent system can also be harnessed to produce innovations that enhance the specific technological capacity of society to face particular challenges arising out of disasters. Technological innovations such as medicines to treat anthrax, engineering materials to strengthen dike-walls, and methods of more rapidly and effectively evacuating large numbers of people can all be specifically promoted through the patent system by adjusting its various incentives. If necessary, it is even possible to weaken, suspend, or even abrogate patent rights to allow easier access to vital patented technologies in disasters.

In assessing what roles the patent system might usefully play in disasters, it is important to integrate a number of significant factors that vary by disaster. The patent system may apply differently to disasters that are foreseeable than to disasters that are unforeseeable surprises. Ensuring the continued enhancement of both general technological capacity and specific technological capacity is important because the options society has in dealing with disasters of all types tend to improve alongside additional technological innovation. Additionally, any immediate compromises to patent rights necessitated by urgent needs arising from disasters must be balanced against prospective interests of ensuring that the patent system continues to provide incentives to spur sufficient future innovation. Policy choices about patent rights in the present will always have consequences for both the patent system and the technological capacity of society well into the future.

This Article assesses the role of the patent system in disasters, and suggests that this role is vital. The Article begins by presenting an overview of the United States patent system. It discusses the taxonomy of disasters, dividing them into foreseeable disasters and unforeseeable,

² Throughout this article the phrases “in disaster(s),” “to disaster(s),” and “with disaster(s)” are used as shorthand to encompass any and all of these disaster-related activities.

or surprise, disasters. Then, it outlines the various legal options available in international and U.S. patent law for the patent system to react to disasters. These options include exceptions to infringement, compulsory licensing, march-in rights, patent breaking, and sovereign immunity. Finally, this Article proposes legal frameworks through which patent law can react rapidly and effectively to foreseeable and surprise disasters, respectively, while preserving prospective incentives to spur future technological innovation and ensure future enhancement of the technological capacity of society.

With care and planning, a delicate balance can be struck between the exigencies that occur as a result of disasters in the present and the continued capacity of the patent system to contribute new technological solutions useful in future disasters.

I. PATENT LAW

A. The Patent Bargain

Society generally abhors monopolies, and much economic theory justifies policies, such as antitrust laws, that oppose them. A monopoly in a particular good or service will tend to cause a deadweight loss to society due to inefficiently low output of that good or service.³ Even in the realm of technical innovation, where patents allow monopoly rights of exclusion to their owners, critics have long advocated free access as preferable to monopolies. A prodigious inventor himself, Benjamin Franklin wrote that “[as] we enjoy great advantages from the Inventions of others, we should be glad of an Opportunity to serve others by any Invention of ours; and this we should do freely and generously.”⁴ Nevertheless, the monopoly right to exclude others given to the owner of a patent represents a clear exception to the general legal presumption that monopolies should be discouraged.

Patents may be tolerated by society because they are widely considered to create incentives for innovation by rewarding inventors for their efforts. To justify receipt of monopoly rights in an invention an inventor must provide society with full disclosure of that invention to “add to society’s storehouse [of knowledge].”⁵ In many

³ N. GREGORY MANKIW, PRINCIPLES OF ECONOMICS 326-334 (3d ed. 2004).

⁴ BENJAMIN FRANKLIN, THE AUTOBIOGRAPHY OF BENJAMIN FRANKLIN 112 (1909).

⁵ *In re Argoudelis*, 434 F.2d 1390, 1394 (C.C.P.A. 1970) (Baldwin, J., concurring).

technological arts⁶ this bargain may be fairly struck, with both patent owners and society benefiting equitably. However, many critics complain that in some technological arts, such as biotechnology, inventors add too little to the storehouse of knowledge to justify the grant of a monopoly.⁷

The high quality of information disclosed to the public by inventors seeking patent rights enhances the technological and scientific capacity of society. Society can use this information for any purpose it chooses except to make, use, sell, offer to sell, or import a claimed invention.⁸ This information enriches the existing body of technological and scientific knowledge, allowing scientists and engineers to build further upon new ideas to create even newer, and increasingly advantageous, ideas. If scientists make progress by standing on the shoulders of giants, then the incentives provided by the patent system contribute additional shoulders on which to stand.

Furthermore, many new innovations are invented as a result of attempts to develop solutions to existing technological challenges. Thus, the products of the inventive process tend to be useful and practically applicable. Disasters often present technological challenges of a practical nature, such as how to protect populations against disease, how to transport supplies through difficult terrain, and how to rebuild infrastructure rapidly and efficiently. The patent system is thus very well placed to develop and deliver solutions to the challenges posed by disasters.

B. Patentable Subject Matter

Myriad inventions can be useful in preparing for, enduring, mitigating, or reacting to disasters. New medicines, methods of treatment, methods of diagnosis, and medical devices are of potential benefit during public health disasters. New protective structures, engineering techniques, and materials, and means of transportation can assist in preventing and mitigating disasters. Even new methods of

⁶ In the language of patent law, "art" means field or area. For example, propellers, wings, and fuselages are all items one might encounter in the aeronautical arts, whereas legs, seats, struts, and backs would belong to the chair-making arts. With respect to natural biochemicals, genes, polypeptides, carbohydrates, and lipids would be considered subjects of the biochemical or biotechnological arts.

⁷ See, e.g., Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 698-701(1998).

⁸ See 35 U.S.C. § 154(a)(1) (2002) (describing content and term of patents).

organization, evacuation, and logistics can assist in responding effectively, efficiently, and rapidly to disasters. Patent law is generally permissive regarding what categories of technology are eligible for patent protection, allowing inventors to seek patent rights covering a tremendous diversity of inventions. Almost any invention with relevance to disasters, whether a drug, building material, food, or method is patentable subject matter.

A particular category of disaster, crude oil spills, inspired an invention that probed the limits of what subject matter is and is not eligible for patent protection. Anand Chakrabarty, a professor of biology at the University of Illinois, genetically engineered a *Pseudomonas* bacterium to enable it to metabolize hydrocarbons.⁹ Chakrabarty intended that his new bacterium could be introduced into a crude oil spill, where, having an abundant hydrocarbon food source, it could reproduce exponentially and consume the oil.¹⁰ Thus, the toxic environmental effects of spilled crude oil could be minimized. Chakrabarty applied for a utility patent in the United States Patent and Trademark Office (“USPTO”), claiming his genetically-engineered bacterium.¹¹ However, the USPTO examiner declined to grant him a patent on his invention on the grounds that living organisms constituted unpatentable subject matter.¹²

Chakrabarty appealed this rejection to the Board of Patent Appeals and Interferences (“BPAI”), a USPTO administrative court, which affirmed the examiner’s rejection on the ground that living organisms were ineligible for patent protection.¹³ In 1980, after an appeal to the Court of Customs and Patent Appeals (“CCPA”), the U.S. Supreme Court held in favor of Chakrabarty.¹⁴ By its decision, the Supreme Court sanctioned recognition of a significant broadening of the scope of patentable subject matter. In a famous statement, the Supreme Court described as patentable “anything under the sun that is made by man.”¹⁵ Because the bacterium at issue had been genetically engineered, and was not merely a product of nature, it was eligible for patent protection. Later judicial and administrative decisions further defined the broad borders of the patentable world to include

⁹ *Diamond v. Chakrabarty*, 447 U.S. 303, 305 (1980).

¹⁰ *Id.*

¹¹ *Id.*

¹² *Id.* at 306.

¹³ *Id.*

¹⁴ *Id.* at 306-309.

¹⁵ *Id.* at 309.

multicellular organisms,¹⁶ plants,¹⁷ mammals,¹⁸ computer software,¹⁹ and even methods of doing business.²⁰

Currently, almost any kind of invention with conceivable use in disasters would be eligible for patent protection in the United States.

C. Patent Requirements

The Patent Act²¹ imposes a number of statutory requirements that patent applications must meet before they can mature into valid patents. Some of these requirements are largely procedural, but several are substantive. The most significant of the latter are legal requirements of novelty,²² nonobviousness,²³ utility,²⁴ and disclosure.²⁵ A patent applicant must also provide a precise description in the patent “claims”²⁶ of the metes and bounds of the invention for which patent protection is sought.

1. Novelty and Nonobviousness

The common purpose of the novelty and nonobviousness requirements is to ensure that any invention on which a patent applicant receives a patent, which confers a powerful monopoly right to exclude others, is truly a new contribution to society. Otherwise, the patent applicant receives a doubly unjustified windfall: a valuable right to exclude society retroactively from practicing an “invention” it was previously able to practice in return for disclosing to society previously known information about the “invention.” The novelty and nonobviousness requirements ensure that, once an invention enters the public domain, it cannot be secondarily clawed back into the realm of private property.

2. Utility

¹⁶ *Ex Parte Allen*, 2 U.S.P.Q.2d 1425, 1426 (Bd. Pat. App. & Interferences 1987).

¹⁷ *J.E.M. Ag. Supply, Inc. v. Pioneer Hi-Bred Int’l, Inc.*, 534 U.S. 124, 124 (2001).

¹⁸ *E.g.*, *Transgenic Non-Human Mammals*, U.S. Patent No. 4,736,866 (issued Apr. 12, 1988).

¹⁹ *Diamond v. Diehr*, 450 U.S. 175, 196 (1981).

²⁰ *State Street Bank & Trust Co. v. Signature Fin. Group, Inc.*, 149 F.3d 1368, 1375 (Fed. Cir. 1998).

²¹ 35 U.S.C. § 1 (2000).

²² 35 U.S.C. § 102 (2002).

²³ 35 U.S.C. § 103 (2004).

²⁴ 35 U.S.C. § 101.

²⁵ 35 U.S.C. § 112.

²⁶ *Id.*

In order to obtain a patent claiming an invention, an applicant must disclose to the public, as represented by the USPTO, a sufficiently detailed description of the invention.²⁷ The precise requirements of this disclosure requirement are set out in the Patent Act at the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner of making and using it, in such full and clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.²⁸

The disclosure requirement reflects the bargain between inventor and society that is fundamental to the patent grant. In return for monopoly rights to exclude others from making, using, offering to sell, or selling the patented invention within the United States, or importing the patented invention into the United States,²⁹ the patentee contributes new information to the public storehouse of knowledge. Although such information may be of limited immediate usefulness because the patent owner retains the right to exclude others during the term of a patent, a patent's teachings immediately provide society with new knowledge or techniques. These new teachings may help other inventors to develop other, unrelated inventions, improvements on the claimed invention, or noninfringing alternatives that directly compete with the claimed invention.³⁰ In addition, once the patent term expires, so does the patent owner's right to exclude others from freely practicing the claimed invention.³¹ The disclosure requirement vouchsafes the fairness of the bargain between inventor and society by ensuring that sufficient high-quality information is provided to the public storehouse of knowledge to justify toleration of the deadweight loss to society caused by the monopoly exclusion right. As the

²⁷ *Id.*

²⁸ *Id.*

²⁹ 35 U.S.C. § 271(a) (2003).

³⁰ Note that these informational amenities all lessen the deadweight loss to society incurred by the monopoly exclusion rights conferred by the patent grant.

³¹ 35 U.S.C. § 154(a)(2) (“[The patent] grant shall be for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States...”).

Supreme Court has stated, the disclosure requirement is “the *quid pro quo* of the right to exclude.”³²

3. Disclosure

Among the rights a patent confers to the patentee is the right to exclude others from making, using, selling, offering to sell, or importing the claimed invention during the term of the patent or from inducing or contributing to such infringement.³³ The term of a patent generally extends twenty years from the filing date of the patent application.³⁴ In return for the limited monopoly right to exclude, an inventor must provide the public with a full description, or “specification,” of the claimed invention.

The first paragraph of 35 U.S.C. §112 includes three distinct requirements that the specification of a patent application must satisfy in order for a patent claim to satisfy the disclosure requirement: written description, enablement, and best mode.³⁵

An applicant for a patent must provide “a written description of the invention.”³⁶ This written description requirement serves a notice function, by providing the public with a specific indication of what the inventor considers the limits on his invention to be. Additionally, it establishes precisely what inventions an inventor possessed as of the date on which the patent application was filed, which limits the inventor from pursuing *post hoc* claims on inventions not disclosed in the patent application as originally filed.

The best mode requirement forces the inventor to disclose the best way of practicing a claimed invention known to the inventor at the time the patent application is filed. A unique peculiarity of the United States patent system, this subjective requirement aims to ensure that the public storehouse of knowledge receives the highest possible quality of information, rather than only the minimum amount of information necessary to enable a claimed invention.³⁷ Beyond acting as a barrier

³² J.E.M. Ag Supply, 534 U.S. at 142 (quoting *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 484 (1974)).

³³ 35 U.S.C. § 271(a).

³⁴ 35 U.S.C. § 154(a)(2).

³⁵ 35 U.S.C. § 112.

³⁶ *Id.*

³⁷ Without the best mode requirement, an inventor might be tempted to provide the bare minimum of information necessary to enable a person of skill in the art to practice the invention *in some manner*, while allowing the inventor to preserve the best manner of practicing it as a trade secret.

to receiving a patent in the first instance, failure to disclose the best mode in a patent application can later render claims in a granted patent invalid.

The enablement requirement represents the very core of the patent bargain, and is “arguably the most important patent doctrine after obviousness.”³⁸ It is crucial for ensuring that society receives more than a *de minimus* description of inventions in exchange for tolerating the monopoly rights to exclude others granted to inventors.³⁹ One of the paramount purposes of the enablement requirement is

to provide the assurance that the public will, in fact, receive something in return for the patent grant. This consideration is, of course, the full and complete disclosure of how to make and use the claimed invention. Thus, the patent adds a measure of worthwhile knowledge to the public storehouse. The incentive to give this added measure of knowledge to the public, which clearly promotes the progress of the “Useful Arts,” is the primary justification for the existence of the patent system.⁴⁰

To be enabled, the written description⁴¹ of an invention must disclose “the manner of making and using it, in such full and clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same.”⁴² Furthermore, as explained in *In re Wright*,

[although] not explicitly stated in section 112, to be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without “undue experimentation.”⁴³

³⁸ *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 323 F.3d 956, 982 (Fed. Cir. 2002) (Radar, J., dissenting).

³⁹ In economic terms, the enablement requirement, along with the written description and best mode requirements, may be viewed as attempts to minimize the deadweight loss to society attending the monopoly right to exclude conferred by a patent.

⁴⁰ *In re Argoudelis*, 434 F.2d at 1394 (Baldwin, J., concurring).

⁴¹ Not to be confused with the “written description” requirement of 35 U.S.C. § 112, is the “written description” of the patent application (or patent), which traditionally consists of specification and “original claims” (that is, the first version of the claims filed). Drawings and other appendices filed along with the patent application are considered to complement the written description.

⁴² 35 U.S.C. § 112.

⁴³ *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993).

And, deciding what level of experimentation is undue “requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art. [Citations omitted]”⁴⁴

4. Claims

The specification must also include “one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.”⁴⁵ These claims provide notice to the public about where the monopoly rights to exclude lie, thus allowing them to order their behavior so as not to infringe. The claims also allow the patent owner to police instances of infringement by comparing the elements in a particular claim to allegedly infringing devices or methods.

D. Practical Aspects of the Patent System

There are a number of practical, but salient, aspects of patents that are relevant to the role the patent system can play in disasters. First, patents are expensive to obtain. On average, an applicant for a patent pertaining to a complex technology will spend more than \$11,000 simply to file a patent application,⁴⁶ and, after filing, considerably more to obtain enforceable patent rights.⁴⁷ The examination system of the USPTO, where patent applications are examined by technically skilled examiners before a patent can issue, acts relatively slowly. Patent prosecution (the process through which a patent application must pass prior to issuance as a patent) generally takes from two and a half to five years,⁴⁸ with the duration of prosecution rising with the complexity of the technology involved.

⁴⁴ *In re Wands*, 858 F.2d. 731, 737 (Fed. Cir. 1988).

⁴⁵ 35 U.S.C. § 112.

⁴⁶ Thomas C. Fiala & Jon E. Wright, *Preparing and Prosecuting a Patent that Holds up in Litigation*, 875 PLI/PAT 515, 521–22 (2006) (“For example, based on the AIPLA Report of the Economic Survey 2005, the average expected charge in 2004 for preparing and filing a utility patent application was \$11,218 for a relatively complex electrical or computer application and \$12,373 for a relatively complex biotechnology/chemical application”).

⁴⁷ Interview with Craig Smith, Partner, Fish & Richardson P.C. (Mar. 5, 2007).

⁴⁸ *Id.* The USPTO Performance Report for fiscal year 2006 reports an average patent pendency time (defined as time from filing until patent issued or application abandoned by applicant) of 31.3 months and shows that this figure has been

Once a patent is actually issued by the USPTO, the term of a patent is almost always significantly less than the theoretical twenty-year term because of time spent in patent prosecution or regulatory approval. Even with patent term extension to compensate for unreasonable federal agency review, the average enforceable lifetime of a patent lasts only about fifteen to seventeen and a half years. If a patent owner decides to enforce the right to exclude others from making, using, selling, offering to sell, or importing a patented invention, the average cost of patent litigation can rise above \$5 million, depending on the amount of damages at issue.⁴⁹ Additionally, patent litigation involves a significant degree of unpredictability, at least in part due to the proliferation of judicial barriers and available defenses to patent infringement.⁵⁰

increasing over the past few years. U.S. PATENT & TRADEMARK OFFICE, DEPT' OF COMMERCE, PERFORMANCE AND ACCOUNTABILITY REPORT: FISCAL YEAR 2006, at 22 (2006), available at <http://www.uspto.gov/web/offices/com/annual/index.html> (last visited March 7, 2007) [hereinafter "PERFORMANCE AND ACCOUNTABILITY REPORT"]. However, the average pendency times estimated by the USPTO are likely underestimates. Kristen Osenga, *Entrance Ramps, Tolls, and Express Lanes—Proposals for Decreasing Traffic Congestion in the Patent Office*, 33 FLA. ST. U. L. REV. 119, 129–30 (2005) ("[T]he average prosecution (or pendency) time for an ultimately successful patent is 3.6 years, with a median of 2.7 years. Anecdotally, the time period from filing to issuance varies by technology and ranges from twenty-four to thirty-six months for chemical and mechanical arts and thirty-six to sixty months for electrical and software arts").

⁴⁹ Thomas C. Fiala & Jon E. Wright, *Preparing and Prosecuting a Patent that Holds up in Litigation*, 875 PLI/PAT 515, 522 (2006) ("In comparison, the average estimated costs associated with litigating a patent in 2005 as reported by the same survey [AIPLA Report of the Economic Survey 2005] were: \$769,562 for a patent infringement suit in which less than \$1 million was at risk; \$2,637,179 for a suit in which between \$1 and \$25 million was at risk; and \$5,175,753 for a suit in which more than \$25 million was at risk").

⁵⁰ See, e.g., David J.F. Gross et al., *Claim Construction, Patent Infringement, and the Growing Importance of the Claim Vitiating Defense*, 841 PLI/PAT 45 (2005) ("This paper reviews the basic principles of claim construction and then discusses the current status of the doctrine of equivalents. As explained below, the Federal Circuit has erected several independent barriers to finding infringement under the doctrine of equivalents, but the most foreboding of such barriers may be the doctrine of claim vitiating."); Douglas R. Nemeck, *Current Trends in Equitable Defenses to Patent Infringement: Prosecution Laches and Inequitable Conduct*, 804 PLI/PAT 1147, 1155 (2004) ("This article also compares several recent Federal Circuit decisions on inequitable conduct, and explores how these cases, together with Symbol Technologies, suggest an inclination by the Federal Circuit toward more vigorous policing and enforcement of the rules of conduct before the PTO").

Finally, patent rights themselves have attracted an increasing amount of controversy among the public in recent years. With regard to disasters, an irony attending this controversy is that the most controversial inventions, such as patented medicines, biotechnological inventions, and methods of doing business, are precisely the kind of innovations most likely to prove useful in disasters.

E. Purpose of the Patent System

Legal authority for a patent system is based within the United States Constitution. Specifically, Article 1, Sec. 8, clause 8 states that “The Congress shall have 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.”⁵¹ Congress has relied on this explicit constitutional authority to offer statutory patent protection for inventions since the original Patent Act of 1790.⁵²

“[To] promote progress of science and the useful arts,” the availability of patent protection provides an incentive for inventors to invest their valuable time and efforts on the development of technological innovations. By virtue of the monopoly right that a patent confers, investments in developing new and useful compositions, devices, and methods can yield profits because inventors can exclude all others from making, using, selling, offering to sell, or importing their inventions for a substantial period of time. A particular fiscal advantage of this incentive system is that Congress need not offer inventors any financial reward for developing innovations because, based on the right to exclude others, patent owners can directly extract monopoly rents from consumers wishing to practice patented inventions. Though monopoly pricing does inflict a deadweight loss on society, the monopoly endures only for a limited period of time, after which competition can drive down prices. Furthermore, the specification of the patent delivers informational benefits to society as soon as it is published.⁵³

II. DISASTERS AND TECHNOLOGICAL INNOVATION

⁵¹ U.S. CONST. art. 1, § 8, cl. 8.

⁵² Patent Act of 1790, ch. 7, 1 Stat. 109 (1790).

⁵³ See 35 U.S.C. §122(b) (2000) (discussing how publication of a patent application generally occurs approximately 18 months after the filing date of the patent application).

A. Taxonomy of Disasters

Disasters comprise a diverse set of phenomena. Some are natural. These include earthquakes, tornados, hurricanes, and extreme weather events. Other disasters are anthropogenic. Military strikes, bombings, and bioterrorism attacks all fall within this latter category.

In considering the role of the patent system preparing for and reacting to disasters, it is important to differentiate between disasters that are foreseeable and those that are unforeseeable surprises. Foreseeability has two distinct aspects. A temporal aspect involves how early a disaster can be predicted before it occurs. An informational aspect involves how much reliable information is known about the disaster before it occurs.

The most foreseeable of disasters are those that can be predicted long ahead of time and about which much reliable information is known. Such disasters can be described as "more foreseeable." As the early predictability of a disaster and the amount of reliable information known about the disaster decline, foreseeability also decreases. These disasters can be described as "less foreseeable." When a disaster cannot be predicted ahead of its occurrence, and no reliable information is known about the disaster, it is unforeseeable. These disasters can be described as "surprises," consistent with the nomenclature developed by William Clark and Robert Kates.⁵⁴ The ways in which the patent system can assist society in disasters vary depending upon whether a disaster is more foreseeable, less foreseeable, or a surprise.

Obviously, the patent system has the best potential to help society with more foreseeable disasters. When a disaster is predictable and well understood, existing incentives created by the prospect of patent protection for inventions will tend to augment the general technological capacity of society.⁵⁵ Furthermore, with warning and knowledge, society can target certain technological challenges likely to accompany a particular disaster by increasing patent incentives so as to

⁵⁴ Robert W. Kates & William C. Clark, *Expecting the Environmental Surprise*, 38 ENVIRONMENT 6-11 (1996).

⁵⁵ Although general technological capacity will tend to increase over time, at least in part in response to incentives created by the prospect of patent protection, this increase will not tend to be uniformly distributed across all technological fields because of variations in market demand for different categories of goods and services. However, more foreseeable disasters should create more demand for goods and services considered useful in the coming disaster, thus increasing incentives and spurring inventive activity to produce goods and services to meet increased demand.

spur technological innovations useful for meeting these challenges. As a result, there will tend to be an increase in technological capacity specific to the approaching disaster.

The patent system will also tend to increase general technological capacity prior to a less foreseeable disaster.⁵⁶ As a simple function of time, the longer the period of time separating recognition of an approaching disaster from its occurrence, the more opportunity there is to increase this general technological capacity. However, the less advance warning and reliable information there is prior to a disaster, the less opportunity there will be for increasing specific technological capacity.

Surprise disasters present a very different set of challenges to the patent system. With no opportunity to prepare for them, the only prospective contribution the patent system can make to surprise disasters is to enhance the general technological capacity of society. However, unlike for the case of both more and less foreseeable disasters, such enhancement of general technological capacity will be entirely unfocused with respect to any specific societal needs arising from the surprise disaster. In the absence of reliable information the market lacks any demand signals regarding which sorts of goods and services will be most useful in the approaching disaster.

The spread of avian influenza (“bird flu”) into North America provides a useful illustration of a relatively foreseeable public health disaster. The family of viruses that cause bird flu is well characterized. The vectors that spread bird flu—usually domestic, rather than wild, birds—are well understood. The devastating public health effects of a bird flu outbreak have already been previewed in several well-studied outbreaks in Southeast Asia. Bird flu has yet to spread widely into the North America, despite the common Arctic breeding grounds many Asian and North American migratory birds share in summer.⁵⁷ The spread of bird flu into North America will likely come from imported poultry or poultry products.⁵⁸ The patent system has already been spurred to action by the prospect of lucrative inventions offering diagnostic methods, preventive methods and products, and treatment

⁵⁶ Less foreseeable disasters are less likely to provide accurate signals to the market regarding what sorts of goods and services will be most useful in the approaching disaster because there is less reliable information available about the disaster.

⁵⁷ Andrew Bridges, *Avian Flu Not Spread by Bird Migration*, available at http://www.livescience.com/humanbiology/051228_ap_migrate_flu.html. (last visited Jan. 30, 2007)

⁵⁸ *Id.*

options for bird flu.⁵⁹ More inventions such as these increase the chances of mitigating any public health disaster eventually resulting from an outbreak of bird flu in North America. In short, there has already been a relatively large amount of time and information about bird flu, allowing enhancement of both general and specific technological capacity prior to any North American bird flu disaster.⁶⁰

The sudden appearance of AIDS in 1981, and its subsequent spread around the world, illustrates the phenomenon of a surprise disaster. The origins of HIV-1, the virus responsible for AIDS, appear to have been among wild chimpanzees in Africa.⁶¹ The virus was probably transmitted to humans in Africa through the ingestion of chimpanzee meat.⁶² Subsequently, HIV-1 was spread among Africans, and then around the world, most commonly by unprotected sexual intercourse.⁶³ Because of the relatively long period of time between infection by HIV-1 and the development of obvious symptoms of AIDS,⁶⁴ the disease was difficult to diagnose and its pandemic spread impossible to prevent. Complete lack of knowledge about AIDS before it spread to humans coupled with the rapid development of the disease into a global pandemic resulted in a surprise public health disaster. There was little that could have been done prior to 1981 to prepare for AIDS. Because of the incentives to invent created by the patent system, the general technological—including medical—capacity of society was greater than it otherwise would have been. However,

⁵⁹ Of the eighty-three published patent applications that mention “H5N1,” thirty-eight (or forty-six percent) were published in 2006 alone. By contrast, only fifteen patents mentioning “H5N1” have been issued by the United States Patent & Trademark Office to date. See U.S. Patent & Trademark Office, Patent Application Full Text and Image Database, at <http://appft1.uspto.gov/netahhtml/PTO/search-bool.html> (last visited Jan. 30, 2007) (showing databases of published patent applications); US Patent Full-Text and Image Database, <http://patft.uspto.gov/netahhtml/PTO/search-bool.html> (last visited Jan. 30, 2007) (showing databases of issued patents). Given the eighteen month waiting period before a patent application is published, this probably underestimates recent patenting activity in the area of bird flu.

⁶⁰ Obviously, the more time and information society possess ahead of a foreseeable disaster, the greater the probability that the disaster can be avoided.

⁶¹ NIAID-Supported Scientists Discover Origin of HIV-1, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, Jan. 1999, at <http://www3.niaid.nih.gov/news/newsreleases/1999/hivorigin.htm> (last visited Jan. 30, 2007).

⁶² *Id.*

⁶³ HIV Infection and AIDS: An Overview, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, Mar. 2005, at <http://www.niaid.nih.gov/factsheets/hivinf.htm> (last visited Jan. 30, 2007).

⁶⁴ *Id.*

without any information about AIDS or warning that it might appear, the patent system was unable to enhance the specific technological capacity of society to meet the challenges of the AIDS disaster ahead of time, with devastating results to public health and the economy.

In short, the patent system can provide society with significant enhancements in both general and specific technological capacity useful in preparing for and reacting to foreseeable disasters, and does so in rough proportion to the foreseeability of the disaster. However, in the face of surprise disasters, the patent system is largely powerless to provide anything other than enhanced general technological capacity.

B. The Patent System and Technological Innovation

Technological innovation has tremendous positive effects upon public health, the economy, and the technological capacity of society to deal with disasters. In fact, if research into historical economic growth by a Nobel laureate economist, Robert M. Solow, is indicative of recent trends, investments into developing new technologies may be responsible for roughly half of the economic growth in the United States.⁶⁵ Furthermore, there is little evidence of theoretical limits to the economic benefits of increasing levels of technological innovation: empirically, as investments in technological innovation increase, economic growth increases without a declining return on investment.⁶⁶ Economic welfare appears to continue increasing indefinitely alongside technological innovation.⁶⁷

Patent protection enhances technological capacity by creating an incentive for inventors to devote their valuable and scarce inventive resources to the search for technological and scientific innovations. In the absence of patent protection, any innovation that does not remain secret can potentially be freely appropriated by others.⁶⁸ Consequently, unless such free-riding is prevented, and inventors are given the prospect of compensation for their investment of scarce time, energy, and other resources that make inventions possible, fewer inventors than the socially optimal number will choose to invent, resulting in less

⁶⁵ See Robert M. Solow, *Technical Change and the Aggregate Production Function*, 39 REVIEW OF ECON. & STAT 312, 319-322 (1957).

⁶⁶ Paul M. Romer, *Increasing Return and Long-run Growth*, 94 J. POL. ECON. 1002 (1986).

⁶⁷ See, e.g., FEDERAL TRADE COMMISSION, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY 74 (Oct. 2003) [hereinafter "FTC REPORT"].

⁶⁸ See *id.*

innovation than is socially optimal.⁶⁹ Patent protection for inventions helps to internalize the externalities caused by free-riding, and creates an incentive to innovate.⁷⁰

With respect to disasters, the patent system provides society with a significant benefit. It creates incentives for inventors to seek out technical and scientific solutions to significant problems. In a general way, the patent system induces inventors to build up the technological and scientific capacity of society. Since inventors have the prospect of financial reward for their innovations, society will tend to have more inventors, developing more technological innovations, than there would be in the absence of a patent system.

The patent system may be harnessed to seek solutions to challenges specific to disasters, as long as such solutions hold the promise of financial reward. For example, the 9/11 attacks have highlighted the need for enhanced security screening, airplane safety systems, and structural improvements to skyscrapers. The post 9/11 anthrax attacks showed the need for better diagnostic and therapeutic solutions to respond to bioterrorism, and the Asian tsunami of 2004 and the 2005 Hurricane Katrina both demonstrated the acute need for improvements in early detection of natural disasters, emergency response to sudden and widespread public health challenges, and engineering of shelters and barriers.

In addition to enhancing the technological capacity of society to deal effectively with disasters, the patent system can be adapted, through the temporary weakening of patent rights, to allow rapid dissemination and employment of inventions needed in disasters.

III. WEAKENING PATENT RIGHTS

In times of disaster society may decide that threats to public health, safety, and property outweigh enforcement of some existing laws. Much of the latest and more advanced technology that is, or could be, useful in disasters will tend to be protected by patents against unauthorized use. However, in the extreme situations that attend disasters, one policy choice available to the government is to increase the availability of needed, but patented, technologies through the weakening or abrogation of patent rights.

⁶⁹ *Id.*

⁷⁰ *Id.*

A number of international patent law treaties contemplate the use of compulsory licenses to gain access to patented technologies during national emergencies. Patent law in the United States also includes a variety of legal avenues through which the right of a patent owner to exclude others may be overridden to make needed patented technologies available *in extremis*. Weakening of patent rights can be accomplished by statutory exceptions to infringement, compulsory licensing, march-in rights, patent breaking, and sovereign immunity. Despite the availability of these legal options for avoiding infringement liability, the U.S. government rarely avails itself of them.

In times of disasters, it may become necessary to weaken existing patent rights in order to make useful technologies immediately and widely available. During a disaster, the patent right to exclude others tends to hamper, rather than help, disaster preparation and relief. Even worse, if patent owners were to perceive a rise in their bargaining power during a disaster, it might be economically rational for them to engage in extortionate pricing practices with captive markets in need of particular patented inventions to deal with the disaster. If society were in dire need of a particular invention in a disaster, then a hold-out situation might ensue, resulting in either an especially large deadweight loss to society arising from the need to pay the extortionate price demanded, or in a reduced capacity to respond effectively to the disaster if the patent owner decided strictly to exercise the right to exclude others.

Fortunately a number of legal options already exist to exclude certain parties from infringement and to weaken the patent right to exclude when necessary to do so.

A. The Patent Exclusionary Right

The rights conferred by a patent are often misunderstood. While it is accurate that a patent confers a monopoly right to its owner, this monopoly right is not absolute. Fundamentally, a patent gives its owner the legal right to exclude others, but grants the patent owner no affirmative right to practice. Other than the patent owner, “whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefore, infringes

the patent.”⁷¹ However, a patent owner possesses no affirmative right to practice a patented invention, and may also be precluded from practicing a patented invention, due either to the risk of infringing other patents or to other legal restrictions on activities necessary to practice the patented invention.

In addition, the right to exclude conferred by a patent does not last forever. It expires along with the patent. Furthermore, because patent prosecution can stretch over a considerable period of years, a patent owner may have to wait a considerable period of time before a patent becomes enforceable. Approximately eighteen months after its earliest priority date, a published patent application carries with it certain “provisional rights,” including the possibility of a reasonable royalty to compensate for pre-grant infringement of a claimed invention.⁷² However, the right to exclude others from practicing a patent does not vest until the patent has actually been issued. Consequently, the term of a patent tends to be considerably less than its theoretical length of twenty years.

B. International Law and Weakening Patent Rights

Several international treaties legally constrain the policy options available to the United States with respect to weakening or abrogating patent rights. The most notable of these treaties are the Paris Convention for the Protection of Industrial Property (“Paris Convention”),⁷³ the Agreement on Trade-Related Aspects of Intellectual Property (“TRIPS”),⁷⁴ which is ancillary to the World Trade Organization (“WTO”), and the North American Free Trade Agreement (“NAFTA”).⁷⁵ In essence, these treaties attempt to ensure a modicum of uniformity in the availability and enforcement of patent rights in the national laws of all nations that are parties to them. In addition to the protection of patent rights, all three treaties provide for weakening of patent rights under exigent circumstances. The United States has traditionally been a strong supporter of patent rights, in both

⁷¹ 35 U.S.C. § 271(a).

⁷² 35 U.S.C. § 154(d).

⁷³ Paris Convention for the Protection of Industrial Property, Mar. 20, 1883 [hereinafter “Paris Convention”].

⁷⁴ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C art. 30, 1869 U.N.T.S. 229, 33 I.L.M. 1197 (1994) [hereinafter “TRIPS”].

⁷⁵ North American Free Trade Agreement, U.S.-Can.-Mex., Dec. 17, 1992, 32 I.L.M. 289 (1993) [hereinafter “NAFTA”].

the domestic and international arenas, and the United States has rarely made use of the legal exceptions to patent rights allowed in these treaties.

1. The Paris Convention

The Paris Convention sets out rules for the granting of compulsory licenses. Article 5(A), entitled “Patents: Importation of Articles; Failure to Work or Insufficient Working; Compulsory Licenses,” states that:

Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent. . .⁷⁶

However, the circumstances under which a country may force a compulsory license for a patented invention from its owner are restrictive.

Efforts by a patent owner to exclude others completely from practicing a patented invention necessary to protect public health, safety, or property in a disaster may qualify as an abuse. Even unreasonable exclusion might qualify as abuse. In the face of abuse, the Paris Convention authorizes the federal government to force a compulsory license with the patent owner.⁷⁷ The availability of a compulsory license may be necessary to curb the temptation on the part of patent owners to engage in hold-out behavior to extort excessive rents in return for access to patented inventions. Even the threat of a compulsory license may be enough to temper such excesses.

Even once the federal government decides to force a compulsory license from a patent owner for “failure to work or insufficient working” of a patented invention, the Paris Convention only permits it to do so for patents of a certain age.⁷⁸ Compulsory licenses can be granted only after a “period of four years from the date

⁷⁶ Paris Convention, *supra* note 73, art. 5(A)(2).

⁷⁷ *Id.*

⁷⁸ *Id.* art. 5(A)(4). If the ground of abuse justifying grant of a compulsory license is other than “failure to work or insufficient working”, then a compulsory license may be immediately grantable. For example, a patent owner might work the patent vigorously, but exclude others completely from the patented invention, either by refusing to sell access to it or holding out for an unreasonably exorbitant price. *Id.*

of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last.”⁷⁹ The average duration of prosecution of a patent application in the USPTO may approach four years.⁸⁰ Thus, the average waiting period for a compulsory license may approach seven years from the filing date of the patent. Furthermore, as long as a patent application is still undergoing prosecution, and has not yet been issued by the USPTO, anyone can practice its claimed inventions.⁸¹ Even if a patent owner fails to work a patented invention sufficiently, “it shall be refused if the patentee justifies his inaction by legitimate reasons.”⁸² Additionally, any compulsory license that is granted must be nonexclusive and nontransferable.⁸³

During a disaster, the need for access to a patented invention must often be met without unreasonable delay or impediment to protect health, safety, or property from harm. Under the Paris Convention, unreasonable delay or impediment in gaining access to a patented invention needed to prevent significant harm, if caused by the patent owner, might qualify as an “abuse” justifying a compulsory license. If the ground of abuse justifying the grant of a compulsory license were other than “failure to work or insufficient working,” then the Paris Convention would appear to allow the immediate granting of a compulsory license. A situation justifying immediate grant of a compulsory license might arise if a patent owner did, in fact, work a patent vigorously, but chose to exclude others completely from the patented invention, either by refusing to sell access to it or holding out for an unreasonably exorbitant price in return for access. Alternatively, if a patent owner were simply incapable of meeting a rapid increase in demand driven by a disaster, failure to meet emergency demand while excluding others from assisting to do so, rather than failure to work, might also constitute abuse justifying a compulsory license.

Complete forfeiture or revocation of patent rights is also contemplated by the Paris Convention.⁸⁴ However, complete forfeiture

⁷⁹ *Id.*

⁸⁰ PERFORMANCE AND ACCOUNTABILITY REPORT, *supra* note 48. However, the average pendency times estimated by the USPTO are likely underestimates. Osenga, *supra* note 48, at 129.

⁸¹ Although no injunctive relief is available to the owner of a patent application, pre-issue use of the claimed invention might trigger liability for a reasonable royalty under 35 U.S.C. § 154(d).

⁸² Paris Convention, *supra* note 73, art. 5(A)(4).

⁸³ *Id.*

⁸⁴ *Id.* art. 5(A)(3).

or revocation is impermissible unless compulsory licensing would not have prevented the abuse of patent rights.⁸⁵ Even then, an attempt must first be made to prevent the abuse through compulsory licensing, because no forfeiture or revocation proceedings are permitted to begin until at least two years after the first compulsory license has been granted.⁸⁶

2. TRIPS

The United States is a member of the WTO,⁸⁷ whose TRIPS legally obliges members of the WTO to provide for a uniform minimum level of intellectual property protection.⁸⁸ Nevertheless, the provisions of TRIPS also contemplate exceptions to the strict enforcement of patents in exigent circumstances, including circumstances that might threaten social welfare and public health. In particular, TRIPS Articles 7, 8, 30, and 31 allow member governments to make exceptions to patent rights.

In Articles 7 and 8, TRIPS describes the general circumstances under which exceptions to patent rights may be permitted. They articulate the “Objectives”⁸⁹ and “Principles”⁹⁰ of TRIPS, and explicitly account for social welfare, in general, and public health, in particular, both of which tend to be strongly implicated in disasters. Among other considerations, member nations are urged to protect and enforce patent rights “in a manner conducive to social and economic welfare, and to a balance of rights and obligations.”⁹¹ Members are permitted to “adopt measures necessary to protect public health and nutrition. . . provided that such measures are consistent with the provisions of this Agreement.”⁹²

Article 30, entitled “Exceptions to Rights Conferred,” allows member nations to “provide limited exceptions to the exclusive rights

⁸⁵ *Id.*

⁸⁶ *Id.*

⁸⁷ Understanding The WTO: The Organization, WORLD TRADE ORG., Jan. 11, 2007, at http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (last visited Jan. 30, 2007).

⁸⁸ Intellectual Property: Protection and Enforcement, WORLD TRADE ORG., at http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm (last visited Jan. 30, 2007).

⁸⁹ TRIPS, *supra* note 74, art. 7.

⁹⁰ *Id.* art. 8.

⁹¹ *Id.* art. 7.

⁹² *Id.* art. 8.

conferred by a patent.”⁹³ However, exceptions to patent rights must be made without unreasonably conflicting with “normal exploitation of the patent.”⁹⁴ Nor can exceptions allowed by a member nation “unreasonably prejudice the legitimate interests of the patent owner.”⁹⁵ Finally, exceptions to patent rights must account for “the legitimate interests of third parties.”⁹⁶ Article 30 does not authorize either compulsory licensing or patent breaking, but rather, it allows member nations to stipulate that some specified uses of patented inventions do not constitute infringement.

Article 31, entitled “Other Use Without Authorization of the Right Holder,” allows member nations to grant compulsory licenses or break patents in certain, usually exigent, circumstances. To qualify, a member nation must have a basis in its own laws for allowing use “by the government or third parties authorized by the government” of a patented invention without permission from the patent owner.⁹⁷ In addition, a member nation must follow a number of principles before authorizing the weakening of a particular patent.⁹⁸ Each case for weakening patent rights must be “considered on its individual merits.”⁹⁹ Prior to authorization, an effort must be made to obtain permission from the patent owner “on reasonable commercial terms and conditions” over a “reasonable period of time,” although such negotiation with the patent owner is unnecessary “in the case of a national emergency or other circumstances of extreme urgency or in cases of public noncommercial use.”¹⁰⁰ The scope and duration of use “shall be limited to the purpose for which it was authorized.”¹⁰¹ Consistent with the Paris Convention, any compulsory license must be nonexclusive and essentially nontransferable.¹⁰² Authorization extends “predominantly

⁹³ *Id.* art. 30.

⁹⁴ *Id.*

⁹⁵ *Id.*

⁹⁶ *Id.*

⁹⁷ *Id.* art. 31.

⁹⁸ *Id.*

⁹⁹ *Id.*

¹⁰⁰ *Id.* art. 31(b).

¹⁰¹ *Id.* art. 31(c).

¹⁰² *Id.* arts. 31(d) and 31(e).

for the supply of the domestic market” of the authorizing member nation.¹⁰³ Authorization only lasts until “the circumstances which led to it cease to exist and are unlikely to recur,” and the continued salience of such circumstances can be subject to review.¹⁰⁴ Reasonable compensation must be paid to the patent owner for use of a patented invention without permission of its owner.¹⁰⁵ Judicial review must be available for both the governmental authorization to use a patented invention without permission of its owner¹⁰⁶ and the reasonableness of the amount of compensation paid to the patent owner.¹⁰⁷

In Doha, Qatar, on November 20, 2001, the WTO issued the “Declaration on the TRIPS agreement and public health” (“Doha Declaration”) as part of the Doha round of WTO trade negotiations.¹⁰⁸ Though most of its provisions are most relevant to developing countries, several parts of the Doha Declaration are relevant to the United States:

We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.¹⁰⁹

¹⁰³ *Id.* art. 31(f).

¹⁰⁴ *Id.* art. 31(g).

¹⁰⁵ *Id.* art. 31(h).

¹⁰⁶ *Id.* art. 31(i).

¹⁰⁷ *Id.* art. 31(j).

¹⁰⁸ World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002) [hereinafter “Doha Declaration”], available at

http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (last visited Jan. 30, 2007).

¹⁰⁹ *Id.* ¶ 4.

Furthermore, the Doha Declaration stated that “Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted”¹¹⁰ and that

Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.¹¹¹

3. NAFTA

The NAFTA includes patent provisions relevant to weakening patent rights that are strikingly similar to that of TRIPS.¹¹² Article 1709(6) of NAFTA is almost identical to TRIPS Article 30, while Article 1709(10) is almost identical to TRIPS Article 31. One relevant difference between the two treaties involves revocation or forfeiture of patent rights. Under NAFTA, a member nation can revoke a patent if “the grant of a compulsory license has not remedied the lack of exploitation of the patent.”¹¹³ Under TRIPS, any decision to revoke or render forfeit patent rights must be accompanied by an “opportunity for judicial review.”¹¹⁴

C. Exceptions to Infringement

The statutory subject matter of patents is exceptionally broad. Patented inventions can include “anything under the sun that is made by man.”¹¹⁵ Methods of medical treatment fall squarely within this broad category. Nevertheless, patents claiming many medical treatments are effectively unenforceable under 35 U.S.C. §287(c).

35 U.S.C. §287(c) states that

¹¹⁰ *Id.* ¶ 5(b).

¹¹¹ *Id.* ¶ 5(c).

¹¹² This is no coincidence, since much of TRIPS is derived, word for word, directly from NAFTA.

¹¹³ NAFTA, *supra* note 75, art. 1709(8)(b).

¹¹⁴ TRIPS, *supra* note 74, art. 32.

¹¹⁵ *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

[with] respect to a medical practitioner's performance of a medical activity that constitutes an infringement under section 271(a) or (b) of this title, the provisions of sections 281 [availability of a civil action for patent infringement], 283 [availability of injunctive relief for patent infringement], 284 [availability of damages for patent infringement], and 285 [availability of attorney fees for patent infringement] of this title shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity.

"Medical activity" is defined as "the performance of a medical activity or surgical procedure on a body" that does not employ certain patented materials and methods.¹¹⁶ "Medical practitioner" means a licensed physician or other supervised medical personnel.¹¹⁷ "Related health care entity" means the medical facility where a medical practitioner carries out the medical activity.¹¹⁸

35 U.S.C. §287(c) approaches the problem of patent liability for medical treatment methods from a creative angle. Instead of creating a category of activities that does not constitute infringement, 35 U.S.C. §287(c) simply removes the possibility of redress for infringement. Inventors can still apply for, and receive, patents claiming methods of medical treatment. However, such patents are rendered effectively unenforceable under 35 U.S.C. §287(c) because physicians, precisely the group most likely to infringe,¹¹⁹ cannot be sued for damages or attorney fees or enjoined from committing further infringing acts. There are several significant exceptions, however. A physician may still be liable and punishable for patent infringement for "the use of a patented machine, manufacture, or composition of matter,"¹²⁰ "the practice of a patented use of a composition of matter,"¹²¹ or "the practice of a process in violation of a biotechnology patent."¹²²

The practical effect of 35 U.S.C. §287(c) is to relieve physicians, ancillary medical staff, and the medical institutions that

¹¹⁶ 35 U.S.C. § 287(c)(2)(A) (2000).

¹¹⁷ *Id.* § 287(c)(2)(B).

¹¹⁸ *Id.* § 287(c)(2)(C).

¹¹⁹ In fact, because it is generally illegal to practice medicine without a license in the U.S., physicians may be the only parties who could normally be sued for patent infringement.

¹²⁰ 35 U.S.C. § 287(c)(2)(A)(i).

¹²¹ *Id.*

¹²² *Id.*

host them of much of the fear of liability for sharing and employing new methods and techniques of medical treatment and surgery. By reducing the risk of liability, 35 U.S.C. §287(c) promotes the effective and efficient practice of medicine. The repose provided to medical personnel also promotes the free exchange of medical ideas and quick medical intervention on behalf of patients whenever needed.

D. Compulsory Licensing

A patent confers upon its owner a right to exclude others from making, using, selling, offering to sell, or importing into the United States any patented invention.¹²³ A patent owner may voluntarily license others to practice a patented invention. Alternatively, a patent owner may choose not to license a patented invention to anyone.¹²⁴ As the U.S. Supreme Court has observed, “[compulsory] licensing is a rarity in our patent system.”¹²⁵ In rare circumstances, however, the government may deem this right to exclude to be outweighed by the need to make a patented invention more widely available than a patent owner might wish. Such rare circumstances could certainly include disasters. One means by which the right to exclude can be loosened is through compulsory licensing.

As the name suggests, a compulsory license compels a patent owner to allow certain others to practice the invention otherwise protected by a patent. In practice, a government acts in the stead of the patent owner to grant a compulsory license to the government itself or to a third party authorized by the government. In return, the patent owner usually receives what the government or courts deem to be a reasonable royalty. As discussed above, the Paris Convention, TRIPS, and NAFTA contemplate compulsory licensing and set international standards for, and limits on, their implementation.

1. Statutory Compulsory Licensing

Compulsory licenses are exceedingly rare in the United States, though they tend to be considered as more legitimate policy options in other countries. Congress has provided for compulsory licenses in two specific instances: air pollution control technology (42 U.S.C. §7608) and nuclear technology (42 U.S.C. §2183(c)). In the negotiations

¹²³ 35 U.S.C. § 271(a).

¹²⁴ *Id.* § 271(d)(4).

¹²⁵ *Dawson Chemical v. Rohm and Haas*, 448 U.S. 176, 215 (1980).

preceding the 1952 amendments to the Patent Act, there were some unsuccessful proposals to provide for a broad compulsory licensing scheme.¹²⁶ Since that time, though Congress has occasionally studied the issue, it has gone no further.¹²⁷

i. The Clean Air Act

In 1970, the U.S. Congress passed major amendments to the Clean Air Act (“CAA”),¹²⁸ which has as one of its primary stated purposes “to protect and enhance the quality of the Nation’s air resources so as to promote the public health and welfare and the productive capacity of its population.”¹²⁹ The CAA recognized that reduction of air pollution is primarily the responsibility of states and local governments.¹³⁰ Among its measures, the CAA mandates that states must reduce the levels of certain specified air pollutants to or below maximum allowable limits. To ease the burden of compliance, Congress also passed a provision allowing states compulsory licenses (“mandatory licenses” in the CAA) to some air pollution reduction technologies if their use is necessary to meet federal air quality standards.¹³¹

The compulsory licensing scheme imposes a number of conditions before a compulsory license can be granted. First, the U.S. Attorney General must receive a request from the Administrator of the U.S. Environmental Protection Agency for a compulsory license allowing governmental or commercial practice, or continued practice, of a patented invention useful in reducing air pollution.¹³² The Attorney General must then certify that the patented invention is “not otherwise reasonably available” and “is necessary” to comply with air quality standards specified by the CAA,¹³³ “there are no reasonable alternative methods to accomplish such purpose,”¹³⁴ and failure to grant

¹²⁶ See STAFF OF H. COMM. ON THE JUDICIARY, 81ST CONG., PROPOSED REVISION AND AMENDMENT OF THE PATENT LAWS: PRELIMINARY DRAFT 91 (Comm. Print 1950).

¹²⁷ See, e.g., STAFF OF H. COMM. ON THE JUDICIARY, 85TH CONG., COMPULSORY LICENSING OF PATENTS UNDER SOME NON-AMERICAN SYSTEMS 1,2 (Comm. Print 1959).

¹²⁸ Clean Air Act Amendments of 1970, 42 U.S.C. § 7401.

¹²⁹ *Id.* § 7401(b)(1).

¹³⁰ *Id.* § 7401(a)(3).

¹³¹ 42 U.S.C. § 7608 (2000).

¹³² *Id.* § 7608(1)(A).

¹³³ *Id.*

¹³⁴ *Id.* § 7608(1)(B).

a compulsory license will be significantly anticompetitive.¹³⁵ Certification must be made to a district court “which may issue an order requiring the person who owns such patent to license it on such reasonable terms and conditions as the court, after hearing, may determine.”¹³⁶

This compulsory licensing was implemented in response to an important requirement upon the states: compliance with specific air quality standards mandated by the CAA. Compulsory licensing was intended to ease the burden upon states successfully to comply. Disasters almost always present challenges of greater urgency than do violations of federal air pollution standards. Consequently, if air quality compliance justifies compulsory licensing of relevant patented inventions, then compulsory licensing to gain access to patented inventions is justified *a fortiori* by disasters.

ii. The Clean Air Act

Congress has also established a detailed statutory framework for compulsory licensing of patented inventions related to nuclear energy.¹³⁷ As a threshold step, the Department of Energy (“DOE”) must, after “giving the patent owner an opportunity for a hearing,” declare that a patented invention “is of primary importance in the production or utilization of special nuclear material or atomic energy” and licensing the patent “is of primary importance to effectuate the policies and purposes of this chapter.”¹³⁸ Once “any patent has been declared affected with the public interest” the DOE is eligible to be licensed to use the patented invention itself.¹³⁹ Under certain circumstances, the DOE may also grant nonexclusive licenses to any third party,¹⁴⁰ as long as the latter is authorized to use the patented invention by the DOE and reveals any previous efforts to obtain a license from the patent owner.¹⁴¹ However, before a compulsory license can be granted to a third party, the DOE must apprise the patent owner of any compulsory license applications¹⁴² and hold hearings to

¹³⁵ *Id.* § 7608(2).

¹³⁶ *Id.*

¹³⁷ See 42 U.S.C. §§ 2183-2188 (discussing the statutory framework).

¹³⁸ 42 U.S.C. § 2183(a).

¹³⁹ *Id.* § 2183(b).

¹⁴⁰ *Id.* § 2183(b)(2).

¹⁴¹ *Id.* § 2183(c).

¹⁴² *Id.* § 2183(d)(1).

consider the applications.¹⁴³ If the DOE then makes findings that the patented invention “is of primary importance in the production or utilization of special nuclear material or atomic energy,”¹⁴⁴ licensing the patented invention “is of primary importance to the conduct of the activities of the applicant,”¹⁴⁵ the proposed licensed activities “are of primary importance to the furtherance of policies and purposes of [Chapter 23¹⁴⁶],”¹⁴⁷ and the “applicant cannot otherwise obtain a patent license from the owner of the patent on terms which the [DOE] deems to be reasonable for the intended use of the patent to be made by such applicant,”¹⁴⁸ it can then grant the applicant a compulsory license “on terms deemed equitable by the [DOE] and generally not less fair than those granted by the patentee or by the [DOE] to similar licensees for comparable use.”¹⁴⁹ The DOE can also grant a compulsory license on a patented invention “of primary use in the utilization or production of special nuclear material or atomic energy” if the patent owner is found to have engaged in certain antitrust violations.¹⁵⁰

The patent owner is entitled to compensation for any compulsory license in the form of a “reasonable royalty fee from the licensee for any use of [the patented invention].”¹⁵¹ If the patent owner and grantee of the compulsory license cannot agree upon a royalty, the DOE may convene a special “Patent Compensation Board” to assist in establishing the amount just compensation.¹⁵² In establishing a reasonable royalty, the DOE must consider the advice of the Patent Compensation Board,¹⁵³ “any defense, general or special, that might be pleaded by a defendant in an action for infringement,”¹⁵⁴ the extent of federal funding that contributed to the development of the patented invention,¹⁵⁵ and “the degree of utility, novelty, and importance [of the patented invention] and [optionally] the cost to the owner of the patent of developing. . . or acquiring [the patented invention].”¹⁵⁶

¹⁴³ *Id.* § 2183(d).

¹⁴⁴ *Id.* § 2183(e)(1).

¹⁴⁵ *Id.* § 2183(e)(2).

¹⁴⁶ Development and Control of Atomic Energy, 42 U.S.C. § 2183.

¹⁴⁷ *Id.* § 2183(3).

¹⁴⁸ *Id.* § 2183(4).

¹⁴⁹ *Id.* § 2183(e).

¹⁵⁰ 42 U.S.C. § 2188.

¹⁵¹ 42 U.S.C. § 2183(g).

¹⁵² 42 U.S.C. § 2187.

¹⁵³ *Id.* § 2187(c)(1)(A).

¹⁵⁴ *Id.* § 2187(c)(1)(B).

¹⁵⁵ *Id.* § 2187(c)(1)(C).

¹⁵⁶ *Id.* § 2187(c)(1)(D).

Once a compulsory license has been granted by the DOE, a patent owner cannot obtain an injunction to prevent the use authorized by the compulsory license.¹⁵⁷ However, a patent owner can bring legal action to recover unpaid royalty fees.¹⁵⁸

2. *De facto* Compulsory Licensing

In recent years, upon a showing of patent infringement a patent owner has been able to obtain a permanent injunction forbidding the allegedly infringer from committing further infringing acts almost as of right. The Court of Appeals for the Federal Circuit has articulated the standard for permanent injunctions emphatically:

We therefore see no reason to depart from the general rule that courts will rule that courts will issue permanent injunctions against patent infringement absent exceptional circumstances.¹⁵⁹

However, the U.S. Supreme Court clarified the standard for permanent injunctions in 2006, overturning the Federal Circuit and bringing the standard for receiving permanent injunctions in patent infringement cases into conformance with the standard in other areas of the law.¹⁶⁰ As the Supreme Court wrote, “These familiar principles [governing permanent injunctions in non-patent law] apply with equal force to disputes arising under the Patent Act.”¹⁶¹ In the absence of the availability of permanent injunctions as of right, the Supreme Court has moved the reasonable expectations of patent owners and potential infringers alike in the direction of a *de facto* compulsory licensing regime. It is too early to gauge the significance of this shift in standards for injunctions, but it may augur well for easier access to patented inventions needed in disasters.

E. March-in Rights

¹⁵⁷ 42 U.S.C. § 2184.

¹⁵⁸ *Id.*

¹⁵⁹ *MercExchange, LLC v. eBay, Inc.*, 401 F.3d 1323, 1339 (Fed. Cir. 2005).

¹⁶⁰ *eBay, Inc. v. MercExchange, LLC.*, 126 S. Ct. 1837, 1839 (2006).

¹⁶¹ *Id.*

The Bayh-Dole amendments to the patent statute included provisions allowing so-called “march-in rights.”¹⁶² March-in rights allow a federal agency that funded a patented invention to grant a license to the patent even if the non-governmental entity that holds legal rights to that patent has failed adequately to put the invention into practice.¹⁶³

Only inventions whose origins can be traced to funding by a federal agency are potentially vulnerable to march-in. The federal government can exercise its march-in rights only under certain circumstances. For example, march-in could be justified if disaster struck and the owner of patent rights on an invention needed in time of disaster had failed to take “effective steps to achieve practical application” of the invention “within a reasonable time”¹⁶⁴ or if the invention were necessary “to alleviate health or safety needs”¹⁶⁵ or “to meet requirements for public use specified by Federal regulations”¹⁶⁶ not reasonably satisfied by the owner of rights to the invention. 35 U.S.C. §203(a)(3) could be particularly useful in time of disaster if federal regulations were promulgated specifically contemplating public use to protect health and safety during disasters.

Several federal agencies have received a number of petitions requesting that march-in rights be granted in cases involving drugs deemed overpriced by the petitioners.¹⁶⁷ However, to date no such petition has resulted a grant of march-in rights by the federal government.

F. Patent Breaking

The most extreme option available to the government is total abrogation or revocation of the rights conferred by a patent. This is referred to as “breaking” a patent. Immediate patent breaking would likely violate the Paris Convention because “[forfeiture] of the patent shall not be provided for except in cases where the grant of compulsory

¹⁶² 35 U.S.C. §§ 200-212.

¹⁶³ 35 U.S.C. § 203.

¹⁶⁴ *Id.* § 203(a)(1).

¹⁶⁵ *Id.* § 203(a)(2).

¹⁶⁶ *Id.* § 203(a)(3).

¹⁶⁷ John H. Raubitschek & Norman J. Latker, *Reasonable pricing – A New Twist for March-In Rights under the Bayh-Dole Act*, 22 SANTA CLARA COMPUTER & HIGH TECH. L.J. 149, 157-160 (2005).

licenses would not have been sufficient to prevent [certain] abuses.”¹⁶⁸ Compulsory licensing is a necessary prerequisite because “[no] proceedings for the forfeiture or revocation of a patent may be instituted before the expiration of two years from the grant of the first compulsory license.”¹⁶⁹ Under the TRIPS and NAFTA agreements patent breaking would be even more difficult to justify, given the necessity that “the scope and duration of [government sanctioned] use shall be limited to the purpose for which it was authorized.”¹⁷⁰ Given the relatively short duration of many disasters, permanent revocation of patent rights would appear to be a disproportionate response by a government. Patent breaking is a very rare occurrence, and has not been employed by the U.S. government in modern times.

1. Anthrax and Cipro®

On September 18, 2001, exactly a week after the 9/11 terrorist attacks, letters contaminated with anthrax entered the U.S. postal system, resulting in a number of deaths.¹⁷¹ Bayer AG, a pharmaceutical company, had a patent covering ciprofloxacin, or Cipro®, an antibiotic used to treat anthrax infections, but could not produce enough of the drug to keep up with the sudden spike in demand.¹⁷² In response, U.S. Senator Charles Schumer of New York urged the federal government to purchase Cipro® from generic drug manufacturers to achieve cost savings and promote enhanced manufacturing capacity.¹⁷³ Senator Schumer’s suggestion would have overridden Bayer’s patent rights. The Canadian government did precisely what Senator Schumer had suggested, and allowed other pharmaceutical companies to produce Cipro® in violation of Bayer’s Canadian patent.

Tommy Thompson, Secretary of Health and Human Services, initially opposed Senator Schumer’s request, in part because he doubted that the government had the right to disregard patent rights.¹⁷⁴ However, after the Canadian government decided to allow other

¹⁶⁸ Paris Convention, *supra* note 73, art. 5(A)(3).

¹⁶⁹ *Id.*

¹⁷⁰ TRIPS, *supra* note 74, art. 31(c); NAFTA, *supra* note 75, art. 1709(10)(c).

¹⁷¹ FBI—Post-9/11 Anthrax Summary, *at* <http://www.fbi.gov/anthrax/amerithraxlinks.htm> (last visited Jan. 13, 2007).

¹⁷² Anthony York, *Is it Time to Bust the Cipro Patent?*, SALON, Oct. 18, 2001, http://archive.salon.com/tech/feature/2001/10/18/cipro_patent/index.html (last visited Jan. 13, 2007).

¹⁷³ *Id.*

¹⁷⁴ *Id.*

pharmaceutical companies to produce Cipro® in violation of Bayer's Canadian patent, Secretary Thompson changed his tactics:

Thursday morning, October 18, Thompson quickly forgot about legal technicalities when Canada jumped into the Cipro fray. The Canadian minister of health signed a contract with a generic manufacturer to make extra ciprofloxacin, expressing concerns about the sufficiency of Canada's stockpile. The next morning, Thompson started publicly bullying Bayer on price, threatening to get the law changed so he could ignore the company's patent.

In the end, it was unnecessary for Secretary Thompson to "ignore the company's patent" because Bayer agreed to lower its price and increase manufacturing capacity for Cipro® considerably.¹⁷⁵

A similar debate over patented medicines ensued in 2005 and 2006 in response to fears of a global bird flu epidemic, with the administration of George W. Bush threatening to break the U.S. patent covering Tamiflu®.¹⁷⁶ However, to date the patent licensed to Roche remains intact.

2. AIDS and Kaletra®

Brazil has used the threat of breaking patents to force Abbott Laboratories, a drug company, to lower the price it charges for a combination of anti-retroviral drugs used to treat patients infected with HIV.¹⁷⁷ Brazil, a developing country with limited financial resources and an epidemic of AIDS, has a comprehensive AIDS treatment program that has become a model around the developing world.¹⁷⁸ In

¹⁷⁵ Matt Fleischer-Black, *The Cipro Dilemma--In the Anthrax Crisis, Tommy Thompson Distorted Patent Law to Save Public Health. Good Move?*, AM. LAW., January, 2002, at <http://www.cptech.org/ip/health/cl/cipro/americanlawyer012002.html> (last visited Jan. 13, 2007).

¹⁷⁶ Sebastian Mallaby, *A Double Dose of Failure*, WASH. POST, Nov. 7, 2005, <http://www.washingtonpost.com/wp-dyn/content/article/2005/11/06/AR2005110601013.html> (last visited Jan. 13, 2007).

¹⁷⁷ Mary Ann Liebert, *Brazil, Abbott Reach Tentative Deal on Kaletra*, 24 BIOTECHNOLOGY L. REPORT 583, 583-584 (2005).

¹⁷⁸ Ubirajara R.Q. Marques, Valeska S. Guimaraes, and Caitlin Sternberg, *Brazil's AIDS Controversy: Antiretroviral Drugs, Breaking Patents, and Compulsory Licensing*, 60 FOOD & DRUG L.J. 471, 471 (2005) [hereinafter "Brazil's AIDS Controversy"].

2005, the Brazilian legislature passed legislation allowing the Brazilian government to break patents on antiretroviral drugs.¹⁷⁹ The government of Brazil had previously threatened to break such patents unless prices of such drugs were significantly reduced.¹⁸⁰ Under threat of losing its patent rights in Brazil, Abbott Laboratories agreed to a price reduction of \$250 million over six years for Kaletra®, its combination antiretroviral drug.¹⁸¹ The head of the World Health Organization, Jim Kim, had these words of support for Brazil: "The Brazilian government is perfectly within its rights to suspend the patent of Kaletra . . . so as to develop it at more accessible prices."¹⁸²

In the end, no patent breaking actually occurred. Indeed, the mere threat of patent breaking by the Brazilian government appears to have been sufficient to convince Abbott Laboratories to compromise. It has even been proposed that Brazil initiated discussion of patent breaking with the intention of extracting a more favorable price for Kaletra®.¹⁸³

Similar disputes have arisen in South Africa and other African countries over patented antiretroviral drugs, with similar results: significantly reduced drug prices with no actual patent breaking.¹⁸⁴ Thailand is notable for having carried through on its threats to break drug patents; there the military junta that ceased power in 2006 did break several drug patents, including those covering Kaletra® and several other medicines.¹⁸⁵

G. Sovereign Immunity

1. Federal Sovereign Immunity

¹⁷⁹ Liebert, *supra* note 177, at 583.

¹⁸⁰ *Brazil's AIDS Controversy*, *supra* note 178, at 474.

¹⁸¹ Liebert, *supra* note 177, at 583.

¹⁸² Philip Thornton, *Abbott Laboratories Faced with Anti-Aids Drug Dilemma*, INDEPENDENT, July 4, 2005, at 52.

¹⁸³ Jonathan Todres, Pamela L. Marcogliese, and Laurel R. Hyle, *International Legal Development in Review: 2005 – Public International Law – International Health Law*, 40 INT'L LAW. 453, 459 (2005).

¹⁸⁴ See, e.g., Gumisai Mutume, *Health and Intellectual Property, Poor Nations and Drug Firms Tussle over WTO Patent Provisions*, at <http://www.un.org/ecosocdev/geninfo/afrec/vol15no1/151aids8.htm> (last visited Jan. 13, 2007).

¹⁸⁵ Financial Times, *Abbott pulls HIV drug in Thai patents protest*

By Amy Kazmin in Bangkok and Andrew Jack in London, Financial Times

Published: Mar 14, 2007

Under the doctrine of sovereign immunity, the federal government possesses the constitutional authority to infringe U.S. patents without the usual penalties.¹⁸⁶ Furthermore, the federal government can authorize others to do the same.¹⁸⁷ However, by federal statute patent owners can seek some redress for infringement of a patented invention by the federal government or those it has authorized. Under 28 U.S.C. §1498(a)

Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture.

For the purposes of this section, the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government, shall be construed as use or manufacture for the United States.

Thus, the United States possesses very broad discretion about when and how to manufacture or use, or authorize to manufacture or use, patented inventions.

The federal government in general, federal agencies in specific, and any nongovernmental personnel or entities authorized by the federal government, can manufacture or make use of any patented inventions. Although the owner of any patented invention manufactured or used in this manner can sue in the United States Court of Federal Claims to recover "reasonable and entire compensation for such use and manufacture," neither injunctive relief, willful damages, nor attorney fees are available. It is fortunate for patent owners that Congress allows patent owners to seek some compensation from the United States under 28 U.S.C. §1498; otherwise, patent owners have few alternative legal avenues to pursue compensation from the federal

¹⁸⁶ *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 842 F.2d 1275, 1282-83 (Fed. Cir. 1988).

¹⁸⁷ 28 U.S.C. §1498(a).

government. As the Court of Appeals for the Federal Circuit has observed, “The government has graciously consented, in [28 U.S.C. §1498], to be sued in the Claims Court for reasonable and entire compensation, for what would be infringement if by a private person.”¹⁸⁸

2. State Sovereign Immunity

The sovereign immunity of states is less forgiving to patent owners than federal sovereign immunity. Congress attempted to remove from states their immunity to patent infringement suits by patent owners by amending the patent statute to add 35 U.S.C. §271(h). The amendment stipulated that “Any State, and any...instrumentality, officer, or employee [of the State] shall be subject to the provisions of [the patent statute] in the same manner and to the same extent as any nongovernmental entity.”¹⁸⁹

The Court of Appeals for the Federal Circuit upheld the constitutionality of 35 U.S.C. §271(h) in authorizing a patent owner to bring suit against a state for infringing a patented invention.¹⁹⁰ However, the United States Supreme Court disagreed, instead finding that 35 U.S.C. §271(h) violated the Eleventh Amendment.¹⁹¹ Thus, states do retain some sovereign immunity against suits alleging patent infringement.

Under the protection of the sovereign immunity conferred by the Eleventh Amendment, a state may be permitted to engage in activities that, but for sovereign immunity, would constitute patent infringement. The sovereign immunity of state governments extends to their instrumentalities and employees. In the face of such infringement, patent owners currently have little effective recourse.

IV. ENHANCING PATENT RIGHTS

¹⁸⁸ *Id.*

¹⁸⁹ 35 U.S.C. § 271(h).

¹⁹⁰ *College Savings Bank v. Florida Prepaid Postsecondary Ed. Expense Bd.*, 148 F.3d 1343, 1355 (Fed. Cir. 1998).

¹⁹¹ *Florida Prepaid Postsecondary Ed. Expense Bd. v. College Savings Bank*, 527 U.S. 627, 647 (1999). “The Eleventh Amendment states that “The Judicial power of the United States shall not be construed to extend to any suit in law or equity, commenced or prosecuted against one of the United States by Citizens of another State, or by Citizens or Subjects of any Foreign State” *Id.*

The patent system provides an economic incentive that promotes innovation. One strategy for increasing the technological capacity of society to face disasters would be to increase the strength of patent incentives, thus promoting even greater innovation. There is economic evidence that, as investments in technological innovation increase, economic growth increases without a declining return on investment.¹⁹² Similarly, economic welfare appears to continue increasing indefinitely alongside technological innovation.¹⁹³ Enhanced patent incentives could be employed to increase both the general and specific technological capacity of society.

A. International Law and Enhancing Patent Rights

The Paris Convention, TRIPS, and NAFTA mandate that all member nations maintain at least a minimum level of patent protection. Both TRIPS Article 27(1) and NAFTA Article 1709(1) require member nations to allow patents “for any inventions, whether products or processes, in all fields of technology” except for the specific categories of subject matter specified in TRIPS Article 27(2) and (3) and NAFTA Article 1709(2) and (3). TRIPS Article 33 sets a minimum patent term of twenty years from a patent’s filing date, while NAFTA Article 1709(12) sets the minimum patent term at either twenty years from a patent’s filing date or seventeen years from a patent’s date of grant. NAFTA Article 1709(12) also allows a member nation to “extend the term of patent protection, in appropriate cases, to compensate for delays caused by regulatory approval processes.”¹⁹⁴ Under all three international agreements, member nations are free to offer greater levels of protection for patents than the mandatory minimum levels.

B. Patent Term Extension

Obtaining a patent can be a lengthy undertaking.¹⁹⁵ When the USPTO causes an unreasonable amount of delay in granting a patent, a patent applicant can apply to have the term of a patent extended to

¹⁹² See Paul M. Romer, *Increasing Return and Long-Run Growth*, 94 J. POL. ECON. 1002 (1986) (discussing the economic evidence).

¹⁹³ See, e.g., FTC REPORT, *supra* note 67.

¹⁹⁴ NAFTA, *supra* note 75, art. 1709(12).

¹⁹⁵ PERFORMANCE AND ACCOUNTABILITY REPORT, *supra* note 48. However, the average pendency times estimated by the USPTO are likely underestimates. Osenga, *supra* note 48, at 129.

compensate for such delay.¹⁹⁶ Similarly, the term of a patent can be extended to compensate for regulatory approval by the Food and Drug Administration.¹⁹⁷

C. Wild-card Patenting

In the wake of the 9/11 terrorist attacks, U.S. Senators Joseph Lieberman and Orrin Hatch proposed a bill named "Bioshield II."¹⁹⁸ Alongside Bioshield II's aims of enhancing industry research into new vaccines and drugs useful against terrorist attacks, the bill included a very creative provision for "wildcard patenting."¹⁹⁹ Wildcard patenting would allow the owner of a new invention certified by the federal government as useful against bioterrorism to extend the term of any other patent in the owner's portfolio of patents for up to two years.²⁰⁰ Such a scheme could provide a significant incentive for companies to invest research and development efforts in bioterrorism, because, by doing so, the companies could potentially extend the term of a lucrative patent and thereby reap a windfall of monopoly profits. As U.S. Representative Henry Waxman complained,

"In other words, if Pfizer developed and obtained approval of a countermeasure, it could obtain a two-year patent extension on Lipitor," he noted. "With U.S. sales of \$7.7 last year, a two-year patent extension on Lipitor would be worth over \$10 billion to Pfizer."²⁰¹

The Bioshield II bill has since been replaced by another bill that lacks provision for wildcard patenting.

¹⁹⁶ 35 U.S.C. § 154(a)-(c) (2000).

¹⁹⁷ 35 U.S.C. § 155 (2000).

¹⁹⁸ Ted Agres, *Cell Culture Breaks Some Eggs*, 9 DRUG DISCOVERY & DEV. 14, 14 (2006). Bioshield II was intended to be a complement to The Project BioShield Act of 2004, Public Law No. 108-276. The BioShield Act of 2004 provided funding and incentives for the development of new defenses against bioterrorism. See, e.g., Frank Rapoport, Christopher C. Bouquet, and Scott Flukinger, *Project BioShield Act of 2004: Dawn of a New Industry?*, 40 SPG PROCUREMENT L. 3, 3 (2005).

¹⁹⁹ Agres, *supra* note 197, at 14.

²⁰⁰ *Id.*

²⁰¹ Chain Drug Review, *Bioshield Legislation Would 'Increase Cost of Drugs'*, 27 CHAIN DRUG REV. 66, 66 (2005).

V. THE PATENT SYSTEM TO THE RESCUE IN DISASTERS

Many patented inventions can be of assistance in disasters. Patent law allows a diverse set of policy options through which the patent system can ensure that society has access to those patented inventions needed in disasters. Among these options are exceptions to infringement for certain specified actions, compulsory licensing, march-in rights, patent breaking, and sovereign immunity. However, in deciding among these options one must bear in mind not just the immediate benefits of having access to needed technology, but also the longer term prospective effects that particular options may have on developing new beneficial technology in the future. Unless the interests of society in dealing with disasters that occur in the near term are judiciously balanced with its interests in dealing with disasters in the future, society risks harming technological capacity tomorrow in favor of access to patented technology today.

Optimal policy options for harnessing the patent system will be different for foreseeable disasters than for surprise disasters. Most significantly, the options available to society for dealing with foreseeable disasters are many, while those available to deal with surprise disasters are fewer. Furthermore, what constitutes a reasonable use of the patent system in a surprise disaster may be unreasonable in response to a foreseeable disaster.

What follows is a modest proposal for how the patent system might best be used by society to deal with disasters, bearing in mind the need to ensure continued improvements in both general and specific technological capacity, the existing structure of international and U.S. patent law, the divergent considerations of the near and far terms, and the salient differences in approach required by foreseeable and surprise disasters.

A. Disaster Method Patenting

In 1998, the Court of Appeals for the Federal Circuit formally endorsed methods of doing business as patentable subject matter.²⁰² Business method patents can range from a system for implementing an investment strategy to an arrangement of furniture, art, and magazines in a physician's waiting room. The main limits on what business

²⁰² *State Street Bank & Trust Co. v. Signature Fin. Group, Inc.*, 149 F.3d 1368, 1376 (Fed. Cir. 1998).

methods can potentially be patented are those imposed by human creativity. Since 1998 there has been a flood of patent applications claiming business methods.²⁰³

Although business methods may not always be highly technological in nature, they possess the potential to be particularly useful in dealing with disasters. Furthermore, this category of patents does not necessarily have to be related to business *per se*. As the experience of Hurricane Katrina demonstrated, new and useful methods of efficiently and effectively evacuating populations from areas affected by disasters have the potential to save many human lives. Inventions such as evacuation methods might be termed “disaster method patents.” Like business method patents, as long as a disaster method invention satisfies all of the statutory requirements of patent law, it should be patentable.

A challenge to promoting the invention of new disaster methods involves the economic rewards expected by inventors. A disaster method would be most useful, and employed most often, during a disaster, a time when the prospect of patent enforcement ebbs especially low. Nevertheless, patent owners could still seek compensation for infringement, compulsory licensing, or invocation of federal sovereign immunity involving disaster method patents, just as they could for other types of patents.

B. Enhancing Patent Rights for Disaster Technology

1. Patent Term Extension

Patent term extension is relevant to disasters in two respects. Patent term extension could be extended by the federal government to patented inventions that are particularly useful in disasters. With the prospect of even longer periods during which they can exclude others and receive monopoly profits for their inventions, inventors will tend to increase their inventive efforts on innovative solutions to problems caused by disasters. The result will tend to be more inventions useful in disasters. Such an enhanced incentive to invent would be most

²⁰³ See, e.g., Robert P. Merges, *As Many as Six Possible Patents before Breakfast: Property Rights for Business Concepts and Patent System Reform*, 14 BERKELEY TECH. L.J. 577 (1999).

useful in the case of foreseeable disasters. On the other hand, if patent rights are weakened or abrogated during a disaster, the temporary loss of the right to exclude others could be compensated, at least in part, by extending the term of the weakened patent commensurate with the period of weakened rights.

2. Wild-Card Patenting

A wildcard patenting system, such as that proposed for BioShield II, could create a very strong incentive for companies to invent and develop new technologies useful in disasters. Companies with existing patent portfolios, and significant inventive capacities, would be particularly attracted to the possibility of wild-card patenting as a means of extending the terms of their most valuable patents. Given the potential windfall of securing a wild-card patent, the government would be well advised to institute a rigorous certification process to ensure that the technological innovations spurred by the wild-card incentive were commensurate with the economic value of extending patent terms. One approach might be for the Federal Emergency Management Agency (“FEMA”) to identify particular challenges caused by disasters, and for the USPTO to agree to award wild-card patents to inventors that successfully develop solutions to these challenges. This approach would be most effective in the case of foreseeable disasters.

C. Weakening Patent Rights in Disasters

1. Exceptions to Infringement

In disasters, 35 U.S.C. §287(c) would be extremely useful. It allows physicians, other medical staff, and medical facilities to be relatively unfettered in delivering medical services to patients in need of medical attention, instead of having to waste valuable time and effort ordering their medical or surgical conduct so as best to avoid the possibility of infringing patent rights. Relief from infringement removes disincentives against participation in disaster relief activities, thus

allowing vital participation in disaster response by medical personnel and institutions.

Amending this provision of the patent statute even further, to eliminate liability during emergencies for the activities enumerated in 35 U.S.C. §287(c)(2)(A)(i)-(iii) would allow medical personnel and institutions to be even more useful in disasters, as it would make a broader array of materials, drugs, and equipment available to treat those harmed in disasters.

In addition, 35 U.S.C. §287(c) could serve as a model for new legislation to create a similar exception to infringement for necessary relief activities carried out by any emergency personnel and institutions during disasters. Such an exception to infringement would facilitate the delivery of disaster assistance even when that assistance involves otherwise infringing patented methods. Although such an amendment to the patent statute could certainly prospectively weaken incentives to create inventions useful in disasters, narrow tailoring to cover only FEMA-certified emergencies and emergency personnel could help minimize harm to patent rights, especially those relating to inventions also useful in contexts other than disasters.

2. Weakening Patent Rights in Foreseeable Disasters

Foreseeable disasters allow society the best opportunity to plan well for the arrival of specific types of disasters. Along with policies that enhance general technological capacity, knowledge about the approaching disaster allows society to deploy policy options aimed at enhancing technological capacity that is specifically relevant to that disaster. To enhance specific capacity, inventors could be offered the prospect of extended patent terms, wild-card patents, or even expedited examination within the USPTO for areas of technology likely to help society in an approaching disaster. The greater the advance warning and the amount of information known about what challenges a disaster will pose to health, safety, and property, the more effectively specific technological capacity can be enhanced ahead of the disaster.

Foreseeability gives society the opportunity to identify existing patented inventions of potential use in an approaching disaster. Rather than wait until the disaster arrives, governments could negotiate with patent owners to acquire access to these inventions. If the patented invention in question is a good (for example, a composition, such as a drug, or a device, such as a water-purifier), the easiest approach might be for the government to purchase a sufficient stockpile of the good to

be deployed in a disaster when needed. Under the doctrine of “first sale,” or “patent exhaustion,” after purchasing a patented good the purchaser of that good requires no further permission from the patent owner to use that good; the right to exclude others is exhausted by the sale.²⁰⁴ On the other hand, if the patented invention in question is a method, stockpiling will not be possible. Instead, the government could negotiate ahead of time for a voluntary license to use the method. Since the price of a license tends to vary with the breadth of the rights it includes, the most cost-effective license might include a narrow field of use restricted only to disasters.

The government could choose to avail itself of the more extreme policy options of exclusions to infringement, compulsory licensing, march-in rights, patent breaking, or invocation of sovereign immunity. However, such extreme measures would tend to harm the prospective incentives for engaging in inventive activity. Even worse, rational inventors would tend to avoid inventive activity likely to result in inventions useful in disasters. The result would be an erosion of future general and specific technological capacity.

Avoidance of extreme measures in favor of voluntary measures, respect for patent rights, and good planning ahead of foreseeable disasters could best balance access to patented inventions needed in disasters with the preservation of prospective incentives to create, which, in turn, would enhance both general and specific technological capacity. Unless the constraints of the political process precluded it, this approach could best balance the interests of the government, inventors, patent owners, and those affected by disasters.

3. Weakening Patent Rights in Surprise Disasters

Surprise disasters are extreme events that may require extreme responses. By their very nature, surprise disasters cannot be prepared for in any specific way. The best preparation society can make with respect to the patent system is to ensure that it provides sufficient incentives to enhance general technological capacity. Increasing general technological capacity raises the probability that at least some innovations will prove useful in disasters, even if it is difficult to predict which particular innovations these will be. Negotiating voluntary licensing agreements with patent owners or stockpiling

²⁰⁴ See, e.g., *Jazz Photo Corp. v. Int'l. Trade Comm'n.*, 264 F.3d 1094, 1109-1111 (Fed. Cir. 2001).

patented goods will tend to be inefficient given the lack of advance information about which particular technology should be licensed or purchased.

Consequently, in surprise disasters it may be reasonable for governments to make use of more extreme policy options, such as exclusions from infringement, compulsory licensing, march-in rights, or sovereign immunity. However, it would be advisable for governments to exercise these options in as prudent a manner as possible so as to comply with obligations imposed by international treaties and U.S. patent law, as well as to minimize prospective damage to the patent system. To accomplish this, governments could borrow and adapt some provisions and principles of existing international and U.S. patent law.

To facilitate the rapid and efficient implementation of compulsory licenses to patented inventions needed in surprise disasters, Congress could authorize a compulsory licensing system for patents covering such inventions. As a model, Congress could use the statutory compulsory licensing frameworks already implemented for air pollution technology²⁰⁵ and nuclear technology.²⁰⁶ However, given the urgency created by surprise disasters, the new statute would work best if the process of obtaining compulsory licenses was more streamlined than the existing statutory schemes for licensing air pollution technology and nuclear technology.

As a threshold step, the head of FEMA could be mandated to certify which particular patented inventions were necessary for dealing with particular surprise disasters. Once certified, FEMA could provide notice of such certification to affected patent owners, and request a voluntary license for whatever field of use and period of time was required. Given the need for rapid response, the patent owner would have to conclude voluntary negotiations very rapidly, though precise deadlines would vary with the circumstances of particular disasters. In the case of a patent owner unwilling to agree to voluntarily license the needed patented invention by the appointed deadline, FEMA should have statutory authority to take for itself, or grant to a third party under its authorization, a compulsory license to make, use, or import the patented invention.

Any compulsory license should comport with principles of international patent law. The scope and duration of use "shall be

²⁰⁵ 42 U.S.C. § 7608.

²⁰⁶ 42 U.S.C. § 2183(c).

limited to the purpose for which it was authorized.”²⁰⁷ Any compulsory license must be nonexclusive and essentially nontransferable.²⁰⁸ Authorization would extend “predominantly for the supply of the domestic market” of the United States.²⁰⁹ And, authorization would only last until “the circumstances which led to it cease to exist and are unlikely to recur.”²¹⁰ Once the compulsory license was granted, FEMA could then proceed to practice the needed invention to deal with the surprise disaster.

To minimize harm to the prospective incentive to invent, FEMA should establish a “Patent Compensation Board” similar to that established by 42 U.S.C. §2187 for nuclear energy inventions. The patent owner of the compulsorily licensed invention could apply to the Patent Compensation Board for compensation. At the very least a patent owner should be compensated with a reasonable royalty. However, this level of compensation would generally be inadequate to compensate for the loss of the core of the patent grant: the right to exclude others. To minimize prospective harm to the patent system, the patent owner should also be compensated for the loss of this important right. Consequently, to make the patent owner whole, the total amount of damages due to any patent owner should be “reasonable and entire compensation,”²¹¹ including a reasonable royalty, additional compensation to reflect the loss of the right to exclude others, costs, and attorney fees.²¹²

Since any compulsory license should not extend much longer than the duration of the surprise disaster and its aftermath, even this level of full compensation would tend not to be an unreasonable burden on government resources, especially when compared with other costs associated with the disaster. Furthermore, full compensation would accomplish two vital goals: it would make whole any individual patent owners with inventions subjected to compulsory licenses; and, it would preserve the prospective incentive to invent created by the availability of patent rights by signaling to potential inventors that, even if patented inventions useful in disasters were ever compulsorily licensed, such incursions on their patent rights would be fully compensated. Patent

²⁰⁷ TRIPS, *supra* note 74, art. 31(c); NAFTA, *supra* note 75, art. 1709(10)(c).

²⁰⁸ Paris Convention, *supra* note 73, art. 5(A)(4); TRIPS, *supra* note 74, arts. 31(d) and 31(e); NAFTA, *supra* note 75, arts. 1709(10)(d) and 1709(10)(f).

²⁰⁹ TRIPS, *supra* note 74, art. 31(f); NAFTA, *supra* note 75, art. 1709(10)(f).

²¹⁰ TRIPS, *supra* note 74, art. 31(g); NAFTA, *supra* note 75, art. 1709(10)(g).

²¹¹ *Cf.* Garlock, Inc., 842 F.2d at 1283 (discussing the total amount of damages).

²¹² 42 U.S.C. § 2187.

owners whose inventions were compulsorily licensed could be authorized to pursue their claims for compensation not only to the administrative Patent Compensation Board, but also in a federal district court in the district most convenient to them.²¹³

One caveat to the process outlined above involves very young patents. Under the Paris Convention, absent a finding of “abuse” other than “failure to work or insufficient working,” compulsory licenses can be granted only after a “period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last.”²¹⁴ Considered in isolation, forcing a compulsory license on very young patents in the face of these restrictions would appear to violate the Paris Convention. However, the provisions of the later NAFTA and TRIPS mollified the obligation to negotiate with the patent owner “in the case of a national emergency or other circumstances of extreme urgency or in cases of public noncommercial use.”²¹⁵ Furthermore, the Doha Declaration, which constitutes an official interpretation of TRIPS, stated that “[each] member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.”²¹⁶ Viewed in the context of later international patent treaties, the provisions of the Paris Convention regarding compulsory licenses to very young patents may not constitute a significant barrier in disasters.

Even in surprise disasters, the need to engage in breaking patents would seldom arise because well regulated compulsory licensing could accomplish sufficient access to patented inventions needed in disasters. Unless compulsory licensing were indeed insufficient, patent breaking could violate both NAFTA and TRIPS, which both state that “the scope and duration of [government sanctioned] use shall be limited to the purpose for which it was authorized.”²¹⁷ Even if patent breaking were employed as a means to gain access to a patented invention, compensation would probably still have to be paid to patent owners, and this compensation might have to be in a greater amount than for compulsory licensing, given the greater magnitude of damage done by breaking, rather than merely licensing, a patent. Patent breaking would also be more harmful than compulsory

²¹³ *Id.*

²¹⁴ Paris Convention, *supra* note 73, art. 5(A)(4).

²¹⁵ TRIPS, *supra* note 74, art. 31(b); NAFTA, *supra* note 75, art. 1709(b).

²¹⁶ Doha Declaration, *supra* note 108, ¶ 5(b).

²¹⁷ TRIPS, *supra* note 74, art. 31(c); NAFTA, *supra* note 75, art. 1709(c).

licensing to prospective patent incentives to invent, thus harming future general and specific technological capacity.

Neither would sovereign immunity, invoked by either the state or federal government, tend to provide significant additional benefits compared to a rapid, flexible, and measured compulsory licensing regime. In the case of federal sovereign immunity, “reasonable and entire compensation” would still be available to patent owners.²¹⁸ States could probably use sovereign immunity to avoid compensation for practicing patented inventions. However, interference with patent rights without compensation would do serious harm to the prospective patent incentive to invent, again harming both general and specific technological capacity in the future.

On balance, the best policy option for gaining access to need patented inventions in disasters would be a reasonable system of compulsory licensing, relying on government certification, narrow time and field of use limits, and reliable procedures for ensuring full compensation to patent owners for any loss to their patent rights. Such a system would best ensure both timely access to existing patented inventions needed in surprise disasters and preservation of prospective patent incentives to support a strong and productive patent system capable of delivering significant amounts of additional technological innovations useful in future disasters.

CONCLUSIONS

The patent system can play a vital role in preparing for, mitigating, reacting to, and preventing disasters. In the far term, it ensures that society continually improves its technological capacity to deal with disasters. In the near term, the patent system includes a diversity of legal options for ensuring access to patented inventions needed in disasters. Foreseeable and surprise disasters require different legal approaches to ensure timely access to patented inventions while ensuring that society is able to continue enhancing both its general and specific technological capacities. Accomplishing optimal results requires careful balancing of far term and near term interests, respect for both international and U.S. patent law, a clear understanding of the interrelation of different aspects of patent law, insight into the incentives that drive technological innovation, and appreciation of the disparate challenges posed by different kinds of disasters. When

²¹⁸ *Cf.* *Garlock, Inc.*, 842 F.2d at 1283.

employed wisely, the patent system can offer society powerful assistance to prevent, prepare for, and mitigate disasters.