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Innovation and Intellectual Property Issues in Homeland Security

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Summary

The U.S. government and private firms alike seek high technology solutions to detect and prevent future terrorist attacks, as well as to respond to any future attacks that do occur. Some concerns exist, however, that patents, trade secrets or other intellectual rights may impede the prompt, widespread and cost-effective distribution of innovations that promote homeland security. In 2001, these concerns arose with respect to pharmaceutical CIPRO, an antibiotic that treats inhalation anthrax. Some commentators called for the U.S. government to "override" a privately owned patent in order to distribute CIPRO to persons who were potential anthrax victims. Although the patent holder ultimately chose to increase production of CIPRO and lower costs, this scenario remains a possibility for other technologies that bear upon homeland security.

Perhaps not fully appreciated during the CIPRO incident was the fact that existing laws provide mechanisms for addressing potential conflicts between intellectual property rights and homeland security needs. The principal statute concerning U.S. government use of intellectual property is 28 U.S.C. § 1498. This statute allows the federal government to exercise eminent domain authority against private intellectual property rights. As a result, the federal government may use patented inventions without the prior consent of the patent owner, subject to an obligation to compensate the rights holder on a monetary basis. The federal government may not be enjoined from infringement of an intellectual property right. Intellectual property owners may enforce this government compensation obligation by bringing suit in the U.S. Court of Federal Claims.

A number of more specialized statutes, such as the Atomic Energy Act, also allow federal government officials to declare a compulsory license with respect to a particular patent. Reportedly these provisions have been used infrequently. Legislative initiatives have proposed that U.S. law provide for other kinds of compulsory licenses, including a compulsory license that the government could invoke during a public health emergency. Existing legislation and proposed reforms should be evaluated in view of the Agreement on Trade-Related Aspects of Intellectual Property Rights. This "TRIPS Agreement" places some limits on the ability of WTO member states to award compulsory licenses for the use of a private person's patented invention.

If an invention was developed using federal government funding, the government may possess certain rights in that invention even though the government contractor obtained a patent. Many entities of the federal government enjoy the statutory authority to purchase a patent or other intellectual property right.

Several other statutes and legislative proposals also concern issues at the intersection of homeland security and intellectual property. The Invention Secrecy Act controls the disclosure of inventions that raise national security concerns. Legislative proposals would also call for patent term extensions to award technological progress in anti-terrorism technologies.

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Innovation and Intellectual Property Issues in Homeland Security

Terrorist attacks on the World Trade Center and the Pentagon on September 11, 2001, resulted in significant endeavors to combat terrorism and ensure homeland security. Among other efforts, the U.S. government and private firms are seeking high technology solutions to detect and prevent such attacks, as well as to respond to any future attacks that do occur.[1] Biometrics, digital surveillance and vaccines are among the anti-terrorism technologies subject to current research.[2]

The intellectual property laws have a role to play in the research and development of anti-terrorism technologies. The patent system has long been viewed as a promoter of technological development, including inventions that may aid homeland security efforts.[3] On the other hand, some commentators have expressed concern that the existence of intellectual property rights may impede homeland security needs.[4] One possibility is that an individual or firm might own a patent that covers an anti-terrorism technology. In such circumstances, the exclusive patent right may be perceived as conflicting with the rapid and widespread deployment of that technology for purposes of homeland security.[5] Intellectual property rights might also increase the market price of the patented technology and limit the ability of others to further develop it.[6] If the patent is owned by a foreign individual or enterprise, then additional security complications may potentially arise.

U.S. government demand for the antibiotic Cipro in late 2001 provides a past example of this potential conflict. In October 2001, an unknown person or persons sent a refined form of the bacteria Bacillus anthracis, commonly known as anthrax,

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[1] See CRS Report RL31914, *Research and Development in the Department of Homeland Security*, by Daniel Morgan.

[2] CRS Report RL31669, *Terrorism: Background on Chemical, Biological, and Toxin Weapons and Options for Lessening Their Impact*, by Dana A. Shea; Shane Ham & Robert D. Atkinson, *Using Technology to Detect and Prevent Terrorism*, Progressive Policy Institute Policy Brief (Jan. 2002).

[3] Roger E. Schechter & John R. Thomas, *Intellectual Property: The Law of Copyrights, Patents and Trademarks* (Thomson-West Group, St. Paul, Minnesota 2003).

[4] See Matt Fleischer-Black, "The Cipro Dilemma,"34 *The American Lawyer* no. 1 (Jan. 2002), 53.

[5] See CRS Report RS21367, *Emergency Preparedness and Response Directorate of the Department of Homeland Security*, by Keith Bea.

[6] See Grace K. Avedissian, "Global Implications of a Potential U.S. Policy Shift Towards Compulsory Licensing of Medical Inventions in a New Era of 'Super-Terrorism'," 18 *American University International Law Review* (2002), 237.

through the U.S. mail to members of Congress and members of the media.[7] The U.S. government responded by administering treatment of a pharmaceutical compound known as "ciprofloxacin hydrochloride" to affected individuals.[8] Ciprofloxacin is sold under the trademark Cipro by the German firm Bayer AG.[9] Although widely prescribed for several medical indications, Cipro was at that time the only antibiotic approved by the U.S. Food and Drug Administration (FDA) for inhalation anthrax.[10]

As the incident proceeded, attention focused on the availability of large quantities of ciprofloxacin hydrochloride for public use. Some observers noted that Bayer owned the pertinent U.S. patents on ciprofloxacin hydrochloride and therefore possessed the ability to exclude other pharmaceutical companies from selling generic versions of the drug in the United States.[11] Additional commentators encouraged the U.S. government to purchase ciprofloxacin hydrochloride from generic manufacturers, who had been producing and selling the drug in foreign countries where Bayer did not possess patent rights.[12] These commentators observed that generic versions of ciprofloxacin hydrochloride were available for much lower prices than Bayer was charging in the United States.[13] Others went even further, calling for the U.S. government to "override" Bayer's patent and purchase ciprofloxacin hydrochloride from other suppliers.[14]

Subsequent events ultimately diffused public concern over the availability of Cipro. Bayer agreed to reduce the prices it charged the U.S. government and to increase production.[15] Also, the FDA quickly approved alternative antibiotics for the treatment of certain strains of anthrax, including the one used in the attacks.[16]

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[7] See Stephen Engelberg & Judith Miller, "Sign of Escalating Threat," *New York Times* (Oct. 17, 2001), A1.

[8] Kathleen Pender, "Cipro Had Big Boost From U.S.," *San Francisco Chronicle* (Oct. 25, 2001), D1.

[9] *Ibid.*

[10] See U.S. Food and Drug Administration, Approval Letter (Aug. 30, 2000) (available at [http://www.fda.gov/cder/foi/nda/2000/19-537S038_Cipro_approv.pdf]).

[11] See, e.g., U.S. Patent No. 4,670,444.

[12] See Letter from Ralph Nader and James Love to Department of Health & Human Services Secretary Tommy Thompson (Oct. 18, 2001) (available at [http://www.cptech.org/ip/health/cl/cipro/nadethom10182001.html]).

[13] *Ibid*.

[14] See Press Release from U.S. Senator Charles E. Schumer, "Schumer: New Cipro Source Could Dramatically Increase Supply," available at [http://www.senate.gov/schumer/state-101601_cipro.htm] (Oct. 16, 2001).

[15] Keith Bradsher, "Bayer Agrees to Charge Government a Lower Price for Anthrax Medicine," *New York Times* (Oct. 25, 2001), B8.

[16] See U.S. Food and Drug Administration, Cipro (Ciprofloxacin Hydrochloride) for Inhalation Anthrax: Information on Cipro for Consumers: Questions and Answers (Nov. 14, 2001) (available at [http://www.fda.gov/cder/drug/infopage/cipro/cipro_faq.htm]).

Nonetheless, this scenario remains a possibility for other technologies that bear upon homeland security.

Perhaps not fully appreciated during the Cipro incident was the fact that existing laws provide mechanisms for addressing potential conflicts between intellectual property rights and homeland security needs.[17] These mechanisms include a government taking of the intellectual property, subject to reasonable compensation owed to the patent owner, as well as government purchase of patents. Legislation introduced in the 107th Congress would have called for the award of a compulsory patent license in the event of a public health emergency. Other current or proposed legislation also relates to the intersection between intellectual property and homeland security, including the Invention Secrecy Act and a proposed patent extension for firms that develop anti-terrorism technologies. This report addresses each of these issues in turn.

Fundamentals of Intellectual Property

The term "intellectual property" identifies a number of legal instruments, including copyrights, patents and trade secrets, that provide innovators with proprietary interests in their intangible creations.[18] Copyright provides authors with exclusive rights in their writings, visual works and other works of authorship; patents relate to products, processes and other useful inventions; while trade secret law concerns secret information that is of commercial value.[19] Discussion concerning the intersection of homeland security issues and the intellectual property law has principally concerned patents. As a result, this report will focus upon the patent law, although its broader discussion of the relationship between homeland security and intellectual property is applicable to trade secrets, copyrights and other similar proprietary interests.

Patent Policy

By providing individuals with exclusive rights to their inventive products and processes, the patent law allows innovators to secure the economic benefits of their discoveries. Absent a patent system, competitors might readily be able to appropriate the benefits of an innovator's research and development efforts. Aware of these potential "free riders," firms might devote few, if any resources towards innovation. The patent law solves this market failure problem by providing economic incentives for individuals and institutions to engage in research and development.[20]

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[17] See Fleischer-Black, *supra* note 4.

[18] Schechter & Thomas, *supra* note 3, at 1-2.

[19] Gordon U. Sanford, III, "An Intellectual Property Roadmap: The Business Lawyer's Role in the Realm of Intellectual Property," 19 *Mississippi College Law Review* (1998), 177.

[20] Simone Rose, "Patent 'Monopolyphobia': A Means of Extinguishing the Fountainhead?," 49 *Case Western Reserve Law Review* 509 (1999).

The patent system is also said to encourage the disclosure of new technologies.[21] Each issued patent must include a description sufficient to enable skilled artisans to practice the patented invention.[22] Issued patents may also encourage others to "invent around" the patentee's proprietary interest. Others can build upon the patentee's disclosure to produce their own technologies that fall outside the exclusive rights associated with the patent.[23]

Patent rights may also facilitate technology transfer.[24] Absent patent rights, an inventor may have no tangible asset to sell or license. In addition, an inventor might otherwise be unable to police the conduct of a contracting party. Any technology or know-how that has been disclosed to a prospective buyer might be appropriated without compensation to the inventor. The availability of patent protection decreases the ability of contracting parties to engage in opportunistic behavior. By lowering such transaction costs, the patent system may make technology-based transactions more feasible.[25]

The patent system may also provide a more socially desirable outcome than its chief legal alternative, trade secret protection. Trade secrecy guards against the improper appropriation of valuable, commercially useful information that is the subject of reasonable measures to preserve its secrecy.[26] Taking the steps necessary to maintain secrecy, such as implementing physical security measures, imposes costs that may ultimately be unproductive for society.[27] Also, while the patent law obliges inventors to disclose their inventions to the public,[28] trade secret protection requires firms to hold their protections in secret. The disclosure obligations of the patent system may better serve the goals of encouraging the diffusion of advanced technological knowledge.

The patent system has long been subject to criticism, however. Some observers believe that the patent system encourages industry concentration and presents a barrier to entry in some markets.[29] Others believe that the patent system too

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[21] Keith E. Maskus, "The Role of Intellectual Property Rights in Encouraging Foreign Direct Investment and Technology Transfer," 9 *Duke Journal of Comparative and International Law* (1998), 10.

[22] 35 U.S.C. § 112 (2006).

[23] Rebecca S. Eisenberg, "Patents and the Progress of Science: Exclusive Rights and Experimental Use," 56 *University of Chicago Law Review* (1989), 1017.

[24] Jonathan Eaton & Samuel J. Kortum, "Trade in Ideas: Patenting and Productivity in the OECD," 40 *Journal of International Economics* (1996), 251.

[25] Robert P. Merges, "Intellectual Property and the Costs of Commercial Exchange: A Review Essay," 93 *Michigan Law Review* (1995), 1570.

[26] American Law Institute, Restatement of Unfair Competition Third § 39 (1995).

[27] David D. Friedman *et al.*, "Some Economics of Trade Secret Law," 5 *Journal of Economic Perspectives* (1991), 61.

[28] 35 U.S.C. § 112 (2006).

[29] John R. Thomas, "Collusion and Collective Action in the Patent System: A Proposal for
(continued...)

frequently attracts speculators who prefer to acquire and enforce patents rather than engage in socially productive activity.[30] Still other commentators suggest that the patent system often converts pioneering inventors into technological suppressors, who use their patents to block subsequent improvements and thereby impede technical progress.[31]

When analyzing these contending views, it is important to note the lack of rigorous analytical methods available for analyzing the effect of the patent law upon the U.S. economy as a whole. The relationship between innovation and patent rights remains poorly understood. Concerned observers simply do not know what market impacts would result from changing the patent term from its current twenty-year period, for example.[32] Consequently, current economic and policy tools do not allow us to calibrate the patent system precisely in order to produce an optimal level of investment in innovation.

Patent Acquisition and Enforcement

Patent rights do not arise automatically. Inventors must prepare and submit applications to the U.S. Patent and Trademark Office ("USPTO") if they wish to obtain patent protection.[33] USPTO officials known as examiners then assess whether the application merits the award of a patent.[34]

In deciding whether to approve a patent application, a USPTO examiner will consider whether the submitted application fully discloses and distinctly claims the invention.[35] In addition, the application must disclose the "best mode," or preferred way, that the applicant knows to practice the invention.[36] The examiner will also determine whether the invention itself fulfills certain substantive standards set by the patent statute. To be patentable, an invention must be useful, novel and nonobvious. The requirement of usefulness, or utility, is satisfied if the invention is operable and provides a tangible benefit.[37] To be judged novel, the invention must not be fully anticipated by a prior patent, publication or other knowledge within the public

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[29] (...continued)
Patent Bounties," *University of Illinois Law Review* (2001), 305.

[30] *Ibid*.

[31] *See* Robert P. Merges & Richard R. Nelson, "On the Complex Economics of Patent Scope," 90 *Columbia Law Review* (1990), 839.

[32] See F. Scott Kieff, "Property Rights and Property Rules for Commercializing Inventions," 85 *Minnesota Law Review* (2001), 697.

[33] 35 U.S.C. § 111 (2006).

[34] 35 U.S.C. § 131 (2006).

[35] 35 U.S.C. § 112 (2006).

[36] *Ibid.*

[37] 35 U.S.C. § 101. (2006).

domain.[38] A nonobvious invention must not have been readily within the ordinary skills of a competent artisan at the time the invention was made.[39]

The USPTO publishes most pending patent applications approximately 18 months after they are filed.[40] For example, if an inventor filed a patent application on August 1, 2006, then the USPTO will make that application available to the public on or after February 1, 2008. Pre-grant publication of patent applications potentially alerts interested parties of the possibility that a patent might later be issued.[41] However, if the inventor has abandoned the application, or has certified that no patent applications on the same technology will be sought outside the United States, then the USPTO will not publish the pending application.[42]

If the USPTO allows the patent to be issued, the patent proprietor obtains the right to exclude others from making, using, selling, offering to sell or importing into the United States the patented invention.[43] The maximum term of patent protection is ordinarily set at 20 years from the date the application is filed.[44] The patent applicant gains no enforceable rights until such time as the application is approved for issuance as a granted patent, however. Once the patent expires, others may employ the patented invention without compensation to the patentee.

Patent rights do not enforce themselves. A patentee bears responsibility for monitoring its competitors to determine whether they are using the patented invention or not. Patent proprietors who wish to compel others to observe their intellectual property rights must usually commence litigation in the federal district courts. The U.S. Court of Appeals for the Federal Circuit ("Federal Circuit") possesses exclusive national jurisdiction over all patent appeals from the district courts.[45] In turn, the U.S. Supreme Court possesses discretionary authority to review cases decided by the Federal Circuit.[46]

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[38] 35 U.S.C. § 102 (2006).

[39] 35 U.S.C. § 103 (2006).

[40] 35 U.S.C. § 122(b) (2006).

[41] See Joseph M. Barich, "Pre-Issuance Publication of Pending Patent Applications: Not So Secret Any More," *Journal of Law, Technology and Policy* (Fall 2001), 415.

[42] 35 U.S.C. § 122(b) (2006).

[43] 35 U.S.C. § 271(a) (2006).

[44] 35 U.S.C. § 154(a)(2) (2006). Although patent term is based upon the filing date, the patentee gains no enforceable legal rights until the USPTO allows the application to issue as a granted patent. A number of Patent Act provisions may modify the basic 20-year term, considering examination delays at the USPTO and delays in obtaining marketing approval for the patented invention from other federal agencies.

[45] 28 U.S.C. § 1295(a)(1) (2006).

[46] 28 U.S.C. §1254(1) (2006).

Government Use of Privately Owned Intellectual Property

Episodes such as the Cipro incident have raised the possibility that intellectual property rights may clash with homeland security needs.[47] If a firm owns a patent that covers an anti-terrorism technology, the exclusive patent right may be perceived as impeding the rapid and widespread deployment of that technology for purposes of homeland security. Current laws provide several possibilities for addressing this conflict, however. One option is a U.S. government taking of the intellectual property, subject to reasonable compensation owed to the patent owner. Another is that the federal government purchase any applicable patents from their owners. Legislative proposals submitted before Congress have suggested additional mechanisms for resolving issues at the interface between homeland security and intellectual property.

Eminent Domain

The U.S. government possesses the power to take private property for public use. For example, the government may condemn a parcel of land in order to build a highway. This authority is ordinarily termed "eminent domain." This government right is not unlimited, however. In particular, in some circumstances the government must compensate the property owner for use of the property. [48]

These general principles are most frequently applied to real estate, but they generally apply to intellectual property as well.[49] As a result, the U.S. government effectively enjoys the ability to declare a "compulsory license" that allows it to use a patented invention without obtaining the permission of the patentee. In turn, the federal government has consented to suit by private patent owners in order to obtain compensation for government uses.[50] Section 1498(a) of Title 28 of the U.S. Code provides in part:

> 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 Claims Court for the recovery of his reasonable and entire compensation for such use and manufacture.

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[47] *See supra* notes 7-16 and accompanying text.

[48] U.S. Library of Congress, Congressional Research Service, *Takings Decisions of the U.S. Supreme Court: A Chronology*, by Robert Meltz, Report 97-122 A, 2 July 2002.

[49] Thomas F. Cotter, "Do Federal Uses of Intellectual Property Implicate the Fifth Amendment?," 50 *Florida Law Review* (1998), 529.

[50] See Lionel Marks Lavenue, "Patent Infringement Against the United States and Government Contractors Under 28 U.S.C. § 1498(a) in the United States Court of Federal Claims," 2 *Journal of Intellectual Property Law* (1995), 389.

The remaining paragraphs of § 1498 provide analogous provisions pertaining to other intellectual property rights, including copyright, plant variety protection certificates, and semiconductor mark works.[51]

Section 1498 potentially applies to the use of any patented invention by the federal government, not necessarily those directly related to homeland security. To the extent the U.S. government engages in such activities as filling abandoned mines[52] or constructing highways,[53] it may be subject to a suit under § 1498(a) if it uses a patented invention without authorization. Certainly a number of these cases have concerned uses by the military, however.[54] At least one § 1498 suit involved the federal government use of the patented pharmaceutical meprobamate, an anti-anxiety agent.[55]

Under § 1498(a), all patent suits against the U.S. government are litigated in the U.S. Court of Federal Claims. From 1855 through 1982, this tribunal was known as the U.S. Court of Claims, and from 1982-1992 it was named the U.S. Claims Court.[56] The Court of Federal Claims also possesses jurisdiction over a number of other causes of action against the U.S. government, including certain tax and government contract cases.[57] The President appoints sixteen judges to the Court of Federal Claims for fifteen-year terms.[58] The Court of Federal Claims has national jurisdiction, allowing the court to subpoena witnesses and documents anywhere in the United States or its possessions.[59]

Court proceedings against the government under § 1498(a) are conducted using the same general standards as does litigation between private parties. The patent owner represents itself, while the Attorney General and Department of Justice are responsible for representing the U.S. government in § 1498 cases.[60] Unlike private patent suits, however, there are no jury trials in § 1498 cases.[61] Appeals from the

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[51] 28 U.S.C. § 1498 (2006).

[52] Dow Chemical Co. v. United States, 226 F.3d 1334 (Fed. Cir. 2000).

[53] Levine v. United States, 76 F. Supp. 716 (Ct. Cl. 1948).

[54] E.g., Brunswick Corp. v. United States, 152 F.3d 946 (Fed. Cir. 1998) (camouflage screens designed to be draped over military hardware); McCreary v. United States, 114 F.3d 1206 (Fed. Cir. 1997) (patented hovercraft invention allegedly used in a U.S. Navy Amphibious Assault Landing Craft); Gargoyles, Inc. v. United States, 113 F.3d 1572 (Fed. Cir. 1997) (patented ballistic/laser protective eyewear alleged used by U.S. Army).

[55] See Carter-Wallace, Inc. v. United States, 496 F.2d 535 (Ct. Cl. 1974).

[56] Peter Verchinski, "Are District Courts Still a Viable Forum for Bid Protests?," 32 *Public Contract Law Journal* (2003), 393.

[57] 28 U.S.C. § 1346 (2006); 41 U.S.C. § 609 (2006).

[58] 28 U.S.C. § 171 (2006).

[59] 28 U.S.C. § 2521 (2006).

[60] 28 U.S.C. § 516 (2006).

[61] 28 U.S.C. § 2402 (2006).

United States Court of Claims proceed to the U.S. Court of Appeals for the Federal Circuit.[62]

As compared to remedies available in patent infringement suits against private parties, the remedies available in § 1498(a) suits are more limited. In private patent litigation, the adjudicated infringer is ordinarily enjoined from using the patented invention throughout the remaining term of the patent.[63] The adjudicated infringer may also have to compensate the patent owner for profits lost due to the infringement.[64] Additionally, if a court deems the defendant to have been a "willful infringer," the court may order the defendant to pay the patent owner up to three times the actual damages suffered.[65]

In contrast, § 1498(a) limits available remedies to "reasonable and entire compensation" to the patent owner. As a result, the government may not be enjoined from practicing a patented invention. The courts have also generally limited the damages that the government must pay to the patentee to the level of a "reasonable royalty."[66] A "reasonable royalty" for purposes of patent infringement damages is "the amount that a person desiring to manufacture or use a patented article, as a business proposition, would be willing to pay as a royalty and yet be able to make or use the patented article, in the market at a reasonable profit."[67] Finally, tripled damages for willful infringement are not available against the government.[68]

The number of § 1498 suits has been relatively modest over the years. One commentator reports that since 1949, the Court of Federal Claims and its predecessor courts have decided an average of 5.5 cases per year.[69] In the twelve-month period ending September 30, 2002, a total of 6 suits under § 1498(a) were filed in the Court of Federal Claims.[70] This number compares with a total of 2,520 patent infringement

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[62] 28 U.S.C. § 1295(a)(3) (2006).

[63] 28 U.S.C. § 283 (2006).

[64] *See Panduit Corp. v. Stahlin Bros. Fibre Works, Inc.*, 575 F.2d 1152 (6th Cir. 1978).

[65] 35 U.S.C. § 284 (2006).

[66] *See* Tektronix, Inc. v. United States, 552 F.2d 343 (Ct. Cl. 1977). Some more recent precedent has suggested that in some cases, the U.S. government may be obliged to pay the full lost profits of the patentee rather than a reasonable royalty. *See* Gargoyles, Inc. v. United States, 113 F.3d 1572 (Fed. Cir. 1997). However, reportedly the last instance that an award of lost profits was made for government use of a patented invention was in 1930. David M. Schlitz & Richard J. McGrath, "Patent Infringement Claims Against the United States Government," 9 *Federal Circuit Bar Journal* (2000), 351.

[67] Wright v. United States, 53 Fed. Cl. 466 (2002).

[68] DeGraffenried v. United States, 228 Ct. Cl. 780 (1981).

[69] Lavenue, *supra* note 50.

[70] Administrative Office of the U.S. Courts, Judicial Business of the United States Courts 2002, U.S. Court of Federal Claims — Cases Filed, Terminated and Pending for the 12-Month Period Ending September 30, 2002 (available at [http://www.uscourts.gov /judbus2002/appendices/g2asep02.pdf]).

suits filed against private defendants in the U.S. federal district courts during the same period.[71]

Government Contractors

Often the federal government purchases goods and services from private contractors. In the event that a private contractor infringes a patent while performing obligations under a federal government contract, § 1498 ordinarily applies. As a result, the patent proprietor's infringement remedy consists of an action in the Court of Federal Claims against the U.S. government. In such cases the private contractor may not be enjoined from infringing the patent while performing a government contract.

In the event the Court of Federal Claims decides that a patent infringement has occurred, ordinarily the U.S. government pays any resulting monetary judgment.[72] If the contract between the private contractor and federal government includes a so-called "patent indemnity" clause, however, the private contractor may have to reimburse the federal government for any damages owed for patent infringement. The Federal Acquisition Regulations (FAR) include a complex set of rules that require a patent indemnity clause for certain government contracts, prohibit it for others, and render the clause optional for still others. For example, the FAR requires that a government contract for any kind of performance that normally appears for sale on the open market include a patent indemnity clause.[73] However, government contracts for small purchases, or for performance that occurs outside the United States, may not contain a patent indemnity clause.[74]

Other Compulsory Licenses

As noted previously, 28 U.S.C. § 1498 provides a compulsory license in favor of the U.S. government for the use of patented inventions. A modest number of additional compulsory licenses exist within the U.S. patent system, each pertaining to specialized subject matter.[75] For example, the Atomic Energy Act allows for compulsory licenses "if the invention or discovery covered by the patent is of primary importance in the production or utilization of special nuclear material or atomic energy."[76] The Clean Air Act contains a similar provision relating to devices for

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[71] Administrative Office of the U.S. Courts, Judicial Business of the United States Courts 2002, U.S. District Courts — Civil Cases Commenced, by Basis of Jurisdiction and Nature of Suit, During the 12-Month Period Ending September 30, 2002 (available at [http://www.uscourts.gov/judbus2002/appendices/c02sep02.pdf]).

[72] Lavenue, *supra* note 50.

[73] 48 C.F.R. § 27.203-1(a).

[74] 48 C.F.R. § 27.203-1(b)(3), (4).

[75] *Dawson Chemical Co. v. Rohm and Haas Co.*, 448 U.S. 176 n.21 (1980).

[76] 42 U.S.C. § 2183 (2006).

reducing air pollution.[77] Finally, the Plant Variety Protection Act provides for the compulsory licensing of seed-bearing plants that are protected by plant variety certificates, a patent-like instrument granted by the Department of Agriculture.[78]

Legal research completed in connection with this report has failed to discover even a single instance where any of these compulsory licenses has actually been invoked. Plainly, none of these provisions has been frequently employed in the past.[79] Some commentators speculate that the threat of a compulsory license usually induces the grant of contractual licenses on reasonable terms. As a result, there is no need for the government to invoke a compulsory license formally.[80]

Legislation introduced in the 109th Congress would have created an additional compulsory license in the patent law. H.R. 4131, the Public Health Emergency Medicines Act, would have allowed the government to use the patented invention without the patent owner's permission if the Secretary of Health and Human Services determined that the invention is needed to address a public health emergency. Under the bill, the Secretary of Health and Human Services would have determined compensation for government use of the patented invention. The bill provided in part:

> In determining the reasonableness of remuneration for use of a patent, the Secretary of Health and Human Services may consider —
>
> (1) evidence of the risks and costs associated with the invention claimed in the patent and the commercial development of products that use the invention;
> (2) evidence of the efficacy and innovative nature and importance to the public health of the invention or products using that invention;
> (3) the degree to which the invention benefitted from publicly funded research;
> (4) the need for adequate incentives for the creation and commercialization of new inventions;
> (5) the interests of the public as patients and payers for health care services;
> (6) the public health benefits of expanded access to the invention;
> (7) the benefits of making the invention available to working families and retired persons;
> (8) the need to correct anti-competitive practices; and
> (9) other public interest considerations.[81]

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[77] 42 U.S.C. § 7608 (2006).

[78] 7 U.S.C. § 2404 (2006).

[79] See Kenneth J. Nunnenkamp, "Compulsory Licensing of Critical Patents Under CERCLA?," 9 *Journal of Natural Resources and Environmental Law* (1993-94), 397, 406 (noting that "there seems to have been no attempts to actually use the compulsory licensing provision" of the Clean Air Act).

[80] Stephen Pericles Ladas, *Patents,Trademarks and Related Rights: National and International Protection* (Cambridge, Mass., Harvard University Press 1975), 427.

[81] H.R. 4131, Section 2 (proposing to add a new § 158 to the Patent Act). The bill had been previously introduced in the 109th Congress as H.R. 4102.

The Implications of the TRIPS Agreement

A leading international agreement on intellectual property bears upon the availability of compulsory licenses under U.S. law.[82] The TRIPS Agreement, or Agreement on Trade-Related Aspects of Intellectual Property Rights, forms one component of the treaties comprising the World Trade Organization (WTO).[83] The TRIPS Agreement addresses a number of intellectual property laws, including patents, copyrights, trademarks and trade secrets. In part this agreement requires WTO signatory states, including the United States, to ensure that their intellectual property laws comply with specified standards.

Part III of the TRIPS Agreement addresses compulsory licenses. As noted above, compulsory licensing refers to the grant of a license by a government to a third party to use a patent without the authorization of the patent holder.[84] The TRIPS Agreement places some limits upon the ability of WTO member states to award compulsory licenses for the use of a private person's patented invention. Among the most detailed provisions of the TRIPS Agreement, Article 31 imposes in part the following restrictions upon the issuance of compulsory licenses:

- Each application for a compulsory license must be considered on its individual merits.
- The proposed user must have made efforts to obtain authorization from the patent owner on reasonable commercial terms and conditions and must demonstrate that such efforts have not been successful within a reasonable period of time. However, this requirement may be waived in the case of a national emergency or other circumstances of extreme urgency.
- Any such use shall be authorized predominantly for the supply of the domestic market of the member authorizing such use.
- The compulsory license must be revocable if and when its motivating circumstances cease to exist and are unlikely to recur.
- The patent owner must be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization.
- The legal validity of any decision relating to the authorization of such use shall be subject to judicial or other independent review.

In light of this obligation, any proposed compulsory licensing provision may need to be examined for its compliance with the TRIPS Agreement. It should be noted that in the 109th Congress, the proposed Public Health Emergency Medicines Act, H.R. 4131, included the following provision:

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[82] See CRS Report RL31132, *Multinational Patent Acquisition and Enforcement: Public Policy Challenges and Opportunities for Innovative Firms*, by John R. Thomas.

[83] *See* Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Annex 1C, 33 I.L.M. 1197 (1994) [hereinafter "TRIPS Agreement"].

[84] *See supra* notes 49-50 and accompanying text.

> CONSISTENCY WITH TRIPS- The Secretary of Health and Human Services may adopt regulations to implement the purposes of this section, consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights referred to in section 101(d)(15) of the Uruguay Round Agreements Act.

In the event that a U.S. law did not comply with the TRIPS Agreement standard, the possibility exists that the United States could be called before the WTO Dispute Settlement Body (DSB).[85] Under the WTO agreements, if one WTO member state believes that another member state is in violation of the TRIPS Agreement, the member states may enter into consultation through the DSB. If the member states cannot resolve their dispute, then the DSB will convene a panel to hear and resolve the dispute. Panel decisions are subject to review by the DSB Appellate Body. The WTO Agreement calls for compensatory trade measures in circumstances where the DSB finds a member state to be in violation of the TRIPS Agreement, yet that member does not amend its laws.[86]

In addition to the possibility of trade sanctions under the TRIPS Agreement, policy makers at the intellectual property-homeland security interface should be aware of recent U.S. foreign policy that has supported the creation of strong patent rights overseas. Many commentators credit the United States with incorporating minimum standards for patent protection within the framework of the WTO.[87] Since the TRIPS Agreement came into effect, the United States has continued to encourage other countries to limit the issuance of compulsory licenses.[88] Some commentators believe that calls from certain U.S. government officials to "override" Bayer's Cipro patent have made it difficult to defend the U.S. view that developing countries should avoid issuing compulsory patent licenses to address their own domestic health needs.[89] As a result, if future discussion occurs over potential reforms to the patent system in view of homeland security needs, it may be advisable to account for possible U.S. foreign policy implications.

Government-Sponsored Research

Some patented inventions of interest to homeland security may have resulted from government funding of research and development that was performed by the

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[85] Understanding on Rules and Procedures Governing the Settlement of Disputes, 15 Apr. 1994, WTO Agreement, Annex 2, Legal Instruments — Results of the Uruguay Round vol. 31, 33 International Legal Materials (1994), 1226.

[86] Mark Clough, "The WTO Dispute Settlement System — A Practitioner's Perspective," 24 *Fordham International Law Journal* (2000), 252.

[87] E.g., Susan K. Sell, "Industry Strategies for Intellectual Property and Trade: The Quest for TRIPS, and Post-TRIPS Strategies," 10 *Cardozo Journal of Comparative and International Law* (2002), 79.

[88] *See* Ellen 't Hoen, "TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha," 3 *Chicago Journal of International Law* (2002), 27.

[89] Divya Murthy, "The Future of Compulsory Licensing: Deciphering the Doha Declaration on the TRIPS Agreement and Public Health," 17 *American University International Law Review* (2002), 1299.

private sector.[90] Current laws set the balance of rights and responsibilities between the federal government and private researchers concerning patented inventions. As the federal government has increased funding for research and development of anti-terrorism technologies,[91] public-private intellectual property ownership issues may be increasingly important in the field of homeland security.

The Bayh-Dole Act governs the ownership of patent rights in inventions resulting from research and development supported by federal government funding.[92] The Bayh-Dole Act is the popular name for P.L. 96-517, which is codified in sections 200-212 of Title 35 of the U.S. Code.[93] The Bayh-Dole Act establishes a presumption that ownership of all patent rights in government-funded research will vest in any contractor who is a nonprofit research institution or small business.[94] A 1987 presidential memorandum instructed federal agencies to apply some Bayh-Dole rights to all contractors, regardless of their size.[95]

The purpose of the Bayh-Dole Act was to encourage companies to undertake the additional efforts necessary to bring government-funded inventions to the marketplace. Experience showed that without title to an invention, firms were less likely to commit resources to commercialize inventions. By providing universities, nonprofit institutions and small businesses with intellectual property rights, Congress intended both to promote collaboration between commercial concerns and nonprofit organizations, as well as to promote the commercialization and public availability of inventions.[96]

The Bayh-Dole Act describes in some detail the license given to the federal government on any subject invention made under a government contract. The contractor may elect to retain title to the invention unless the U.S government determines that it is in the nation's best interest to take title to the invention.[97] If the U.S. government makes this determination, the U.S. government must pursue a lengthy process of justifications and approvals before it can take title under the statute. If the contractor is allowed to retain title, the federal government receives "a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the

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[90] See CRS Report RS21542, *Department of Homeland Security: Issues Concerning the Establishment of Federally Funded Research and Development Centers (FFRDCs)*, by Michael E. Davey.

[91] See Morgan, *supra* note 1.

[92] 35 U.S.C. § 210 (2006).

[93] See Diane M. Sidebottom, "Updating the Bayh-Dole Act: Keeping the Federal Government on the Cutting Edge," 30 *Public Contract Law Journal* (2001), 225.

[94] 35 U.S.C. § 202 (2006).

[95] See Exec. Order No. 12,591, 3 C.F.R. 220 (1988).

[96] See CRS Report RL30320, *Patent Ownership and Federal Research and Development (R&D): A Discussion of the Bayh-Dole Act and Stevenson-Wydler Act*, by Wendy H. Schacht.

[97] 35 U.S.C. § 202(a) (2006).

world."[98] This license is not negotiable and is the minimum that the government receives under a procurement contract, grant, or cooperative agreement. This minimum license allows the government to use the intellectual property for its own purposes and to give such intellectual property to any other entity, including another commercial entity, to build or to use on the government's behalf.[99]

The Bayh-Dole Act also provides for so-called "march-in rights." The U.S. government can require the contractor to grant reasonable licenses to third parties under a specific set of circumstances. For example, if a patentee fails to take effective steps in a reasonable amount of time to achieve practical application of the invention, or the action is necessary for public health and safety reasons, or is required by public use regulations, the federal government can require a contractor to grant a license or can even grant a license itself.[100]

The federal government has also established "data rights regulations" that operate independently of the Bayh-Dole Act. These regulations apply both to "technical data" and computer software produced during the performance of government contracts.[101] The term "technical data" includes research and development data, engineering drawings, manuals and any other recorded information of a scientific or technical nature that is proprietary to the government contractor.[102] The data rights regulations provide the federal government with the right to access and utilize computer software and technical data that belongs to government contractors. The regulations also establish conditions under which contractors can maintain rights in their software and data against the government.[103]

The data rights regulations have been described as "some of the most complicated regulations in the government procurement system."[104] In brief, however, when technical data and computer software are developed by a contractor exclusively with federal funds, the United States enjoys "unlimited rights" to use the information and freely disclose it to others.[105] In other circumstances, however, the government obtains more restrictive rights to use contractor technical data and software. For example, if the government has funded only part of the costs of developing technical data, and the contractor indicates that the data is confidential,

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[98] 35 U.S.C. § 202(c)(4) (2006).

[99] Sidebottom, *supra* note 93.

[100] 35 U.S.C. § 203 (2006). See Tamsen Valoir, "Government Funded Inventions: The Bayh-Dole Act and the *Hopkins v. Cellpro* March-In Rights Controversy," 8 *Texas Intellectual Property Law Journal* (2000), 211.

[101] SeeLionel M. Lavenue, "Technical Data Rights in Government Procurement: Intellectual Property Rights in Computer Software and the Indicia of Information Systems and Information Technology," 32 *University of San Francisco Law Review* (1997), 1.

[102] 48 C.F.R. § 27.401 (2002).

[103] *See generally* Leonard Rawicz & Ralph C. Nash, Jr., *Intellectual Property in Government Contracts: Technical Data Rights* (Commerce Clearing House 2001).

[104] Lavenue, *supra* note 101, at 31.

[105] 10 U.S.C. § 2320(a)(2)(A) (2006).

then in some circumstances the government has a reduced ability to share the data with others and must maintain the data as confidential.[106]

Opinions vary on whether the Bayh-Dole Act and data rights regulations have been fair and effective. Some commentators believe that these rules are inflexible and overly favor the government's position vis-a-vis contractors. For example, Richard N. Kuyath, an attorney in the Office of General Counsel of Minnesota Mining and Manufacturing Company (3M), contends that unless the laws are reformed to improve the intellectual position of government contractors, "many commercial laboratories will continue to refuse government-sponsored R&D."[107] Attorney Diane Sidebottom has argued in accord, contending that current government contracting rules are too rigid and lead to "one size fits all" thinking. In her view, the governing laws and regulations should be changed to "encourage flexibility in the negotiation of intellectual property rights in government contractual arrangements."[108] On the other hand, controversy continues over the ability of government contractors to obtain valuable proprietary interests in the fruits of research that was financed by taxpayer dollars.[109]

Other Issues at the Interface Between Intellectual Property and Homeland Security

Alongside the various laws pertaining to U.S. government use of subject matter protected by an intellectual property right, other legislation relates to the issues at the intersection of homeland security and intellectual property. This report next considers the more significant of these statutes.

Government Purchase of Intellectual Property

In addition to invoking a compulsory license of a proprietary right, another government option is to seek a voluntary license, or simply purchase outright, an intellectual property right that pertains to homeland security. Congress has already authorized the Armed Forces to license, or purchase outright, patents and other proprietary rights:

> Funds appropriated for a military department available for making or procuring supplies may be used to acquire any of the following if the acquisition relates to supplies or processes produced or used by or for, or useful to, that department:
>
> (1) Copyrights, patents, and applications for patents.
> (2) Licenses under copyrights, patents, and applications for patents.

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[106] Lavenue, *supra* note , at 58-64.

[107] Richard N. Kuyath, "Barriers to Federal Procurement: Patent Rights," 36 *Procurement Law* (Fall 2000), 1.

[108] Sidebottom, *supra* note 101, at 241.

[109] E.g., Brett Frischmann, "Innovation and Institutions: Rethinking the Economics of U.S. Science and Technology Policy," 24 *Vermont Law Review* (2000), 347.

(3) Design and process data, technical data, and computer software.
(4) Releases for past infringement of patents or copyrights or for unauthorized use of technical data or computer software.[110]

This legislation provides for a voluntary negotiation between the Armed Forces and the intellectual property rights holder. The extent to which the Armed Forces, or any other federal government entity, has in fact licensed or purchased an intellectual property right from a private party is unclear. Notably, if a U.S. government entity in fact uses the patented invention without authorization, the maximum extent of its liability is "reasonable and entire compensation" to the patent owner within the meaning of 28 U.S.C. § 1498. This amount is ordinarily set to the value of a voluntarily negotiated license, an amount presumably less than the total worth of the intellectual property right.[111] Given the availability of 28 U.S.C. § 1498, the ability to license or purchase an intellectual property may be of comparatively limited value to the government.

The Invention Secrecy Act

Although technological innovations may contribute to the solution of national security problems, in some circumstances the disclosure of new technologies may itself lead to possible homeland security issues.[112] Recognizing this potential, Congress enacted the Invention Secrecy Act of 1951 in order to control the disclosure of certain inventions based upon concerns of national security.[113] Under the act, the Director of the USPTO possesses the power to withhold from issuance patent applications due to national security concerns. If the Director believes that the disclosure of a particular invention may be detrimental to national security, he makes the patent application available to the head of the appropriate defense agency.[114] If that individual agrees with the Director's assessment, the Director may issue a secrecy order on that patent application. This order obliges the applicant not to disclose the invention to others for the duration of the order.[115] Failure to comply results in the rejection of the patent application and possibly a fine and imprisonment.[116]

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[110] 10 U.S.C. § 2386 (2006).

[111] *See supra* notes 66-68 and accompanying text.

[112] See CRS Report RL31845, *"Sensitive But Unclassified" and Other Federal Security Controls on Scientific and Technical Information: History and Current Controversy*, by Genevieve J. Knezo.

[113] Invention Secrecy Act of 1951, ch. 4, 66 Stat. 3 (1952). *See* Sabing H. Lee, "Protecting the Private Inventor Under the Peacetime Provisions of the Invention Secrecy Act," 12 *Berkeley Technology Law Journal* (1997), 345.

[114] 35 U.S.C. § 181 (2006).

[115] 35 U.S.C. § 181 (2006).

[116] 35 U.S.C. § 186 (2006).

Secrecy orders are announced for one-year periods.[117] They may be renewed on an annual basis upon a showing by the appropriate agency head that the national interest continues to support the secrecy order. Secrecy orders can be terminated prematurely if these national security interests cease to exist.[118]

Inventors whose applications are subject to a secrecy order are entitled to certain relief. First, applicants may file a petition to have the secrecy order withdrawn.[119] Applicants whose patents have been withheld due to a secrecy order have a right to compensation.[120] If a patent does ultimately issue from an application that was subject to a secrecy order, the patent is entitled to term extension on a day-per-day basis for the length of the secrecy order. Because the 20-year patent term is ordinarily based upon the filing date, this provision ensures that the inventor receives the same term that he would have had the patent been issued without a secrecy order.[121]

Incentives for Bioterrorism Countermeasure Development

During the 109th Congress, several bills were introduced (although not enacted), including S. 3, the Protecting America in the War on Terror Act, S. 975, the Project Bioshield II Act, and S. 1873, the Biodefense and Pandemic Vaccine and Drug Development Act, that would have generated additional incentives for the creation of new technologies to counteract potential biological threats. S. 3 and S. 975 would have allowed for the restoration of that portion of the patent term used during the FDA approval process, and/or the extension of a patent term to reward technological innovation in the area of bioterrorism countermeasures. The proposed legislation also would have provided for additional FDA-administered marketing exclusivities for eligible and designated countermeasures. S. 1873 would have permitted a countermeasure product to qualify as an orphan drug and thereby obtain a ten-year period of marketing exclusivity. These unenacted legislative proposals are addressed in greater detail in a separate report.[122]

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[117] 35 U.S.C. § 181 (2006).

[118] *Ibid.*

[119] 37 C.F.R. § 5.4 (2006).

[120] 35 U.S.C. § 183 (2006).

[121] See James W. Parrett, Jr., "A Proactive Solution to the Inherent Dangers of Biotechnology: Using the Invention Secrecy Act to Restrict Disclosure of Threatening Biotechnology Patents," 26 *William & Mary Environmental Law & Policy Review* (2001), 145.

[122] See CRS Report RL32917, *Bioterrorism Countermeasure Development: Issues in Patents and Homeland Security*, by Wendy H. Schacht and John R. Thomas.

Concluding Observations

Intellectual property is an important consideration for the federal government as it shapes homeland security policy. Policy makers should be aware that there is a long history of using patents in order to encourage innovation, accompanied by legislative safeguards that protect government interests. In particular, existing law allows intellectual property owners to obtain compensation should the government use privately owned intellectual property to protect public health and safety without prior authorization. This and other laws attempt to achieve the goals of the prompt, widespread use of critical anti-terrorism technologies, along with the continued encouragement of firms to use their research and development capabilities to help the government fight terrorism in the future.

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