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Inoculation Inventions: The Interplay of Infringement and Immunity in the Development of Biodefense Vaccines

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INTRODUCTION

In the months following September 2001, patents were featured prominently in the news in connection with a national anthrax scare.[1] At the time, the only drug that was approved to treat inhalation anthrax was Cipro,[2] a patented drug produced by Bayer.[3] Cipro was quickly hailed as the drug of choice.[4]

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1. *See* Matt Fleischer-Black, *The Cipro Dilemma: In the Anthrax Crisis, Tommy Thompson Distorted Patent Law to Save Public Health. Good Move?*, 24 AM. LAWYER 53 (2002); *see, e.g.*, Matthew Herper, *Cipro, Anthrax and the Perils of Patents,* FORBES.COM (Oct. 17, 2001), *at* http://www.forbes.com/2001/10/17/1017cipro.html (last visited Feb. 24, 2005); Anthony York, *Is It Time to Bust the Cipro Patent?,* SALON.COM (Oct. 18, 2001), *at* http://archive.salon.com/tech/feature/2001/10/18/cipro_patent/print.html (last visited Feb. 24, 2005). *See also* Tamar Lewin, *A Nation Challenged: Fear of Infections; Anthrax Scare Prompts Run on an Antibiotic,* N.Y. TIMES, Sept. 27, 2001, at B8 (noting that people were stockpiling anthrax out of fear); Eric Lipton & Jim Rutenberg, *A Nation Challenged: The Incidents; Anthrax Reports Widen, But No Link is Found*, N.Y. TIMES, Oct. 14, 2001, at A1 (reporting new anthrax cases, including exposed NBC employees); Michael Stroh, *'No Guarantees' That Mail Is Safe, Postmaster Says*, BALT. SUN, Oct. 25, 2001, at 1A (noting actions taken by the United States Postal System in light of the anthrax scare including new machines and additional screening facilities).

2. FDA, DHHS, FDA TALK PAPER, APPROVAL OF CIPRO FOR USE AFTER EXPOSURE TO INHALATIONAL ANTHRAX (Aug. 31, 2000), *at* http://www.fda.gov/bbs/topics/ANSWERS/ANS01030.html (last visited Feb. 24, 2005). Although other antibiotics were available to treat general anthrax, they were not specifically approved to treat inhalation anthrax. *E.g.*, Gina Kolata, *A Nation Challenged: Other Medications; Cipro Isn't the Only Drug That Can Be Prescribed, Anthrax Experts Say*, N.Y. TIMES, Oct. 17, 2001, at B7 (noting that penicillin and tetracycline had been approved to treat cutaneous anthrax and gastrointestinal anthrax and that they were expected to also be effective against anthrax spores).

3. U.S. Patent No. 4,670,444 (issued June 2, 1987).

4. *E.g.*, Jessica Reaves, *Drug of the Moment: Cipro*, TIME.COM (Oct. 18, 2001), *at* http://www.time.com/time/nation/printout/0,8816,180092,00.html (last visited Feb. 24, 2005); Sarah Boseley, *After September 11: Drug Dealing: Three People Have Died of Anthrax in the U.S.*, GUARDIAN (London), Oct. 24, 2001, at 2 (reporting that Cipro "is the best chance of life for anyone who has inhaled anthrax spores."); Lewin, *supra* note 1, at B8 (reporting huge demand for Cipro, despite lack of definitive scientific evidence that it is clearly superior for treatment of anthrax). In addition to Cipro's unique position in the market, news coverage may have also further solidified

However, because patents traditionally allow their owners the right to exclude all others from making and selling the patented invention,[5] concern developed that Bayer would not only be profiting from bioterrorism,[6] but also possibly endangering public health if Bayer could not adequately supply enough Cipro. To address fears of a potential shortage, Senator Charles Schumer of New York, as well as public interest groups, advocated that Bayer's patent rights should be secondary to ensuring adequate supplies; in particular, the Senator proposed to force compulsory licensing of the patent on Cipro to enable generic companies to enter the market.[7] Initially, former Secretary of Health and Human Services, Tommy Thompson, asserted that such action was not possible under the patent laws.[8] However, after Canada decided to impose a compulsory license on Cipro, Secretary Thompson began threatening to do the same.[9] Shortly thereafter, Bayer

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Cipro's prominence in the public mind. For example, Tom Brokaw of the NBC Nightly News held a bottle of Cipro before the camera and stated "In Cipro we trust." Herper, *supra* note 1.

5. 35 U.S.C.A. § 271(a) (West 2001). Of course, there are some exceptions to the patent rights, as described in greater detail later in this article. *See* discussion *infra* Part III.

6. Although Bayer was already providing the drug at a discount to the government ($1.77 per pill, compared to the wholesale price of $4.67 per pill), Bayer was nonetheless criticized for appearing to profit from bioterrorism in comparison to generic companies that were clamoring for the opportunity to sell the drug for a mere forty cents per pill. *E.g.*, Gardiner Harris, *Questions of Security: Bayer is Accused of Profiteering on Cipro*, WALL ST. J., Oct. 26, 2001, at A6; Reaves, *supra* note 4 (noting that Bayer angrily denied accusations that it was profiting from the anthrax situation). Vanessa Fuhrmans & Ron Winslow, *The Treatment: Its Image Under Fire, Bayer AG Scrambles to Meet Cipro Demand*, WALL ST. J., Oct. 22, 2001, at A1 (noting that although Bayer initially kept a low profile to avoid the perception that it would be seen as exploiting an opportunity, it then launched a public relations "counteroffensive" to repair its public image); Robert Kuttner, *War Profiteering on Anthrax Meds*, BOSTON GLOBE, Oct. 22, 2001, at A13 (noting that "America could be on the verge of a public health catastrophe" and suggesting that Bayer's resistance of government licensing of the Cipro patent was part of the problem). *But see* Editorial, *The Cipro Circus*, WALL ST. J., Oct. 25, 2001, at A20 (suggesting that Bayer had been unfairly treated in the press in the context of the Cipro crisis and concluding that drug patent rights are in fact essential to national security); Lea Paterson, *US Patent Reappraisal Poses Long-Term Dangers*, TIMES (London), Oct. 29, 2001 (suggesting that any deviation from Bayer's patent rights would be tantamount to penalizing "success" and moreover would be addressing immediate problems at the risk of long-term "fundamentals").

7. *See* Letter from Ralph Nader & James Love, to Tommy G. Thompson, Secretary of Health and Human Servs. (DHHS) (Oct. 18, 2001), *at* http://www.cptech.org/ip/health/cl/cipro/nadethom10182001.html (last visited Feb. 24, 2005) (noting that "we were shocked by your comments . . . indicating that you do not have the legal authority to authorize generic production of ciprofloxacin, a drug used to treat victims of an anthrax attack. This, of course, is not true."); *see also* Donald G. McNeil, Jr., *A Rush for Cipro, and the Global Ripples*, N.Y. TIMES, Oct. 17, 2001, at A1 (noting Senator Schumer's proposal that the government buy generic versions of Cipro for an emergency stockpile); Memorandum from Al Engelberg, to Senator Schumer (Oct. 13, 2001), *at* http://lists.essential.org/pipermail/ip-health/2001-October/002113.html (last visited Feb. 24, 2005) (providing extensive legal analysis regarding authority for compulsory licenses of Cipro under 28 U.S.C. § 1498); York, *supra* note 1 (suggesting that it is "ludicrous" for Thompson to suggest that he can not use his authority under 28 U.S.C. § 1498).

8. Elisabeth Bumiller, *Administration Won't Allow Generic Versions of Drug*, N.Y. TIMES, Oct. 18, 2001, at B8.

9. *E.g.*, Dan Ackman, *A New Deal on Cipro*, FORBES.COM (Oct. 24, 2001), *at* http://www.forbes

negotiated substantially discounted prices with both Canada and the United States, promising to increase production to satisfy the necessary demand, such that the compulsory license issue became moot. [10]

Although the patent on Cipro has now expired,[11] the issues that surrounded the Cipro patent continue to persist. In particular, although the United States would not have supply issues in the event of another terrorist attack utilizing anthrax, similar legal and political problems would likely be resurrected. Patent applications have been on the rise since the anthrax scare, including applications and issued patents on methods of treating biological warfare.[12] Accordingly, patent issues will likely need to be addressed in defending against future attacks. While domestic authority continues to exist for the federal government to issue compulsory licenses of patented drugs, [13] doing so may still be inconsistent with international obligations, or at least may expose the United States to claims of hypocrisy. Indeed, considering that the United States was accused of hypocrisy for even considering use of a compulsory license in the context of Cipro, any actual use of such licensing is likely to have negative implications. [14]

.com/2001/10/24/1024topnews_print.html (last visited Feb. 24, 2005) (quoting Tommy Thompson as saying to talk show host Larry King that "[Bayer is] going to either meet our price, which is less than $1, or else we're going to go to Congress . . . ."); Shankar Vedantam & DeNeen L. Brown, *U.S. Seeks Price Cut from Cipro Maker; Bayer to Announce Pact 'Shortly,'* WASH. POST, Oct. 24, 2001, at A16.

10. Keith Bradsher & Edmund L. Andrews, *U.S. Says Bayer Will Cut Cost of Its Anthrax Drug*, N.Y. TIMES, Oct. 24, 2001, at B7; Keith Bradsher, *Bayer Agrees to Charge Government a Lower Price for Anthrax Medicine*, N.Y. TIMES, Oct. 25, 2001, at B8; Harris, *supra* note 6, at A6 (noting Bayer's announcement of a "historic" agreement to sell Cipro for 95 cents a pill to the government).

11. Henry Dummett, *Flood Gates Opened to Generic Cipro Market in U.S.*, WORLD MKTS. ANALYSIS, June 11, 2004 (noting that Cipro patent expired on June 9, 2004, and FDA approval of more than ten generic versions are pending).

12. *See infra* notes 116-18 and accompanying text (concerning specific patent applications regarding biodefense vaccines).

13. *See infra* note 177 and accompanying text.

14. *E.g.*, Emma Clark, *America's Anthrax Patent Dilemma*, BBC NEWS ONLINE, Oct. 23, 2001 (reporting that the United States would be accused of hypocrisy if it decided to use a compulsory license); Jill Carroll & Ron Winslow, *Bayer Agrees to Slash Price for Cipro Drug*, WALL ST. J., Oct. 25, 2001, at A3. Editorial, *Patent Abuse*, FINANCIAL TIMES (London), Oct. 22, 2001 (noting that "[w]estern governments are guilty of double standards" in comparison to the eleven confirmed cases of anthrax infection versus the 25 million people faced with dying of AIDS in Africa for lack of medical treatment); Press Release, Oxfam America, Oxfam America Calls on U.S. to Make Anti-Anthrax Medicine Available (Oct. 23, 2001), *at* http://www.oxfamamerica.org/newsandpublications/press_releases/archive2001/art245.html (last visited Feb. 27, 2005); McNeil, *supra* note 7; Geoff Dyer & Adrian Michaels, *A Bitter Pill for the Drug Makers*, FINANCIAL TIMES (London), Oct. 23, 2001, at 27 (noting a double standard between United States action concerning Cipro versus action against South Africa and Brazil); Paul Blustein, *Drug Patent Dispute Poses Trade Threat; Generics Fight Could Derail WTO Accord*, WASH. POST, Oct. 26, 2001, at E1 (noting the global implications of the Cipro patent fight, including WTO negotiations scheduled to take place at Doha); Boseley, *supra* note 4, at 2 (comparing the two anthrax deaths to the thousands of daily deaths in Africa from HIV in the context of United States hypocrisy in enforcing patents in developing countries, such as Thailand and South Africa).

Against this backdrop of potential political controversy and continuing threats of terrorism, there has been a surge of interest in vaccines to address bioterrorism. Despite a clearly recognized need to address bioterrorism by developing new vaccines,[15] the demand to ensure legally adequate bases for addressing patent liability that may arise with respect to such vaccines seems largely absent from both popular and academic perspectives since the anthrax/Cipro crisis.[16] This article aims to address this void by providing a timely examination of the scope of patent rights under both domestic and international law.

In particular, this article addresses the complex intersection of innovation and infringement relevant to the development of vaccines that could inoculate against bioterrorist threats. Proponents of the patent system suggest that the exclusivity of rights guaranteed by a patent provides an incentive for research and development of commercial products.[17] However, researchers suggest that strong patent rights unduly interfere with scientific research.[18] In addition, consumer

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15. JONATHAN BAN, ET AL., CHEMICAL AND BIOLOGICAL ARMS CONTROL INSTITUTE (CBACI), MEETING THE BIODEFENSE CHALLENGE: A "ROAD MAP" FOR A NATIONAL VACCINE STRATEGY, REPORT OF THE CBACI NATIONAL VACCINE STRATEGY WORKING GROUP 1 (2004) [hereinafter BIODEFENSE ROAD MAP], http://www.cbaci.org/pubs/reports/vaccineroadmap.pdf (last visited Feb. 24, 2005); S. 666, 108th Cong. (2003) (providing incentives to foster research concerning vaccines to prevent and treat illnesses associated with bioterrorism). *See also* Elizabeth White, *Patent Incentive is Focal Point of Debate at Senate Hearing on Future 'Bioshield II' Bill*, PAT., TRADEMARK & COPYRIGHT J., Oct. 15, 2004 (noting legislation based on S. 666 for planned introduction in the 109th Congress to help ensure a thriving biodefense industry).

16. *But see* Daniel R. Cahoy, *Treating the Legal Side Effects of Cipro: A Reevaluation of Compensation Rules for Government Takings of Patent Rights*, 40 AM. BUS. L. J. 125 (2002) (discussing current legal issues surrounding patent law and government action); BIODEFENSE ROAD MAP, *supra* note 15, at 32 (noting that a "vaccine strategy must also address the role of patents, which could potentially act as a barrier to the development of vaccines or their use in response to an incident"); Grace K. Avedissian, Note, *Global Implications of a Potential U.S. Policy Shift Toward Compulsory Licensing of Medical Inventions in a New Era of "Super-Terrorism,"* 18 AM. U. INT'L L. REV. 237 (2002) (discussing patent issues that would arise if the present patent laws were amended to include more compulsory licensing).

17. *E.g.*, PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PHRMA), FACT SHEET, *at* http://www.phrma.org/publications/publications/17.06.2003.746.cfm (last visited Feb. 24, 2005) (noting the importance of patent incentives to pharmaceutical companies); BIOTECHNOLOGY INDUSTRY ORG., PRIMER: GENOME AND GENETIC RESEARCH, PATENT PROTECTION AND 21ST CENTURY MEDICINE, *available at* http://www.bio.org/ip/primer/printer.asp (last visited Feb. 24, 2005) (concluding that "without patents, companies would be reluctant to invest in research and drug discovery programs" because of the expense and risks involved in bringing a drug to market). In addition, the Supreme Court has stated that patents provide a social good. *See,* Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 150-51 (1989) (noting that patent laws provide "a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology and design in return for the exclusive right to practice the invention for a period of years."); Kewanee Oil Co. v. Bicron Corp, 416 U.S. 470, 480 (1974) (stating that patent laws promote progress "by offering a right of exclusion for a limited period as an incentive to inventors to risk the often enormous costs in terms of time, research, and development").

18. Patent rights entitle their owners to exclude all others from making, using, selling, offering to sell, or importing the patented invention. 35 U.S.C. § 271(a) (2000). Although there are some

advocates have challenged the incentive rationale and argued that patents create a social harm by condoning unduly high prices on necessary treatment.[19] There are some statutory and common law doctrines that suggest a middle ground between these two positions by providing exceptions or immunities from the standard liability that ensues from unauthorized use of a patented invention.[20] However, the validity of these exceptions under both domestic and international law may in some cases be questionable. Accordingly, this article seeks to provide a more detailed analysis of the interplay between these various issues in order to properly understand the true patent barriers to the development of biodefense vaccines, as well as ways to negotiate those obstacles.

Part I of this article provides an overview of both the domestic and international laws that govern the proper scope of patents in the United States. Part II then addresses the extent to which the present patent system poses barriers to the development of biodefense vaccines, both by illustrating potential patent liability at various stages of vaccine development, as well as the potential bars to development that may be imposed if a patent on a new vaccine is sought. Part III provides a detailed analysis of specific exceptions that may minimize traditional patent infringement, including various types of immunity from suit, or more limited exceptions to infringement. Part III is organized into two main sub-categories: existing limitations to patent liability and *possible* limitations. The existing limitations include a range of common law and statutory exceptions for government as well as private actors. The section also analyzes whether the exceptions could withstand either Constitutional scrutiny or an international challenge under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The discussion of possible limits to patent liabilty includes existing equitable remedies that individual judges may provide, as well as paramount considerations for any future legislation that may be proposed.

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exceptions, general experimental use is not recognized either in the Patent Act or by common law. *See infra* notes 203-07 and accompanying text (discussing limited doctrines of experimental use).

19. Editorial, *The People vs. Patents: The Drugs Industry is Taking Us Where Nobody Sensible Wants to Go,* NEW SCIENTIST, July 13, 2002, at 3; Tim Hubbard & James Love, *We are Patently Going Mad: Lifesaving Drugs Must Be Developed Differently For All of Our Sakes,* GUARDIAN (London), March 4, 2004, at 6. Within the realm of intellectual property, patents are routinely characterized as the strongest and most valuable type of protection. In fact, the strength of patent rights has sometimes been characterized as analogous to a strict liability regime. *E.g.*, Florida Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank, 527 U.S. 627, 645, 654 n.5 (1999) (citing 5 D. CHISUM, PATENTS 16.02[2], p. 16-31 (rev. ed. 1998)) (noting that patent infringement does "not require any showing of intent to infringe."); Hilton Davis Chem. Co. v. Warner-Jenkinson Co., 62 F.3d 1512 (Fed. Cir. 1995) (stating that "infringement is, and should remain, a strict liability offense"); Blair v. Westinghouse Elec. Corp., 291 F. Supp. 664, 670 (D.D.C. 1968) (stating that "it is, of course, elementary, that an infringement may be entirely inadvertent and unintentional and without knowledge of the patent.").

20. *See infra* Part III.

I. BACKGROUND

A. Legal Landscape of Patents

The present legal landscape concerning patent protection involves an examination of both national and international laws. In particular, although patents are traditionally governed by national laws, to the extent that nations have entered into international agreements that mandate minimum levels of national patent protection, those agreements are also pertinent.[21]

1. United States

Patents issued by the United States are governed by the Patent Act, which was enacted by Congress pursuant to Constitutional authority. Notably, the United States Constitution authorizes, but does not require, Congress to enact laws which "promote the Progress of Science and useful Arts" by providing to inventors a limited period of exclusivity.[22] In other words, Congress may implement restrictions on present patent law since Congress is not obligated to provide patent rights in the first instance; stated more bluntly, there is no absolute Constitutional right to a patent.[23] This point will become particularly relevant to discussion of

21. At present, no international agreement mandates uniform substantive patent law. However, there is one agreement presently being negotiated under the auspices of the World Intellectual Property Organization (WIPO) that would purport to provide uniform levels of patent protection. GRAIN, ONE GLOBAL PATENT SYSTEM? WIPO'S SUBSTANTIVE PATENT LAW TREATY (Oct. 2003), *at* http://www.grain.org/briefings/?id=159 (last visited Feb. 24, 2005); CARLOS M. CORREA, SOUTH CENTRE, THE WIPO DRAFT SUBSTANTIVE PATENT LAW THEORY: A REVIEW OF SELECTED PROVISIONS (March 2004), http://www.southcentre.org/publications/workingpapers/paper17/wp17.pdf (last visited Feb. 24, 2005); SISULE F. MUSUNGU & GRAHAM DUTFIELD, QUAKER UNITED NATIONS OFFICE (QUNO) & GENEVA QUAKER INT'L AFFAIRS PROGRAMME (QIAP), MULTILATERAL AGREEMENTS AND TRIPS-PLUS WORLD: THE WORLD INTELLECTUAL PROPERTY ORGANISATION (WIPO), TRIPS ISSUES PAPERS 3, at 11-12 (2003). The negotiations are presently stalled. INT'L CTR. FOR TRADE & SUSTAINABLE DEV. (ICTSD), MOVING FORWARD THE 'DEVELOPMENT AGENDA' IN WIPO, 8 BRIDGES WKLY. NEWS DIG. 33, (Oct. 6, 2004), *at* http://www.ictsd.org/biores/04-05-28/story1.htm (last visited Feb. 24, 2005); ICTSD, *Disclosure Requirements Remain Divisive in WIPO Patent Reform*, 4 BRIDGES WKLY. NEWS DIG. 10 (May 28, 2004), *at* http://www.ictsd.org/biores/04-05-28/story1.htm (last visited Feb. 24, 2005). Moreover, even if the Substantive Patent Law Theory (SPLT) were enacted, because it is not tied to the WTO's powerful enforcement mechanisms, it is questionable whether nations would feel compelled to comply.

22. U.S. CONST., art. I, § 8, cl. 8. At the time the Constitution was drafted, the term "Science" actually referred to literature, whereas "useful Arts" referred to things in the scientific realm. Karl B. Lutz, *Patents and Science: A Clarification of the Patent Clause of the United States Constitution*, 18 GEO. WASH. L. REV. 50, 51 (1949); Alan L. Durham, *'Useful Arts' in the Information Age*, 1999 BYU L. REV. 1419, 1426 (1999); David Silverstein, *Patents, Science and Innovation: Historical Linkages and Implications for Global Technological Competitiveness*, 17 RUTGERS COMPUTER & TECH. L.J. 261, 291-92 (1990). However, the distinction between these two terms is not important for this article.

23. *See infra* notes 133-36 and accompanying text.

some present United States laws that may not withstand international scrutiny if challenged for lack of compliance with international obligations.

2. International (TRIPS and Beyond)

In addition to considering current patent laws and the Constitutional parameters that would govern any changes, constraints based on international agreements that the United States has signed are also important to examine. The most important international agreement is the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS),[24] which is the first international agreement to mandate minimum levels of patent protection[25] for all member states of the World Trade Organization (WTO), including the United States.[26]

Although TRIPS is not the only international agreement governing United States patent laws, it is the only one that is tied to powerful dispute resolution procedures under the WTO.[27] The procedures are important for the United States to bear in mind because failure to comply with TRIPS can result in a dispute brought against the United States before the WTO, with the potential for trade sanctions as a consequence.[28] However, not every failure to comply with TRIPS

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24. Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Including Trade in Counterfeit Goods, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, LEGAL INSTRUMENTS – RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 1197 (1994) [*hereinafter* TRIPS].

25. *See, e.g.* Rochelle Cooper Dreyfuss & Andreas F. Lowenfeld, *Two Achievements of the Uruguay Round: Putting TRIPS and Dispute Settlement Together*, 37 VA. J. INT'L L. 275, 279 (1997) (contrasting the requirements under TRIPS to those under the General Agreement on Tariffs and Trade (GATT)); J. H. Reichman, *From Free Riders to Fair Followers: Global Competition Under the TRIPS Agreement*, 29 N.Y.U. J. INT'L. L. & POL. 11 (1997); Carlos M. Correa, *Patent Rights, in* INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE: THE TRIPS AGREEMENT 189 (Carlos M. Correa & Abdulqawi A. Yusuf eds., 1998); DANIEL GERVAIS, THE TRIPS AGREEMENT (2d ed. 2003).

26. As of Jan. 3, 2005, there are 148 Members to the WTO. *See* WORLD TRADE ORGANIZATION (WTO), UNDERSTANDING THE WTO: THE ORGANIZATION: MEMBERS AND OBSERVERS (2004), *at* http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (last visited Feb. 25, 2005). In addition, since TRIPS was signed in 1996, the United States has entered into a series of bilateral and regional agreements with other countries that in many cases impose higher standards than those specified under TRIPS. *See* GRAIN, TRIPS-PLUS: WHERE ARE WE NOW? AN INFORMAL REPORT FROM GRAIN FOR THE THIRD SAARC PEOPLES FORUM 1, 3 (2003), *available at* http://www.grain.org/rights_files/trips-plus-where-2003-en.pdf (last visited Feb. 25, 2005); *See* DAVID VIVAS-EUGUI, QUNO, QIAP, & ICTSD, REGIONAL AND BILATERAL AGREEMENTS AND A TRIPS-PLUS WORLD: THE FREE TRADE AREA OF THE AMERICAS (FTAA), TRIPS ISSUES PAPERS 1, at 3-4 (2003), http://geneva.quno.info/pdf/FTAA%20(A4).pdf (last visited Feb. 25, 2005). Because of the higher standards, they are often referred to as "TRIPS-plus" agreements.

27. The WTO dispute resolution procedures are uniformly regarded as the most effective means of enforcing international laws. *See, e.g.*, Laurence L. Helfer, *Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 YALE J. INT'L L. 1, 2 (2004) (commenting that TRIPS has "teeth"); Dreyfuss & Lowenfeld, *supra* note 25, at 276-77 (noting that the new dispute settlement system was a significant achievement of the Uruguay Round).

28. Daniel Kalderimis, *Problems of WTO Harmonization and the Virtues of Shields Over Swords*, 13 MINN. J. GLOBAL TRADE 305, 312 (2004); Sungjoon Cho, *The Nature of Remedies in International*

results in an official complaint processed through this proceeding, let alone warrants trade sanctions.[29] In fact, according to one study by the United States Trade Representative (USTR), no nation has complied with TRIPS in its entirety.[30] However, noncompliance with TRIPS would nonetheless make the United States vulnerable within the WTO forum. In particular, the actions of the United States will be particularly scrutinized,[31] given its history of aggressively pursuing questionable cases of noncompliance with TRIPS[32] as well as threatening

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Trade Law, 65 U. PITT. L. REV. 763, 764 (2004); *see also* WTO, UNDERSTANDING THE WTO: SETTLING DISPUTES: A UNIQUE CONTRIBUTION, *at* http://www.wto.org/english/thewto_e/whatis_e/tif_e/disp1_e.htm (last visited Feb. 27, 2005).

29. The DSU requires parties to first attempt to resolve disputes before involving the WTO adjudicatory process. Understanding on Rules and Procedures Governing the Settlement of Disputes, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, LEGAL INSTRUMENTS – RESULTS OF THE URUGUAY ROUND, VOL. 31, 33 I.L.M. 1226, 1228-30 (1994) [hereinafter DSU] (requiring parties to first consult with each other before requesting that a panel be established); *see also* WTO, UNDERSTANDING THE WTO: SETTLING DISPUTES: THE PANEL PROCESS, *at* www.wto.org/english/thewto_e/whatis_e/tif_e/disp2_e.htm (last visited Feb. 25, 2005) (providing a graphical illustration of dispute settlement process, beginning with consultation of parties). There are a number of cases where countries officially request consultations but fail to proceed to a panel decision, let alone sanctions for noncompliance. *See, e.g.*, GATT SECRETARIAT, UPDATE OF WTO DISPUTE SETTLEMENT CASES: NEW DEVELOPMENTS SINCE LAST UPDATE, WT/DS/OV/19 (Feb. 6, 2004), *available at* http://docsonline.wto.org/gen_search.asp?searchmode=simple (last visited Feb. 25, 2005) (to access documents on the WTO web site, click on simple search, and enter the document symbol). Moreover, politics often play a role in whether countries assert a violation of TRIPS. *E.g.*, Peter S. Menell, *Economic Implications of State Sovereign Immunity From Infringement of Federal Intellectual Property Rights*, 33 LOY. L.A. L. REV. 1399, 1453 (2000) (commenting that a variety of issues implicate a decision to pursue a perceived TRIPS inconsistency). For example, developed nations, such as the United States, may elect to use unilateral trade sanctions, or TRIPS-plus agreements to reach desired results, rather than risk a negative decision (and possible sanctions) within the WTO system. *E.g.*, Sara M. Ford, Note, *Compulsory Licensing Provisions Under the TRIPS Agreement: Balancing Pills and Patents*, 15 AM. U. INT'L L. REV. 941, 968-69 (2000) (noting that developed nations are not likely to risk a binding negative decision by bringing the disputes before the WTO). Developing nations, on the other hand, may be reluctant to raise a TRIPS noncompliance issue for fear of damaging foreign relations and potentially creating vulnerability to unilateral trade sanctions. *Id.* at 969.

30. Menell, *supra* note 29, at 1453.

31. One classic example is that the United States was mocked for its hypocrisy in suggesting compulsory licensing of the patented Cipro compound in the wake of anthrax attacks because the United States had suggested that more modest actions by other nations, such as Brazil and South Africa, should not qualify for compulsory licensing under TRIPS. *See supra* note 14 and accompanying text.

32. *See* Tim Reason, *Euro Clash*, CFO MAGAZINE, May 2004, *at* http://www.cfo.com/article.cfm/3013415/c_3046612?f=magazine_featured (last visited Feb. 25, 2005) (noting that the United States has initiated more complaints under the Dispute Settlement process than any other country). In particular, the United States aggressively pursued both Brazil and South Africa on the grounds that their systems of providing compulsory licenses of patented drugs violated TRIPS. *E.g.*, Lawrence O. Gostin, *The Global Reach of HIV/AIDS: Science, Politics, Economics, and Research*, 17 EMORY INT'L. L. REV. 1, 35-37 (2003) (discussing United States involvement with international generic drugs); James Thuo Gathii, *Construing Intellectual Property Rights and Competition Policy Consistently with Facilitating Access to Affordable AIDS Drugs to Low-End Consumers*, 53 FLA. L. REV. 727, 768 (2001) (discussing United States opposition to South Africa's compulsory licensing law); Frederick M. Abbott, *The TRIPS-Legality of Measures Taken to Address Public Health Crises: A Synopsis*, 7 WIDENER L. SYMP.

unilateral trade sanctions against countries who refuse to establish standards beyond TRIPS.[33]

3. Patent Standards Under Domestic and International Law

a. Patentability

The basic/default standards of patentability and patent rights under domestic and international law are presently in accord and thus can be easily discussed together.

i. Patentable Subject Matter

First, with respect to subject matter that is patentable, TRIPS states that inventions in all fields of technology should be patentable if they satisfy the technical criteria of patent protection – new, non-obvious, and useful – unless they fall within two exceptions.[34] In particular, TRIPS permits but does not require member states to exclude from patentability inventions regarding methods of treatment, as well as inventions that violate *ordre public* or morality.[35]

J. 71, 75 (2001) (noting that the United States has alleged TRIPS violations for granting compulsory pharmaceutical licenses, even where use was authorized under Article 31 for health emergencies); *see generally* SUSAN K. SELL, PRIVATE POWER, PUBLIC LAW: THE GLOBALIZATION OF INTELLECTUAL PROPERTY RIGHTS, 151-57 (2003) (discussing United States trade pressure on South Africa and Thailand, as well as the successful efforts of non-governmental advocates in countering such pressure). The United States only dropped its case against Brazil after substantial public backlash; the Brazil case was a public relations nightmare since Brazil had extraordinary and unprecedented success in fighting its AIDS epidemic and one important element was their compulsory licensing of patented drugs to treat AIDS. Chakravarthi Raghavan, *U.S. Beats a (tactical) Retreat over Brazil's Patent Law,* THIRD WORLD NETWORK, June 25, 2001, *at* http://www.twnside.org.sg/title/tactical.htm (last visited Feb. 25, 2005); Stephen Buckley, *U.S., Brazil Clash Over AIDS Drugs; 'Model' Treatment Program Seen at Risk in Dispute on Patents and Pricing*, WASH. POST, Feb. 6, 2001, at A1; SELL, *supra*, at 158 (noting that after Brazil's successful program of distributing HIV/AIDS medicines under compulsory license was given "prominent and positive press," the United States withdrew its case against Brazil).

33. *See, e.g.*, OXFAM, OXFAM BRIEFING PAPER 33: U.S. BULLYING ON DRUG PATENTS: ONE YEAR AFTER DOHA 3 (Nov. 2002), *available at* http://www.oxfam.org/eng/pdfs/pp021112_bullying_patents.pdf (last visited Feb. 27, 2005).

34. TRIPS, *supra* note 24, at art. 27. In addition to the explicit exceptions to patentable subject matter, some have argued that because TRIPS does not define what constitutes an "invention," countries have leeway in deciding to eliminate certain inventions from patent protection. *See, e.g.*, Correa, *supra* note 25, at 198 (noting that although the United States and European Patent Convention permit patenting of isolated gene sequences, "[t]here is nothing in the TRIPS Agreement that would oblige members to follow this . . . approach" and that definitions of inventions in other countries that exclude such matter from inventions are in fact consistent with TRIPS).

35. TRIPS, *supra* note 24, at art. 27(2)-(3) (providing that member countries *may* exclude certain subject matter from patentability). Moreover, to the extent that the United States has signed agreements since TRIPS that are more restrictive of exceptions to patentable subject matter, the TRIPS exceptions may not be truly available. In addition, Article 27(3)(b) provides for additional exceptions from patentability for plant varieties that are protected by alternative *sui generis* system. *Id.* at art. 27(3)(b). However, this provision is not applicable to the discussion of human vaccines.

The present United States system does not take advantage of either of the two explicit TRIPS exceptions to patentable subject matter. Rather, the United States Patent Act provides no explicit subject matter exceptions from patentability.[36] The United States Supreme Court has also broadly interpreted the scope of patent protection and suggested that it covers "anything under the sun that is made by man."[37] The United States Patent and Trade Office (PTO) and lower courts have taken this broad language to support further expansion of the scope of patentable subject matter to cover subjects such as isolated gene sequences.[38]

Congress could, however, potentially exclude isolated gene sequences from patentability. This would be well within the bounds of Congressional authority.[39] Moreover, such action would arguably be permissible under TRIPS if such sequences were not considered "inventions," as some countries have already suggested.[40] Of course, the United States has been advocating that other countries recognize all biological subject matter as patentable, including isolated gene sequences.[41] Reversing course might raise political or foreign relations issues, which, while theoretically possible, might not present a politically viable option.

ii. Technical Requirements of Patentability

In addition to satisfying the eligible subject matter requirement, an invention, as disclosed in a patent application, must satisfy additional technical requirements of patentability. As stated above, under TRIPS, as well as United States patent law, an invention must be useful, new, and non-obvious.[42] The application must

36. *See* 35 U.S.C. § 101 (2000).

37. Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980) (quoting S. REP. NO. 82-1979, at 5 (1952), *reprinted in* 1952 U.S.C.C.A.N. 2394, 2399; H.R. REP. NO. 82-1923, at 6 (1952), *reprinted in* 1952 U.S.C.C.A.N. 2394, 2399); J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124 (2001) (declining to narrow the reach of patent law and issuing utility patents for plants).

38. *See infra* note 46 and accompanying text (discussing patentability of gene sequences under present United States law).

39. Since Congress need not create patents in the first instance, Congress can certainly limit the bounds of patent protection. *See supra* note 22 and accompanying text (concerning authority for Congressional power); *see also* Paul J. Heald & Suzanna Sherry, *Implied Limits on the Legislative Power: The Intellectual Property Clause as an Absolute Constraint on Congress*, 2000 U. ILL. L. REV. 1119 (2000).

40. *See* Correa, *supra* note 25, at 198.

41. GRAIN, "TRIPS-PLUS" THROUGH THE BACK DOOR (2001), http://www.grain.org/briefings_files/trips-plus-en.pdf (last visited Feb. 25, 2005) (noting that some TRIPS-plus agreements specifically mandate protection of biotechnological inventions).

42. TRIPS, *supra* note 24, at art. 27; 35 U.S.C. §§ 101-03 (2000). Although the text of TRIPS uses different terminology, a footnote to the text indicates that the terms are synonymous to those used under the United States Patent Act. *See* TRIPS, *supra* note 24, at art. 27 n. 5.

sufficiently disclose the invention such that someone who is similarly skilled in the art could replicate it.[43]

However, because TRIPS fails to define any of these terms, there is at least the possibility that individual nations have the flexibility to change their definition of what constitutes new or non-obvious.[44] Although a well-established history concerning what constitutes new or non-obvious already exists in the United States, the TRIPS flexibility is an important consideration to the extent that Congress may want flexibility in "re-defining" some terms to better address innovation or public access to innovation. For example, there is no global consensus on whether patents on isolated gene sequences are either "inventions" or sufficiently new under patent law.[45] The United States has long considered them new,[46] but since the Constitution and TRIPS allow for a more restrictive scope of patentability, Congress technically has power to declare a narrower scope by legislative fiat. This might be particularly relevant in the vaccine context to the extent that some bioterrorism vaccines could require the use of patented gene sequences.[47]

b. Patent Rights

i. General/Basic Scope of Protection

The basic patent rights required pursuant to TRIPS and the United States Patent Act are presently essentially identical. Both allow the owner of a patent to exclude others from making, using, selling, offering to sell, or importing the patented invention for the term of the patent.[48] The patent term, under both TRIPS and the United States Patent Act, is twenty years from the filing of the patent

43. 35 U.S.C. § 112 (2000).

44. *See generally* Correa, *supra* note 25, at 200-01; J.H. Reichman, *The TRIPS Agreement Comes of Age: Conflict or Cooperation With the Developing Countries?*, 32 CASE W. RES. J. INT'L. L. 441, 457 (2000) (noting that there is still no clear definition of the terms "novelty" and "non-obvious").

45. Correa, *supra* note 25, at 198; CARLOS M. CORREA, INTELLECTUAL PROPERTY RIGHTS, THE WTO AND DEVELOPING COUNTRIES: THE TRIPS AGREEMENT AND POLICY OPTIONS 52-54 (2000); Donna M. Gitter, *International Conflicts Over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and A Fair-Use Exemption*, 76 N.Y.U. L. REV. 1623, 1624-25 (2001).

46. *See, e.g.*, Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501 (Fed. Cir. 1997) (upholding a DNA sequence patent); Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1203 (Fed. Cir. 1991) (allowing a patent for the DNA sequence for human erythropoietin). However, in response to public protest, the United States Patent and Trade Office (PTO) has heightened the patentability requirements such that sequences with utility only as a general research probe are no longer patentable. Utility Examination Guidelines, 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001).

47. *See infra* note 119 and accompanying text.

48. TRIPS, *supra* note 24, at art. 28; 35 U.S.C. § 271(a) (2000). In addition, although not a requirement under TRIPS, the United States imposes liability for those who indirectly assist in infringement. 35 U.S.C. § 271(b)-(c).

application.[49] Since no patent rights exist while the application is pending, the effective term of a patent is twenty years minus the time the PTO takes to examine the application.[50] Although the examination period varies for different types of inventions, the average time is slightly over two years, thus making the average patent term around seventeen to eighteen years, although it may be considerably shorter if the examination time is lengthy.[51]

An unstated but nonetheless important understanding behind both TRIPS and the United States Patent Act is that patents do not provide an affirmative right to use the patented invention. Patents only provide a right to *exclude* others.[52] To be entitled to *use* the patented invention, the owner must determine if there are additional laws that bar use, or which require additional affirmative activities before use is permitted. For example, before a patented pharmaceutical can be sold, it needs regulatory approval from the Food and Drug Administration,[53] a process separate from the process of obtaining patent rights.[54] In addition, the patent owner may need to determine if permission from another patent owner is required to avoid infringement.

TRIPS and the United States Patent Act part ways with respect to what exceptions exist for typical patent rights. Because the United States must meet the minimum standards of TRIPS, the TRIPS requirements will be first discussed as providing a template for understanding United States exceptions, including whether the present exceptions fail to comply with TRIPS.

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49. TRIPS, *supra* note 24, at art. 33; 35 U.S.C. § 154(a)(2).

50. TRIPS, *supra* note 24, at art. 33; 35 U.S.C. § 154(a)(2).

51. U.S. PTO, PERFORMANCE AND ACCOUNTABILITY REPORT: FISCAL YEAR 2003, at 19 (2003), http://www.uspto.gov/web/offices/com/annual/2003/2003annualreport.pdf (last visited Feb. 25, 2005) (noting average pendency to patent issuance or abandonment in 2003 was 26.7 months).

52. TRIPS, *supra* note 24, at art. 28; 35 U.S.C. § 271(a).

53. The FDA must approve all new drugs before they can be sold through interstate commerce. 21 U.S.C. § 355(a) (2000). Moreover, the definition of a "drug" is broad enough to include vaccines. *See* 21 U.S.C. § 321(g)(1).

54. The separate approval process can further shorten the effective term of patent protection if the FDA approval time is longer than the time to examine and issue the patent, which it often is. *See, e.g.*, CONGRESSIONAL BUDGET OFFICE (CBO), HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY 38 (1998), http://www.cbo.gov/showdoc.cfm?index=655&sequence=5#N_6_ (last visited Feb. 25, 2005) (noting that the average effective patent term is about eleven to twelve years). *See also* WTO, DISPUTE SETTLEMENT REPORTS: CANADA-PATENT PROTECTION OF PHARMACEUTICAL PRODUCTS ¶¶ 7.73-7.74 (2000) [hereinafter CANADA-GENERICS] (describing effective patent term as only about eight to twelve years, such that those subject to regulatory review are deprived of a substantial part of the period that inures to other patent owners); CENTER FOR DRUG EVALUATION AND RESEARCH (CDER), SMALL BUSINESS ASSISTANCE, FREQUENTLY ASKED QUESTIONS ON THE PATENT TERM RESTORATION PROGRAM (2003), *at* http://www.fda.gov/cder/about/smallbiz/patent_term.htm (last visited Feb. 25, 2005) (noting that patent term restoration aims to somewhat compensate for regulatory delays that would otherwise reduce the effective patent term for pharmaceuticals).

ii. Exceptions under TRIPS

There are two explicit TRIPS provisions that articulate exceptions to the standard patent rights. In particular, TRIPS permits a "limited exception" to patent rights under Article 30, if certain ambiguously stated exceptions are met.[55] In addition, Article 31 of TRIPS permits use without the authority of the patent holder in cases where Article 30 is not met *and where the Member has complied with* more than ten procedural conditions.[56] Although some have suggested that other articles within TRIPS could also be used as exceptions,[57] there is only a consensus concerning the use of Articles 30 and 31 and therefore discussion will be limited to these provisions.[58]

(a) Article 30

On its face, Article 30 seems to be an ambiguous exception,[59] but the provision has been interpreted by the WTO Panel in the Canada-Generic

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55. TRIPS, *supra* note 24, at art. 30.

56. *Id.* at art. 31.

57. In particular, some have suggested that Articles 7 and 8 of TRIPS, which are labeled as "objectives" and "principles" might serve as free-standing exceptions to patent rights. *See* J.H. Reichman, *Beyond the Historical Lines of Demarcation: Competition Law, Intellectual Property Rights, and International Trade After the GATT's Uruguay Round*, 20 BROOK. J. INT'L L. 75, 100 (1993). *But see* GERVAIS, *supra* note 25, at 116, 121 (suggesting that Article 7 "is a 'should' provision that probably may not be used to reduce the scope of 'shall'" requirements of other provisions of TRIPS and that Article 8 is more of a policy statement). However, to date, no DSU panel has endorsed such arguments. Notably, the WTO Panel did not endorse this approach, although it was definitely advocated by third parties. *See* CANADA-GENERICS, *supra* note 54, at ¶ 7.26 (stating that the limiting conditions under Article 30 "testify strongly" that there should not be a "renegotiation" of the rights under TRIPS, although Articles 7 and 8.1 could be "borne in mind" in interpreting provisions such as Article 30); *see also id.* at ¶ 5.23 (noting Israel's position that because Articles 7 and 8 are in the text of the agreement, rather than in the Preamble, that should underscore their utility as "primary tools for interpretation," such that Article 30 should be interpreted in light of Article 8 to grant members discretion to limit patent rights where social and economic welfare dictate); *id.* at ¶ 5.27 (noting Poland's position that the Preamble as well as Articles 7 and 8 confirm that protection of public health is paramount under TRIPS). Moreover, the Doha Declaration's statement that all provisions of TRIPS should be interpreted in light of the Preamble, as well as the objectives and principles, further suggests that these provide additional context in which to view other exceptions, but are not free-standing exceptions themselves. *See* WTO, *Fourth Ministerial Conference, Declaration on the TRIPS Agreement and Public Health*, WT/MIN(01)/DEC/2, at ¶ 5(a) (Nov. 14, 2001), *available at* http://docsonline.wto.org/gen_search.asp?searchmode=simple (last visited Feb. 25, 2005) [hereinafter *Doha Declaration*].

58. In addition, although the Canada-Generic case raised an issue with respect to whether exceptions must be applied in a nondiscriminatory manner pursuant to Article 27(1), this seems a very low threshold to satisfy. The alleged discrimination is permissible if it is not a "sham, or of no actual or potential importance." CANADA-GENERICS, *supra* note 54, at ¶ 7.104. Even though the provision at issue in that case was clearly directed at only the pharmaceutical industry, the Panel nonetheless said that the "primary purposes" for passing the legislation was not dispositive. *Id.* at ¶ 7.90. Accordingly, nondiscrimination will not be discussed at length.

59. *See, e.g.*, Correa, *supra* note 25, at 207 (noting that TRIPS Article 30 used very general wording, especially in comparison to more specific proposals that were made and rejected during the negotiation process).

Medicines case to have fairly stringent parameters.[60] Although WTO Panel decisions technically have no stare decisis effect [61] and are only binding on parties to the dispute, they are often cited in subsequent Panel decisions, which WTO members closely follow.[62] Accordingly, although a subsequent WTO Panel faced with interpreting Article 30 could take an entirely different approach, given the fact that this is unrealistic, the guidelines set forth in the existing decision will be outlined here as parameters for interpreting Article 30.[63]

(i) Canada-Generic Medicines case

To better understand the context of the Panel's decision in Canada-Generic Medicines, a brief background of the factual context may be helpful. There were two provisions in Canada's patent laws that the European Union challenged as violations of the Article 28 right to exclude, the Article 33 patent term, and the nondiscrimination requirement of Article 27.[64] One provision, commonly known as the "regulatory review exception," enabled potential manufacturers of generic drugs to submit documentation for regulatory approval by the necessary agency to obtain marketing approval for the sale of drugs before the patent term expired.[65] Canada did not contest the facial violation of Article 28 rights, but argued instead

60. CANADA-GENERICS, *supra* note 54, pt. B; TRIPS, *supra* note 24, at art. 31.

61. *E.g.*, WTO, DISPUTE SETTLEMENT REPORTS, INDIA-PATENT PROTECTION FOR PHARMACEUTICAL AND AGRICULTURAL CHEMICAL PRODUCTS, WT/DS79/R ¶ 7.30 (1998) [hereinafter WTO-INDIA] (noting that "panels are not *bound* by previous decisions of panels or the Appellate Body even if the subject-matter is the same."). *But see* Raj Bhala, *The Myth About Stare Decisis and International Trade Law (Part One of a Trilogy)*, 14 AM. U. INT'L. L. REV. 845, 877-85 (1999) (discussing the "myth" of the absence of stare decisis from international trade law in the context of the WTO); Raj Bhala, *The Power of the Past: Towards* De Jure Stare Decisis *in WTO Adjudication (Part Three of a Trilogy)*, 33 GEO. WASH. INT'L. L. REV. 873, 876-78 (2001) (same).

62. *See, e.g.*, WTO, DISPUTE SETTLEMENT REPORT, JAPAN – TAXED ON ALCOHOLIC BEVERAGES, COMPLAINTS BY THE EUROPEAN COMMUNITIES (WT/DS8), CANADA (WT/DS10), AND THE UNITED STATES (WT/DS11) 106-08 (1996) (noting the importance of adopted Panel reports); WTO-INDIA, *supra* note 61, at ¶ 7.30 (taking into account the conclusions of the Panel in a prior decision); David Palmeter & Petros C. Mavroidis, *The WTO Legal System: Sources of Law*, 92 AM. J. INT'L L., 398, 403 (1998); Dana T. Blackmore, *Eradicating the Long Standing Existence of a No-Precedent Rule in International Trade Law - Looking Toward* Stare Decisis *in WTO Dispute Settlement*, 29 N.C. J. INT'L L. & COM. REG. 487, 502-03 (2004). *Cf.* CANADA-GENERICS, *supra* note 54 (noting that only parties to the dispute may appeal a panel decision).

63. Even before the decision, some commentators had already suggested a three-part requirement to the Article 30 exception. *E.g.*, Correa, *supra* note 25, at 207. There is at least one commentator who has suggested the decision was so off-base and incorrect that it should not be considered. Robert Howse, *The Canadian Generic Medicines Panel: A Dangerous Precedent In Dangerous Times*, 3 J. WORLD INTELL. PROP. 493, 494-95 (2000). *See also* Helfer, *supra* note 27, at 77-78 (2004) (citing Howse as an example of how WTO panels should consider soft law for interpreting TRIPS provisions such as Article 8).

64. CANADA-GENERICS, *supra* note 54, at ¶ 3.1.

65. *Id.* at ¶ 7.2 (citing Canadian Patent Act § 55.2(1)).

that this provision was a limited exception to patent rights under Article 30.[66] The second provision, known as the "stockpiling exception," enabled the same companies who qualified for regulatory approval to have a right to make the patented inventions during the last six months of the patent term.[67] As with the regulatory review exception, Canada did not contest violation of Article 28 patent rights, but instead argued that this was another limited exception under Article 30.[68] The Panel ultimately found that the regulatory review exception was a limited exception under Article 30 but that the stockpiling exception was not.[69] However, it is important to also note the Panel's underlying interpretation of Article 30 in order to determine what other situations would appropriately fall under Article 30.

The Canada-Generic Medicines case interpreted Article 30 to have three separate and distinct requirements which were cumulative in nature.[70] In dissecting each requirement, the Panel noted that it was applying the customary international law for interpreting international treaties, as mandated under WTO rules.[71] First, it noted that Article 30 required that there be a "limited exception," as a requirement to be interpreted separately from the other parts of Article 30. Second, the exception must not "unreasonably conflict with normal exploitation"

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66. *Id.* at ¶ 7.12.

67. *Id.* at ¶¶ 7.7-7.10 (citing Canadian Patent Act § 55.2(2)). The rationale of this provision was that it would accelerate the provision of cheaper drugs to the Canadian public after the patent expired; Canada submitted that but for the stockpiling provision, consumers would be forced to wait another three to four months after the patent expired before generic versions were made available and that the patent owner would obtain an unfair defacto extension of patent term. *Id.* at ¶ 7.10.

68. *Id.* at ¶ 7.12

69. *Id.* at ¶ 8.1.

70. *Id.* at ¶ 7.20. The Panel noted that the three separate elements must be "presumed to mean something different" from each other, or else there would be redundancy. *Id.* at ¶ 7.21.

71. Dispute settlement panels must comply with customary rules of interpretation of public international law. DSU, *supra* note 29, at art. 3.2. Some have suggested that this is a vague standard. *E.g.*, Dreyfuss & Lowenfeld, *supra* note 25, at 289 (calling the standard a "vague guidepost"). However, customary rules include at least the rules under the Vienna Convention, which requires that a treaty be interpreted in "good faith" in accordance with the "ordinary meaning" of the treaty terms in their context and in light of the object and purpose of the treaty. Vienna Convention on the Law of Treaties, opened for signature May 23, 1969, art. 31(1), 1155 U.N.T.S. 331, 8 I.L.M. 679 (1969) [hereinafter Vienna Convention]. However, unlike interpretation of United States statutes, negotiating history is *not* typically part of the interpretation process. In particular, there are only two situations where it is proper to use such history: (1) to *confirm* the meaning based on the good faith interpretation of the treaty terms, or (2) to determine the meaning of the treaty terms if the standard interpretation leads to a meaning that is ambiguous or manifestly absurd. *Id.* at art. 32. Accordingly, resort to negotiating history is very limited. Moreover, even if permissible, there is very limited documentation of negotiating history for TRIPS. *See, e.g.* GERVAIS, *supra* note 25, at viii (noting that many essential parts of the deliberations were "informal," including a complete lack of written record of oral arguments, such that only the chairman's draft reflects the history of the negotiations). One final tool available under the Vienna Convention that is also dissimilar from United States practice is that "subsequent practice" of parties may be taken into account to the extent that it establishes agreement of the parties regarding interpretation of the negotiation. Vienna Convention, *supra*, at art. 31(3)(b).

of the patent. Third, the exception must not "unreasonably prejudice" the "legitimate interests of the patent owner," taking into account the "legitimate interests of third parties." Accordingly, each of the three part requirements of Article 30 is discussed below.[72]

Limited Exception

The WTO Panel interpreted the first element of Article 30 as a "limited exception" to be a free-standing requirement from the remainder of the elements under Article 30. In interpreting this exception, the Panel relied on definitions from the Oxford English Dictionary to support its interpretation that there must be a very "narrow exception" that involves a "small diminution of the rights in question."[73] In addition, whether something is "limited" is determined with respect to the Article 28 rights that are curtailed, but without consideration to the economic impact[74] or the number of Article 28 rights impacted.[75] Based on these parameters, the Panel found that the stockpiling exception was *not* appropriately limited because of the lack of limits on the quantity of production.[76] In contrast, the Panel found the regulatory review exception was limited because it was confined to conduct necessary for regulatory approval, with no commercial use made of resulting products.[77]

72. The Panel first analyzed the stockpiling exception and then the regulatory review exception, interpreting the elements of Article 30 within each one. However, for purposes of this article, each Article 30 requirement will draw from the Panel's comments/decision with respect to both of the Canadian exceptions at issue.

73. CANADA-GENERICS, *supra* note 54, at ¶ 7.30.

74. *Id.* at ¶ 7.31 (noting that the other two conditions of Article 30 are more relevant to economic impact); *id.* at ¶¶ 7.48-49 (noting that although the Canadian regulatory review exception could have a "considerable" economic impact, the issue of economic impact is only addressed in the other two conditions of Article 30).

75. *Id.* at ¶ 7.32 (noting that the "panel does not agree, however, with the EC's position that the curtailment of legal rights can be measured by simply counting the number of legal rights impaired."). Similarly, the Panel rejected Canada's assertion that "limited" exception existed so long as the patent owner maintained the exclusive right to sell. *Id.* at ¶ 7.33. According to the Panel, the panoply of patent rights under TRIPS Article 28 were not hierarchical based on the fact that if the right to sell were the only right of relevance, the other stated Article 28 rights would not be necessary. *Id.*

76. *Id.* at ¶ 7.33.

77. *Id.* at ¶ 7.45. An interesting and important note here is that the Panel explicitly discounted Canada's arguments concerning the beliefs of some WTO members about the scope of Article 30, as well as the enactment by some countries of similar provisions after TRIPS. *Id.* at ¶ 7.47. In particular, the Panel noted that there was "no documented evidence of the claimed negotiating understanding" because acts by some countries failed to constitute sufficient subsequent practice within the meaning of the Vienna Convention. *Id.*

No Unreasonable Conflict with "Normal Exploitation"

The next major requirement focused primarily on what constitutes "normal exploitation" of a patent.[78] The Panel once again looked to the dictionary definition of "normal" and concluded that the normal practice for a patent owner would include the "more or less brief" period of market exclusivity that typically exists after the patent expires.[79] However, it noted that the longer period of exclusivity that occurs due to the "unintended consequence" of patent and regulatory laws pertaining to pharmaceutical approval would not be normal.[80] Because the Panel found the stockpiling exception to exceed normal exploitation, it never opined on what would constitute an unreasonable conflict with such exploitation.[81]

Unreasonable Prejudice to "Legitimate Interests" of Patent Owner

The Panel initially referred to the common definition of "legitimate" in evaluating the final prong of Article 30[82] and the negotiating history[83] before finding that there was no "legitimate interest" for pharmaceutical patent owners to maintain an effective patent term equivalent with those of patent owners who did not need regulatory approval to make use of their inventions.[84] Because the Panel concluded that there were no legitimate interests asserted, it never reached an

78. This element was only interpreted with respect to the regulatory review exception since the stockpiling exception failed to satisfy the initial requirement of being a "limited exception." *See supra* note 69 and accompanying text.

79. *Id.* at ¶¶ 7.53-7.56.

80. *Id.* at ¶ 7.57.

81. *Id.* at ¶ 7.59.

82. *Id.* at ¶ 7.68 (citing two definitions from THE NEW SHORTER OXFORD DICTIONARY 1563 (4th ed. 1993)). The Panel rejected the EC's attempt at equating legitimate interests with the full range of legal interests under Article 28 as emasculating the final provision of Article 30. *Id.*

83. The Panel noted that the exception was derived in part from the Berne Convention, which had slightly different language. Although the Panel could not decide why the Berne language was not utilized, it nonetheless used the Berne drafting committee report to allegedly confirm its interpretation of unreasonable prejudice and legitimate interests. *Id.* at ¶ 7.71-7.72 (noting that the Berne drafting report suggested that a large number of copies would not per se constitute unreasonable prejudice of legitimate interests of the copyright owner if equitable remuneration were paid). *But see* Howse, *supra* note 63, at 502 (suggesting that the Panel improperly resorted to the Berne preparatory text, because Berne dealt with copyrights and not patents).

84. The Panel noted that "[o]n balance . . . the interest claimed on behalf of patent owners whose effective period of market exclusivity had been reduced by delays in marketing approval was neither so compelling nor so widely recognized *that it could be regarded as a 'legitimate interest' within the meaning of Article 30.*" CANADA-GENERICS, *supra* note 54, at ¶ 7.82 (emphasis added). Moreover, the Panel noted that although some countries had regulatory review provisions at the time TRIPS was being negotiated, the fact that these exceptions "were apparently not clear enough, or compelling enough, to make their way explicitly into the recorded agenda of the TRIPS negotiations" suggested that they should not be considered part of the legitimate interests. *Id.* Stated differently, the Panel noted that adjudication should not be utilized to decide a "normative policy issue that is still obviously a matter of unresolved political debate." *Id.*

analysis of what would constitute unreasonable prejudice to such interests.[85] Similarly, it did not explicitly address how third party interests should be balanced against the patent owner's legitimate interests, other than to opine that legitimate interests must include something broader than legal interests.[86]

(ii) Moving beyond Canada-Generics

The Canada-Generics case can be distinguished on the facts from any bioterrorism situation since bioterrorism was not an issue in that case. Rather, it involved whether two different Canadian patent provisions that allowed for faster public access to lower-cost generic drugs were permissible exceptions under Article 30. In addition, at several points in the Panel decision, the Panel explicitly noted other factual contexts in which it was specifically not rendering judgment.[87] Even though the case did not specifically address bioterrorism vaccines, this does not preclude application of the analytical framework, which is not tied to the facts.[88]

An issue Canada-Generics did not expressly address is the extent that Article 30 might cover compulsory licensing. There have been arguments that Article 30 could be interpreted to enable developing countries without manufacturing capacity to import patented drugs from other countries as a way around a limitation to compulsory licensing under Article 31.[89] This has never been an issue directly addressed by a WTO Panel. However, the decision of the general council of TRIPS to move forward with amending Article 31, rather than utilize Article 30,

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85. *Id.* at ¶ 7.83 (noting that since neither of the claims of legitimate interests asserted by the EC were in fact "legitimate" under Article 30, there was no undue prejudice to such interests).

86. *Id.* at ¶ 7.71.

87. For example, although the Panel found that Canada's then-existing stockpiling suggestion failed to be sufficiently limited, it suggested that a stockpiling exception could be crafted that would fall within Article 30. *Id.* at ¶¶ 7.33-7.35. In addition, in the context of interpreting the term "legitimate interests," it discussed "one of the most widely adopted Article 30-type exceptions in national patent laws – the exception under which use of a patented product for scientific experimentation, during the [patent] term . . . is not an infringement." *Id.* at ¶ 7.69. The Panel technically utilized this issue to show policy arguments regarding what were legitimate societal interests, but nonetheless stated that "the Panel draws no conclusion about the correctness of any such national exceptions in terms of Article 30 of the TRIPS Agreement." *Id.* at ¶ 7.69.

88. In addition, although the parties to the decision had opposing views on how the elements of Article 30 should be interpreted, they agreed on the "basic structure" of Article 30, suggesting that this structure will not be disputed. *Id.* at ¶ 7.20.

89. *See* Letter from CPTech, Oxfam, MSF, and HAI, to WTO Delegates (Dec. 19, 2002), *at* http://www.cptech.org/ip/wto/p6/ngos12192002.html [hereinafter CPTech et al. Letter] (regarding December 16, 2002 Chairman's Text for "solution" to Paragraph 6 of the Doha Declaration on TRIPS and Public Health stating that Article 30 is a solution to compulsory licensing/importing problem) (last visited Feb. 25, 2005); *see also* GERVAIS, *supra* note 25, at 242 (noting that after the initial Doha Declaration some broad interpretations of Article 30 were proposed); Avedissian, *supra* note 16, at 267-69 (noting that a liberal interpretation of Article 30 to authorize exports of medicine under a compulsory license may be possible).

perhaps suggests that a WTO Panel might be similarly disinclined to favor the use of compulsory licensing under Article 30;[90] in addition, many have suggested or even assumed that Article 31 is the only relevant provision for addressing compulsory licensing.[91] Moreover, even if there is no per se prohibition of using Article 30, the narrow interpretations of the three requirements would likely make this exception still generally inapplicable to domestic laws regarding compulsory licensing, as will be addressed in more detail later in this article.

(b) Article 31

Article 31 applies to national legislation that permits unauthorized use by the government, or use by third parties authorized by the government in situations that do not fall under Article 30. However, Article 31 imposes a long list of procedural requirements that must be satisfied before the exception applies. The requirements have been reported to be intended as a detailed "checklist" for member states to provide safeguards against abuse.[92] A brief overview of the requirements most

90. An interpretation under Article 30 would have logistically been easier since no formal amendment to TRIPS would be required. Indeed, that was touted by some as the advantage of dealing with the Doha ¶ 6 exception under Article 30. *See* Permanent Mission of Brazil – Communication dated June 21, 2002, *Paragraph 6 of the Ministerial Declaration on the TRIPS Agreement and Public Health,* IP/C/W/355, at 4 (June 24, 2002), *available at* http://docsonline.wto.org/gen_search.asp?searchmode=simple (last visited Feb. 25, 2005) (stating in conclusion that an "authoritative interpretation of Article 30 is preferable to those based on Article 31, as the former would be administratively less burdensome, involving less steps for implementation"); OXFAM INTERNATIONAL, ROBBING THE POOR TO PAY THE RICH? HOW THE UNITED STATES KEEPS MEDICINES FROM THE WORLD'S POOREST, OXFAM BRIEFING PAPER 56 (Jan. 28, 2002), http://www.oxfam.org/eng/pdfs/pp031201_robbing_medicines_US.pdf (last visited Feb. 25, 2005) (suggesting that the United States is not living up to the letter and spirit of the Doha Declaration). Other proposals suggested an amendment of Article 31, or a waiver of Article 31(f), as well as a moratorium on dispute settlement regarding the provision. *See, e.g.,* Permanent Mission of the United States – Second Communication dated June 25, 2002, *Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health,* IP/C/W/358, at 6 (July 9, 2002), *available at* http://docsonline.wto.org/gen_search.asp?searchmode=simple (last visited Feb. 25, 2005) (suggesting that the most expeditious solution would be either a moratorium on dispute settlement or a waiver of Article 31(f)); Permanent Mission of Kenya – Communication dated June 18, 2002, *Proposal on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health,* IP/C/W/351, at 2 (June 24, 2002), *available at* http://docsonline.wto.org/gen_search.asp?searchmode=simple (last visited Feb. 25, 2005) (noting that Article 31(f) should be deleted or an authoritative interpretation adopted); *see also* GERVAIS, *supra* note 25, at 242 (citing Thomas A. Haag, *TRIPS Since Doha: How Far will the WTO Go Toward Modifying the Terms for Compulsory Licensing?* 84 J. PAT. & TRADEMARK OFF. SOC'Y 945, 955-66 (2002)).

91. *See, e.g.*, Correa, *supra* note 25, at 208-10 (noting that Article 31 provides conditions for granting of compulsory licenses, as well as summarizing the grounds and conditions required under this provision); JEROME H. REICHMAN & CATHERINE HASENZAHL, UNCTAD-ICTSD PROJECT ON INTELLECTUAL PROPERTY RIGHTS AND SUSTAINABLE DEVELOPMENT, NON-VOLUNTARY LICENSING OF PATENTED INVENTIONS § 2.3 (2002), http://www.iprsonline.org/unctadictsd/projectoutputs.htm (last visited Feb. 25, 2005) (noting that TRIPS provides for non-voluntary licenses under Article 31).

92. GERVAIS, *supra* note 25, at 165 (1st ed. 1998). Compulsory licensing under the Paris Convention is incorporated into TRIPS, although whether this provides for a separate avenue of compulsory licensing is unclear. REICHMAN & HASENZAHL, *supra* note 91, at § 2.3 (noting that

applicable to present United States statutes that might be subject to Article 31 will be provided here.[93]

An important requirement of Article 31 is that there must first be an attempt to negotiate for a license directly from the patent holder before imposing a compulsory license. In particular, Article 31 states that compulsory "use may only be permitted" where the proposed user has first "made efforts to obtain authorization" for use from the patent owner on "reasonable commercial terms" and where those efforts have "not been successful within a reasonable period of time."[94] However, this provision also provides for waiver of the voluntary negotiations with the patent owner in case of "national emergency or other circumstances of extreme urgency."[95] The 2001 Doha Declaration on Public Health clarified that individual countries have "the right to determine what constitutes a national emergency or other circumstances of extreme urgency."[96] Moreover, it specifically noted that it is "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."[97]

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whether the Paris Convention statement that failure to work a patent locally justifies compulsory licensing is unclear in light of the nondiscrimination provision of TRIPS art. 27). Indeed, the United States had challenged Brazil's local working requirement, but under political pressure the United States withdrew its suit, such that a WTO Panel has never resolved the issue. *See* Permanent Mission of the United States & Permanent Mission of Brazil – Notification of Mutually Agreed Solution, *Measures Affecting Patent Protection*, WT/DS199/4, at 19 (July 19, 2001), *available at* http://docsonline.wto.org/gen_search.asp?searchmode=simple (last visited Feb. 25, 2005); *see also* Dyer & Michaels, *supra* note 14 (describing United States action against Brazil to contrast United States action concerning Cipro); *supra* note 31 and accompanying text (discussing United States pursuit of both Brazil and South Africa, as well as the United States's subsequent withdrawal of such action).

93. This section primarily addresses the portions of Article 31 that seem to play a role in compulsory licensing of vaccines by the United States. The provisions that apply to compulsory licensing as a remedy to address anti-competitive practices are not addressed. TRIPS, *supra* note 24, at art. 31(k). Similarly, although potentially applicable, since there is presently no United States legislation that suggests the use of compulsory licensing specifically to enable exploitation of a second patent without infringement of an initial patent pursuant to the terms of TRIPS Article 31(l), the additional three requirements that must be met in that situation will not be further detailed. TRIPS, *supra* note 24, at art. 31(l).

94. TRIPS, *supra* note 24, at art. 31(b).

95. *Id.* Even in cases where waiver of negotiations with the patent owner is applicable, the patent owner must be notified of the emergency use "as soon as reasonably practicable." *Id.*

96. *Doha Declaration, supra* note 57, at ¶ 5(c). Although the document is technically not part of TRIPS and not enforceable via the WTO dispute settlement procedure, it does have some legal weight at least as persuasive authority. *See, e.g.*, James Thuo Gathii, *The Legal Status of the Doha Declaration on TRIPS and Public Health under the Vienna Convention on the Law of Treaties*, 15 HARV. J.L. & TECH. 291, 314 (2002) (discussing the Doha Declaration as a form of "soft law with substantial hortatory authority"); REICHMAN & HASENZAHL, *supra* note 91, at § 2.4 (noting that although the legal status is "uncertain," on a practical level, the Declaration could be an authority from which future panels "draw guidance" when deciding cases).

97. *Doha Declaration*, *supra* note 57, at ¶ 5(c).

Since 2001, however, the scope of public health crises that would justify waiver of voluntary negotiations has continued to be controversial.[98]

There are a number of conditions that apply to all cases of compulsory use, regardless of whether the grounds for issuing a compulsory license is based upon refusal to negotiate or an emergency.[99] The conditions are highly specific and depart from prior international agreements concerning compulsory licenses. For example, conditions governing the grant of the license include that use shall be "considered on its individual merits" [100] and that the scope and duration of the use must be "limited" to the authorized purpose.[101] In addition, there are mandatory procedural safeguards in the form of judicial or other independent review of the use authorization.[102] Even if the use is authorized, it is still contingent on "adequate remuneration" being paid to the right holder that takes into account the "economic value of the authorization." [103] Moreover, as with the review of the use authorization, remuneration decisions must be subject to judicial or other independent review. [104]

Furthermore, Article 31 requires that use be authorized "predominantly for the supply of the domestic market of the Member authorizing such use." [105] In other words, if the United States were to allow compulsory use of a patented invention, the use should predominantly supply needs of the United States market, rather than be used to export to other countries. Moreover, the United States would not be permitted to import vaccines made under compulsory license in Canada if Canada were doing so primarily for export rather than to address a domestic crisis. Although there has been a decision to waive this requirement for some developing countries that lack sufficient manufacturing capacities to

98. In particular, the United States has contended that the *only* possible emergencies are those noted in the Doha Declaration, while developing countries have argued for a broader interpretation. *E.g.*, BROOK K. BAKER, HEALTH GAP, DOHA REDUX – U.S. ENTERS NEW PHASE OF BAD FAITH BARGAINING (2003), *at* http://www.cptech.org/ip/wto/p6/hgap07022003.html (last visited Feb. 25, 2005); MARY MORAN, MEDICINS SANS FRONTIERES, RENEGING ON DOHA (2003), http://www.cptech.org/ip/wto/p6/msf052003.pdf (last visited Feb. 25, 2005); CPTECH ET AL., DEADLOCK OVER SCOPE OF DISEASES THREATENS TO KILL SOLUTION, Nov. 27, 2002, *at* http://www.cptech.org/ip/wto/p6/ngos11272002.html (last visited Feb. 25, 2005); CHAKRAVARTHI RAGHAVAN, THIRD WORLD NETWORK, TRIPS CONSULTATIONS ON IMPLEMENTING DOHA RECESSED (Nov. 29, 2002), *at* http://www.twnside.org.sg/title/5246a.htm (last visited Feb. 25, 2005).

99. In addition, other grounds include non-commercial use, dependent patents, and anti-competitive practices. TRIPS, *supra* note 24, at art. 31.

100. *Id.* at art. 31(a).

101. *Id.* at art. 31(c).

102. *Id.* at art. 31(g), (i).

103. *Id.* at art. 31(h).

104. *Id.* at art. 31(j).

105. *Id.* at art. 31(f).

domestically produce necessary products,[106] there is no question that the United States has sufficient manufacturing capacity to create its own products. Moreover, the United States and other industrialized countries such as Canada have pledged not to take advantage of any developed waiver to this requirement.[107]

II. PATENT BARRIERS TO DEVELOPMENT OF BIOTERRORISM VACCINES

There are two different patent problems that impact the development of bioterrorism vaccines. The most likely problem for development and use of any such vaccine is that the process of developing or using a final product may infringe upon one or more patents.[108] A second patent problem only arises for those who pursue a patent on a new vaccine. In particular, there are provisions of the Patent Act that could not only delay the issuance of a patent, but also delay public use and commercialization of a viable vaccine. Although such delay could present a serious hurdle to development, because a patent is not technically required for developing a vaccine[109] whereas patent infringement is always a potential risk, infringement problems will be addressed first.

A. Infringement

This section will highlight some key issues with respect to identifying potential pitfalls with patent infringement.[110] While there are some exceptions to

106. The Doha Public Health Declaration specifically requested that the TRIPS general council find a solution as expeditiously as possible. *Doha Declaration*, *supra* note 57, at ¶ 6. The general council did in fact come up with a detailed solution that essentially waives this requirement in certain cases for developing countries. WTO, GENERAL COUNCIL, IMPLEMENTATION OF PARAGRAPH 6 OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH, WT/L/540 (Sept. 1, 2003), *at* http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm (last visited Feb. 25, 2005) [hereinafter PARAGRAPH 6 DECISION]. The solution was intended to be incorporated into TRIPS as a formal amendment. *Id.* at ¶ 11 (noting that the decision "shall terminate . . . on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect . . ."). However, due to disagreements between WTO member states, the formal inclusion of this has been delayed. INSIDE U.S. TRADE, WTO MEMBERS RE-OPEN FIGHT OVER SUBSTANCE OF TRIPS-HEALTH AGREEMENT, March 12, 2004, *at* http://www.cptech.org/ip/wto/p6/insideustrade03122004.html (last visited Feb. 25, 2005).

107. PARAGRAPH 6 DECISION, *supra* note 106, at ¶ 6.

108. This is not a problem unique to vaccines, or even bioterrorism vaccines. However, it is obviously an important issue that needs further analysis.

109. However, a patent does confer commercial advantages, such that many entities are nonetheless likely to pursue one despite the likelihood of patent infringement.

110. A complete analysis of patent infringement is a complex endeavor. For example, many companies regularly obtain legal opinions concerning potential infringement of patents before engaging in commercial sale of a single product. These opinions typically focus on infringement of a *single* patent with respect to a single product and still regularly span 50-100 pages in length. Obviously for the purposes of this article, a complete infringement analysis of every existing or potential biodefense

patent infringement that may apply and are discussed later, this section aims to first clarify the specific activity that gives rise to infringement. In particular, this section will briefly describe what activities from a vaccine's original conception to its final commercial use might result in patent infringement.[111]

Patent infringement may be predicated on any one of five different enumerated acts – making, using, selling, offering to sell, or importing the patented invention – and many of these acts are pertinent to the development of bioterrorism vaccines.[112] Each listed act would be a separate type of patent infringement; accordingly, even if someone is making the patented invention though not selling it, patent liability would still exist.[113] Moreover, there may be multiple patented inventions within the same patent that can each be enforced against others.[114]

One major caveat to possible infringement is that if the entity that is developing a vaccine actually owns *all* patents relevant to making that vaccine, there would be no infringement issue because the use would be authorized by the patent owner. However, it is often rare to own all relevant patents because many inventions are cumulative. Accordingly, even though the federal government or its various branches already own many biodefense patents, to the extent that use of any of those patented inventions requires the use of even a single patent owned by another, patent infringement is still an issue.[115]

Vaccines that use modern techniques of recombinant DNA are particularly vulnerable to infringing pre-existing patents. In particular, for a vaccine developed

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vaccine is not possible. However, this section aims to highlight issues that should be further explored with patent counsel to best negotiate potential patent barriers.

111. Patent infringement may also arise from importing a patented invention, but since the focus of this symposium has been on development, and primarily development within the United States, this section will not discuss importations. However, if another country were making and selling biodefense vaccines that would be of utility to the United States, importing those vaccines would be an infringement *if* the vaccine were patented in the United States. If the vaccine was only patented in another country, that would not result in infringement within the United States since patent rights are only enforceable within the territory of the granting nation. *See* 35 U.S.C. § 271(a) (stating the scope of patent rights); *see also* Gretchen Ann Bender, *Clash of the Titans: The Territoriality of Patent Law vs. The European Union*, 40 IDEA 49, 50 (2000), http://www.idea.piercelaw.edu/articles/40/40_1/2.Bender.pdf (last visited Feb. 25, 2005).

112. 35 U.S.C. § 271(a) (2000).

113. *Id.* Moreover, although every patent must contain at least one claim defining the parameters of the patented invention, most patents have multiple claims and infringement of *any* single claim constitutes infringement of the patent. *See id.*

114. By law, each patent must have at least one claim that defines the patentable invention. 35 U.S.C. § 112. In addition, the claims are what define the legal parameters of what may be enforced against others. *See id.* However, to the extent that a patent has multiple claims, each can be individually asserted against others. *Cf.* 35 U.S.C. § 282 (noting that each claim of a patent is presumed valid independently of the soundness of other claims). Accordingly, infringement may be predicated on infringement of a single patent claim.

115. Although a complete review of existing patents and patent applications pertinent to the development of biodefense vaccines is beyond the scope of this article, this section highlights some important patent liabilities that may arise.

based on a particular gene or marker, and that underlying gene – in an isolated or purified form – is patented, use of the gene for development of testing will constitute infringement. A developer may infringe upon a pre-existing patent for developing a new smallpox vaccine using recombinant DNA – even if the developer owns the corresponding vaccine patent – if someone else owns a patent on isolated sequences of smallpox. To the extent that DNA-based vaccines are being developed for conditions associated with bioterrorism, [116] such as anthrax[117] and smallpox,[118] this is a major issue. In addition, vaccines to treat SARS could also face the same problem since applications have already been filed on gene sequences for the SARS viruses;[119] although SARS has not yet been used as a

116. Current research and development activities concerning biodefense vaccines have focused on smallpox, anthrax, botulism, cholera, plague, and Q fever. *See, e.g.*, Philip K. Russell, *Vaccines in Civilian Defense Against Bioterrorism,* 5 EMERGING INFECT. DISEASES 531, 531-33 (1999) (discussing smallpox and anthrax in detail as posing the greatest risk for large numbers of casualties), http://www.cdc.gov/ncidod/EID/vol5no4/pdf/russell.pdf (last visited Feb. 25, 2005); *see also* NOVA ONLINE, BIOTERROR, AGENTS OF BIOTERROR (2001) (listing agents of bioterrorism), *at* http://www.pbs.org/wgbh/nova/bioterror/agents.html (last visited Feb. 25, 2005)

117. There are pending patent applications for DNA vaccines to combat anthrax. *E.g.*, Press Release, University of Wisconsin – Madison, Researchers Announce Anthrax Research Breakthrough (Oct. 23, 2001), *at* http://www.news.wisc.edu/releases/6693.html (last visited Feb. 25, 2005) (noting that the Wisconsin Alumni Research Foundation (WARF) and Harvard Medical School have jointly filed for a patent on the anthrax toxin receptor); U.S. Patent Application No. 60/171459 (filed Dec. 22, 1999) (providing genes for constructing a "DNA-based vaccine which can be used to immunize . . . against the pathogenic effects of B anthracis infection").

118. Although the currently available smallpox virus, sold as Dryvax, is made from live vaccine, there is a new smallpox DNA vaccine under development. Associated Press, *Army Scientists Eye New Smallpox Vaccine*, ABC 7 NEWS, Apr. 27, 2004, http://www.wjla.com/news/stories/0404/142778.html (last visited Feb. 25, 2005). In addition, the Army is the assignee for one DNA vaccine against smallpox. U.S. Patent No. 6,562,376 (issued May 13, 2003). However, there is at least one other patent owned by a private corporation, Virogenetics, that could pose an infringement problem if one or more of its sequences were used to create a smallpox vaccine. U.S. Patent No. 6,537,594 (issued Mar. 25, 2003).

119. *E.g.*, WTO, PATENT APPLICATIONS FOR SARS VIRUS AND GENES (May 29, 2003) (noting that teams of scientists have filed patent applications on all or part of the SARS virus genome and on the virus itself that are reported to be sufficiently broad to cover most diagnostic tests, drugs, or vaccines that would be developed to deal with an outbreak), www.who.int/ethics/topics/sars_patents/en/ (last visited Feb. 25, 2005); *see also* U.S. Patent No. 6,194,212 (issued Feb. 27, 2001). Some applications have been expressly filed for the purpose of maintaining freedom to operate for researchers. Peg Brickley, *Preemptive SARS Patents: U.S. and Canadian Agencies Say Patents will Preserve Openness*, THE SCIENTIST, May 9, 2003, http://www.biomedcentral.com/news/20030509/02 (last visited Feb. 25, 2005). However, even if there is only one patent that is owned and enforced, that could be enough to jeopardize the development of a vaccine against SARS. The World Health Organization seems cognizant of potential patent problems. *See* WHO, UPDATE 91 – SARS RESEARCH: THE EFFECT OF PATENTS AND PATENT APPLICATIONS (June 30, 2003), *at* http://www.who.int/csr/don/2003_06_30/en/ (last visited Feb. 25, 2005).

weapon of terror, its high levels of infection and mortality make it a candidate for biological terrorism.[120]

A patent may be infringed by making the patented invention without regard to what stage of development the invention is made. For example, infringement may exist if the patented invention is made during initial laboratory screening of possible compounds. Similarly, there is no per se immunity from infringement when a vaccine is in human clinical trials since FDA procedures are separate from patent liability. Accordingly, if a vaccine in clinical trials uses a patented invention and there is no prior authorization for that use, infringement exists – unless there is an exception that applies. Indeed, it is entirely possible that use of a patented invention during laboratory testing might escape notice of the patent holder but would be more easily detected once clinical testing began and news reports of such testing were public.[121] The same is also true after a vaccine completes testing and enters general commercial sales. At this point, publicity concerning the vaccine is likely even more widespread and infringement is probably more of a problem because the patented invention is likely to be not only made – which already constitutes infringement, but the patented invention is likely to be sold, or at least offered for sale – each of which constitute additional, separate acts of infringement.[122]

B. Bars to Patentability – Secrecy Provision

Although infringement is the most typical patent barrier to developing bioterrorism vaccines, there is another possible, albeit more obscure barrier, if a patent is sought in conjunction with vaccine development.[123] In particular, there

120. SARS has been officially added to a list of Priority Pathogens by the National Institute of Allergy and Infectious Diseases (NIAID) as a "class C pathogen." NIAID, NIAID BIODEFENSE RESEARCH: NIAID CATEGORY A, B & C PRIORITY PATHOGENS, *at* http://www2.niaid.nih.gov/Biodefense/bandc_priority.htm (last visited Feb. 25, 2005). This categorization is the third highest priority for pathogens and includes "emerging pathogens that could be engineered for mass dissemination in the future" because of their availability, ease of production, and dissemination, as well as the potential for "high morbidity and mortality." Ali S. Chan, et al., CDC, *Biological and Chemical Terrorism: Strategic Plan for Preparedness and Response, Recommendations of the CDC Strategic Planning Workgroup*, 49 MORBIDITY AND MORTALITY WEEKLY (MMWR) 1 (Apr. 21, 2000), *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/rr4904a1.htm (last visited Feb. 25, 2005).

121. Moreover, even if testing was not initially noticed by the patent holder, infringing activity may be subject to an infringement lawsuit up to six years after the activity. *See* 35 U.S.C. § 286 (2000). Accordingly, the failure of the patent holder to immediately discover the infringing use does not prevent an ultimate infringement suit. Moreover, multiple uses of a patented invention may lead to increased damages because damages must be adequate to compensate for the infringement. *See* 35 U.S.C. § 284.

122. 35 U.S.C. § 271(a).

123. It is difficult to assess how often secrecy orders are imposed, let alone determine the specific inventions that are subject to secrecy. Therefore, it is hard to tell whether any such orders have been imposed on inventions related to bioterrorism vaccines. However, even if they have not yet been imposed, at least one commentator has suggested that they could be used. James W. Parrett, Note, *A*

are provisions of the Patent Act that permit the federal government under certain circumstances to declare the invention that is subject to the patent application to be held secret for at least a year on grounds of national security.[124]

Although the imposition of a secrecy order may be appealed,[125] if it is not overturned, an inventor essentially must cease development of the vaccine until the secrecy order is lifted and the patent permitted to issue because the breadth of the secrecy order goes beyond just the issuance of the patent; in other words, it prohibits *any use or disclosure of the invention.*[126] The wide breadth of the secrecy order is further enforced by strict penalties for failure to comply, which include not only forfeiture of patent rights,[127] but also financial penalties as well as possible imprisonment.[128] The applicant is only entitled to limited compensation,[129] and

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Proactive Solution to the Inherent Dangers of Biotechnology: Using the Invention Secrecy Act to Restrict Disclosure of Threatening Biotechnology Patents, 26 WM. & MARY ENVTL. L. & POL'Y REV. 145 (2001) (advocating the use of secrecy provisions to address potentially dangerous biological inventions). However, this suggestion acknowledged that there would need to be some modifications to the existing law before the secrecy provisions could be aggressively used to police biotechnology. In particular, the present statute only explicitly authorizes patent applications to be reviewed by the Atomic Energy Commission, or the Secretary of Defense, or "the chief officer of another department or agency of the Government so designated" as a defense agency by the President of the United States. 35 U.S.C. § 181. Parrett suggests that the President could easily designate agencies that monitor and regulate biotechnology research as defense agencies under this provision, but provides little explanation for why they should be classified as such, other than a passing comment that the CDC already addresses epidemic disease outbreaks, so that regardless of whether the source is from terrorism should not matter. Parrett, *supra*, at 173.

124. 35 U.S.C. § 181. The statute explicitly allows for the order to be renewed annually. *Id.* Moreover, the term of the secrecy order that is imposed "during a time when the United States is at war" would be in effect for the entire "duration of hostilities and one year following the cessation of hostilities." *Id.* The statute does not define when the United States is "at war," but to the extent that the United States could be presently characterized as waging a war against terrorism of indefinite duration, a secrecy order could also be of indefinite duration.

125. The appeal would be to the Secretary of Commerce pursuant to the statute. *Id.* However, there is no judicial review provided concerning review of a secrecy order. DONALD S. CHISUM, CHISUM ON PATENTS: A TREATISE ON THE LAW OF PATENTABILITY, VALIDITY & INFRINGEMENT §1.06(2)(a) (2004); *see generally* 35 U.S.C. § 181 (providing no explicit language for judicial review of secrecy orders).

126. 35 U.S.C. § 181.

127. *Id.* § 182 (declaring that inventions subject to a section 181 secrecy order will be "held abandoned" if it is established that the order was violated by publication or disclosure of the invention or filing of a patent application in a foreign country without permission of the PTO).

128. If an inventor is found to "willfully publish or disclose" the invention, or even "material information" regarding the invention, he may be subject to a fine of up to $10,000 or imprisonment for not more than two years, or both. *Id.* § 186.

129. *Id.* § 183 (permitting an applicant whose patent is withheld to sue for compensation). The compensation is for either damage caused by imposition of the secrecy order or the use of the invention by the government, or both. *Id.*

even then, the case law suggests that the actual opportunity for compensation is more limited than the statute may suggest.[130]

The existence of secrecy provisions can negatively impact overall development of biodefense vaccines not only for individual inventors who are subject to secrecy provisions,[131] but also for all inventors who are aware that the government may bar public use and disclosure of their inventions. In particular, if obtaining a patent is shrouded with legal uncertainty, that uncertainty may undermine the ability of patents to provide an incentive to research, in direct contradiction to fundamental patent policy.[132]

Despite the potential breadth of application of secrecy provisions, their impact on biodefense vaccines is not necessarily as broad if such provisions are invalid or impermissible under either domestic or international regulations. In particular, the secrecy provisions could potentially be challenged as unconstitutional. Moreover, there is a stronger possibility that the secrecy provisions may fail to comport with the United States's obligations under TRIPS.

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130. A number of cases specifically deny compensation because the government had not actually used the invention, such that there were no damages that required compensation. *E.g.*, Constant v. United States, 1 Cl. Ct. 600, 608-09 (1982); Weiss v. United States, 146 F. Supp. 2d 113, 128-29 (D. Mass. 2001) (denying compensation for failure to show actual damages); Clift v. United States, 808 F. Supp. 101, 110-11 (D. Conn. 1991) (denying compensation on grounds that government had never used the invention and no damages were shown from secrecy order alone). However, evaluating actual compensation awarded is difficult to determine since applicants subject to a secrecy order do not necessarily obtain compensation through judicial means; in particular, the applicant can also apply to the agency that issued the order and obtain a settlement agreement. *See* 35 U.S.C. § 183.

131. Although the statute states that the term of secrecy imposed is for one year, it also explicitly allows for this period to be renewed, and the few published cases that exist suggest that the secrecy time period can be quite substantial. *See, e.g.* Halpern v. United States, 258 F.2d 36, 37 (2d Cir. 1958) (pending secrecy order more than 10 years after initial order); AT&T v. United States, 4 Cl. Ct. 157, 158-59 (1983) (twenty-six year secrecy order); Farrand Optical Co. v. United States, 317 F.2d 875, 877 (2d Cir. 1962) (nearly six years); Hornback v. United States, 40 Fed. Cl. 524, 525 (1998) (twelve year secrecy order); Weiss v. United States, 37 Fed. Appx. 518, 520 (Fed. Cir. 2002) (almost six years). Moreover, even once the patent is issued, the delay could result in a reduced patent term in which to exploit the patented invention (once the patent issues) since patent terms are calculated from the date of the filing of the initial patent application. 35 U.S.C. § 154(a)(2) (providing that general duration of patent 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"). Although the present Patent Act allows for extension of patent term for some delays due to the Patent Office, this is capped at five years, such that if the secrecy order exceeded five years, the effective time for exploitation would be reduced. *See id.* § 154(b)(1).

132. Moreover, it might lead to inventions only being developed through trade secrecy. Although that provides some protection, it is much more limited than patent protection and hence the number of companies interested in investing in research for limited protection would likely be low. In addition, promoting trade secrets, rather than patent protection, may be less beneficial to society because the information is not shared.

1. Constitutionality

Although no one contests Congress's authority to enact the secrecy provisions,[133] whether they may nonetheless be unconstitutional has occasionally been raised as an issue. The most commonly asserted argument against the secrecy provisions is that they may constitute an impermissible restraint on free speech.[134] In addition, at least one commentator has suggested that the secrecy provisions may be inconsistent with the Due Process Clause and the Takings Clause of the Fifth Amendment.[135] The takings argument is weaker than a due process argument

133. Sources of Congressional authority to authorize the Invention Secrecy Act may reside in the right to provide for the common defense, as well as eminent domain power. U.S. CONST., art. I, § 8, cl. 1 (The Patent Clause); *see also* Sabing H. Lee, *Protecting the Private Inventor Under the Peacetime Provisions of the Invention Secrecy Act,* 12 BERKELEY TECH. L.J. 345, 378 (1997) (specifically noting three possible grounds for Congressional authority to pass the secrecy provision, including the Patent Clause, Defense Clause, and eminent domain).

134. *E.g.*, Lee, *supra* note 133, at 381 (asserting that the Founding Fathers understood the importance of academic freedom and therefore intended scientific freedom to be included under the protections of the First Amendment). In addition, some well-respected intellectual property scholars have noted in passing that the Invention Secrecy Act may be one of the few circumstances in which patent law restricts speech, but that it may be a permissible restraint on speech based on grounds of national security. Mark A. Lemley & Eugene Volokh, *Freedom of Speech and Injunctions in Intellectual Property Cases*, 48 DUKE L.J. 147, 235-36 (1998). There are actually two separate First Amendment issues here – first, whether the secrecy order per se constitutes a violation of the right to speech, and second, whether punishment for violation of the secrecy order constitutes an unconstitutional prior restraint on speech. For the first issue, there is no clear authority on whether scientific expression constitutes "speech" that would be entitled to the full protection of the First Amendment. *See* Lee, *supra* note 133, at 381 (noting that expression of scientific information has never received explicit First Amendment protection). Rather, the limited discussion of this issue seems to focus more on whether scientific expression is analogous to the types of speech that are typically given less protection, such as advocacy of illegal conduct. Moreover, even if the scientific expression would *not* rise to the level of speech fully protected under the First Amendment, the prohibition of public disclosure could nonetheless be an impermissible prior restraint. Again, there is virtually no authority directly on point. However, there is a single district court case that suggests restraint of scientific information was appropriate where the magazine article in question described the hydrogen bomb and could have been used to create an atomic bomb. United States v. Progressive, Inc., 467 F. Supp. 990, 999-1000 (W.D. Wis. 1979). So, the issue for biodefense vaccines is whether disclosure of patents would be likely to wreak similar havoc as a patent application on an atomic bomb. Arguably, vaccines to combat terrorism do not have the same deadly potential to destroy as a bomb. On the other hand, disclosure of potential vaccines could be used by terrorists to help determine biological vulnerability. However, with biodefense vaccines, the link to potential havoc seems at least one step removed from the H-bomb situation.

135. Lee, *supra* note 133, at 399-409. For there to be a takings issue in the first instance, there is a threshold question of whether inventors have an adequate property interest that the Takings Clause would protect. *Id.* at 404-05. In addition, even if a patentable invention were a qualifying type of property interest, there is a second question of whether a secrecy order constitutes an actual taking of the property interest. *Id.* at 405-07. Third, even if the secrecy order does rise to this level, there is a question concerning whether the taking is for public use and whether just compensation is provided. *Id.* at 407-09. On the last two issues, a secrecy order issued on grounds of national security would seem to be for public use in light of a broad reading of the public use requirement, and there is an explicit statutory provision that provides for compensation under 35 U.S.C. § 183. There is limited judicial authority that supports the proposition that a secrecy order *in some instances* could constitute a taking.

since the secrecy order is typically imposed before a patent has issued; moreover, as previously noted, there is no absolute Constitutional right to a patent.[136]

2. TRIPS

In addition, there may also be an issue with respect to whether the secrecy provisions are vulnerable to a challenge concerning TRIPS compliance. In particular, they may be inconsistent with the Article 33 patent term requirement, the Article 62 requirement of reasonable procedures for patent grants, or possibly both provisions. Compared to some other exceptions discussed in this article, the TRIPS problem here may be more ambiguous because it could be argued that there are no existing patent rights at the time the secrecy order is imposed.[137] Moreover, unlike other exceptions, there may be a TRIPS-based exception here; in particular, there may be a defense under the Article 73 exception for national security.

The first issue is whether a secrecy order would result in a violation of the required patent term under TRIPS Article 33. At first glance, there does not seem to be a facial violation because Article 33 only states that the term of protection available "shall not end before the expiration of a period of twenty years counted from the filing date."[138] In other words, Article 33 does not guarantee an absolute

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E.g., Constant v. United States, 16 Cl. Ct. 629, 632-33 (1989) (finding no taking for mere issuance of secrecy order, but implying that *if* actual government use could be established, a takings rationale would be applicable). On the other hand, most cases dealing with secrecy orders address compensation explicitly under the statutory provision of § 183, rather than the Fifth Amendment. Lee, *supra* note 133, at 405-07. Again, this seems to be a case where there is unclear characterization of government action and compensation procedures, but there is no dissent with respect to whether the action is proper under some rationale.

136. However, there could be an argument that the Takings Clause would apply regardless of whether a patent exists if an invention itself is considered to be private property. Although there is clear authority that patents are private property, Consolidated Fruit-Jar Co. v. Wright, 94 U.S. 92, 96 (1876) (holding that a "patent for an invention is as much property as a patent for land [and] [t]he right rests on the same foundation, and is surrounded and protected by the same sanctions"), it is unclear whether inventions that are not yet patents, or inventions that may not even satisfy the patentability standard, would also be considered private property. Moreover, even assuming *arguendo* that inventions could be property subject to the Takings Clause, there still may be no actionable takings claim for the same reasons that exist with patented inventions. In particular, if a secrecy order is imposed for public use and the compensation is deemed adequate, the issue would seem to be moot.

137. In addition, if the invention is under secrecy, there is technically no patent issued, such that perhaps the typical patent right to exclude all others from the invention under Article 28 is not yet applicable. Moreover, even if this right was applicable, if the government is only keeping the invention secret, and not actually using the invention, there would still be no activity that falls under Article 28. *See* TRIPS, *supra* note 24, at art. 28. In addition, if such activity existed, it could arguably fall under the exceptions of Articles 30 and 31.

138. TRIPS, *supra* note 24, at art. 33. Similarly, the lack of immediate issuance of the patent does not seem to necessarily violate the Article 27 requirement that "patents shall be available" without discrimination as to the subject matter of the invention. *Id.* at art. 27. Pursuant to the most recent interpretation of the nondiscrimination requirement in the Canada-Generics case, the statute providing for secrecy orders would seem to pass the threshold that there be no "sham," particularly since the statute does not specify any specific type of invention, just like the Canada-Generics case. CANADA-

period of patent protection; the fact that the negotiators specifically considered and ultimately rejected a provision to extend protection for certain products that are delayed by regulatory approval processes, such as pharmaceuticals, further confirms that this provision does not guarantee an absolute period of exclusivity.[139]

However, there is also an issue with respect to whether secrecy orders violate the patent term prescribed under Article 33 when read in conjunction with Article 62, which requires reasonable procedures for granting patents. In the sole case involving interpretation of these two articles, Canada-Term of Patent Protection, the Appellate Body[140] considered whether Canada's patent term of seventeen years from the date of patent issuance complied with the TRIPS rule that a patent term be twenty years from date of filing.[141] In that context, the Appellate Body found Canada's law was inconsistent with Article 33 because there were some cases where the TRIPS term was "available, as a matter of legal right . . . and certainty."[142] However, the situation with secrecy orders is different in that the Article 33 time period of twenty years from filing is available as a matter of certainty, *but* the effective period may be significantly shorter.

Even if there is no TRIPS compliance problem based on Article 33, there could nonetheless be a problem based on Article 62 alone. In particular, Article 62 provides that members "may require, as a condition of the acquisition" of patent rights under TRIPS, "compliance with *reasonable* procedures and formalities."[143] This provision further states that members must permit the granting of a patent right "within a reasonable period of time so as to *avoid unwarranted curtailment of the period of protection.*"[144] The secrecy orders *could* result in an unwarranted and substantial curtailment of the effective patent term, but it is presently unclear whether such an order would alone run afoul of Article 62.

Even if there is a facial violation of the secrecy provisions under TRIPS Article 62, the violation could be permissible pursuant to the "security exceptions" clause under Article 73. The Clause states that nothing under TRIPS "shall be

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GENERICS, *supra* note 54, at ¶ 7.104; *see also supra* note 58. In addition, unlike the case against India where patents were not legally available, patents are technically available even where a secrecy order is applied. Report of the Appellate Body, *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products,* WT/DS50/AB/R (Jan. 16, 1998), *available at* http://docsonline.wto.org/gen_search.asp?searchmode=simple (last visited Feb. 25, 2005).

139. GERVAIS, *supra* note 25, at 256 (noting that there was an attempt to extend protection).

140. The Appellate Body reviews appeals from panel proceedings pursuant to the DSU, but only if one of the parties requests appeal. Understanding on Rules and Procedures Governing the Settlement of Disputes, General Agreement on Tariffs and Trade (GATT), Annex 2, art. 17, at 4 (1994) (noting that parties may appeal panel decisions).

141. WTO, REPORT OF THE APPELLATE BODY: CANADA-TERM OF PATENT PROTECTION ¶ 2 (2000) [hereinafter CANADA-TERM OF PATENT PROTECTION].

142. *Id.* at ¶ 90.

143. TRIPS, *supra* note 24, at art. 62(1) (emphasis added).

144. *Id.* at art. 62(2) (emphasis added).

construed . . . to prevent a Member from taking any action which it considers necessary for the protection of its essential security interests . . . taken in time of war or other emergency in international relations."[145] This provision has yet to be officially interpreted in the context of TRIPS, but it has a close correspondence to a provision in the General Agreement on Tariffs and Trade (GATT), which preceded the WTO agreement.[146] Under the analogous provisions in GATT, economic security interests alone were considered inadequate. Beyond that limited situation, it has been suggested that Article 73 enables member states to decide for themselves what constitutes a "national emergency," but the decision is subject to review under the DSU. The discussion of Article 73 thus far focuses on the fact that essential security interests extend beyond armed attack, but that the risk must be "reasonable" and the measures designed to protect those interests must be "necessary."[147] Given that the secrecy orders are premised on some type of national security problem analogous to armed attack – except with the use of biological weapons – there may at least be a plausible basis for arguing that this provision would apply.

III. ELIMINATING THE SPECTRA OF PATENT PROBLEMS

There are a number of different ways to avoid or limit liability for patent infringement. For example, the Patent Act specifies that a defendant may establish noninfringement as well as invalidity of the patent.[148] Moreover, the Patent Act notes that a proper defense would be "absence of liability for infringement," which can include both a statutory exception under the Patent Act, as well as common law defenses.[149] Although potential invalidity and noninfringement are viable

145. *Id.* at art. 73(b)(iii).

146. *See* WTO, WTO ANALYTICAL INDEX: TRIPS: AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS, *at* http://www.wto.org/english/res_e/booksp_e/analytic_index_e/trips_03_e.htm#article73B (last visited Feb. 25, 2005) (noting that there has not yet been any authoritative interpretation of TRIPS Article 73); GERVAIS, *supra* note 25, at 373 (noting that the provision "essentially corresponds to Art. XX:I of the GATT"); UNCTAD/ICTSD CAPACITY BUILDING PROJECT ON INTELLECTUAL PROPERTY RIGHTS AND SUSTAINABLE DEVELOPMENT: TRIPS AND DEVELOPMENT: RESOURCE BOOK, PART SIX: TRANSITIONAL AND INSTITUTIONAL ARRANGEMENTS – 6.6 SECURITY EXCEPTIONS 3 (Jan. 2004), [hereinafter CAPACITY BUILDING PROJECT] (noting that the provision is almost identical to Article XXI of the GATT and Article XIV *bis* of the General Agreement on Trade in Services (GATS)), http://www.iprsonline.org/unctadictsd/ResourceBookIndex.htm (last visited Feb. 27, 2005).

147. REICHMAN & HASENZAHL, *supra* note 91, at §2.2 (based upon a case before the International Court of Justice). In particular, one suggestion is that security interests are necessary if there is some proportionality between the threatened security interest and the measure taken in response to the threat. *Id.*

148. 35 U.S.C. § 282 (2000).

149. *Id.*

defenses in every patent infringement suit, establishing these defenses during litigation can be both costly and time-consuming.[150] A full analysis of those issues requires a careful analysis of the particular patents and products – something that would be difficult to do for all patents relating to biodefense vaccines and all potential infringers. Accordingly, this section focuses on highlighting some limitations and exceptions from infringement liability that seem most pertinent to the development of biodefense vaccines.[151]

A. Exceptions to Infringement

1. Absolute State Sovereign Immunity

One exception that may be relevant for use and distribution of vaccines is that states presently enjoy immunity from patent infringement with no requirement to compensate for the loss of federal patent rights. In particular, the United States Supreme Court has struck down Congressional attempts to abrogate state sovereign immunity with respect to patent infringement.[152] Although there have been some legislative proposals to reverse this position,[153] until such legislation is passed, state governments can make, use, and import vaccines without full liability for patent infringement.[154] In addition, because state universities are considered state

150. Another defense that may often be made is that the patent is unenforceable because of inequitable conduct by the patent applicant, sometimes referred to as "fraud on the patent office." *See* U.S. PATENT AND TRADEMARK OFFICE, U.S. DEP'T OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE § 2016 (8th ed., rev. 2 2004). However, again, this is a defense that requires a detailed analysis of the patent at issue and is beyond the scope of this article.

151. There are some exceptions to the Patent Act that have no applicability to the vaccine context. For example, there is a limited exception with respect to business method patents, as well as an exception from damages for medical procedure patents. *See, e.g.*, 35 U.S.C. § 273(b)(3)(a) (providing for a limited prior use defense in the case of business method patents); 35 U.S.C. § 287(c) (providing that medical providers are immune from damages for using certain types of patented medical procedures).

152. Florida Prepaid Postsecondary Educ. Expense Bd. v. Coll. Savs. Bank, 527 U.S. 627, 643-44 (1999). The decision actually held that there was no procedural due process violation in depriving the patent owner of his property right in a patent. *Id.* at 647-48. Rather, the Court stated that only if a state "provides no remedy, or only inadequate remedies" could a deprivation of property without due process result. *Id.* at 643. In this case, the state of Florida provided remedies to patent owners either through a statutory claim or through a judicial takings claim. *Id.* at 644 n. 9. In addition, the Court noted that despite lack of a federal remedy, states might still be liable for some state-based remedy pursuant to a taking of property rationale. *Id.* at 643. However, commentators have criticized such a proposal as unlikely or at least not uniformly available in every situation where a patent would be infringed.

153. *E.g.*, S. 1191, 108th Cong. (2003); H.R. 2344, 108th Cong. (2003); S. 2031, 107th Cong. (2002); S. 1611, 107th Cong. (2001); S. 1835, 106th Cong. (1999).

154. The issue of state sovereign immunity is actually a complex one. Although there is technically state sovereign immunity, there is also the possibility that state officials could be prospectively enjoined from infringement under the *Ex parte Young* doctrine. *Ex parte* Young, 209 U.S. 123, 136-37 (1908); *see also* Daniel J. Meltzer, *Overcoming Immunity: The Case of Federal Regulation of Intellectual Property*, 53 STAN. L. REV. 1331, 1334 (2001). Although the Supreme Court narrowed this decision in

actors, they would also have immunity from patent infringement.[155] This may be of particular relevance because universities often engage in research, but the perceived exception from infringement for experimental academic research has recently been narrowed.[156]

If many states were to make patented vaccines under the present immunity provision, it is possible that a subsequent court challenge might find the use to be impermissible. In particular, the Supreme Court noted that the Congressional attempt to revoke sovereign immunity did not respond to a history of "widespread and persisting deprivation of constitutional rights."[157] In light of the current health care crises that are prompting some state governors to suggest importing patented drugs in violation of typical patent infringement rights, it is possible that state patent infringement will rise, particularly if coupled with extensive use of patented vaccines.[158]

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recent years, the doctrine continues to exist. *See, e.g.*, Vicki C. Jackson, Seminole Tribe, *the Eleventh Amendment, and the Potential Evisceration of* Ex Parte Young, 72 N.Y.U. L. REV 495, 496-513 (1997); *see also* Christina Bohannan & Thomas F. Cotter, *When the State Steals Ideas: Is the Abrogation of State Sovereign Immunity from Federal Infringement Claims Constitutional in Light of* Seminole Tribe?, 467 FORDHAM L. REV. 1435, 1438-39 (1999)) (noting that injunctive relief is probably still available for ongoing, unauthorized uses of intellectual property by state actors unless those uses constitute takings for a public purpose despite recent Supreme Court cases). Moreover, there is also the possibility that state use of a patent would ultimately require compensation to the patent owner, albeit not under the patent statute. In particular, inverse condemnation theory or other "takings" rationales, as well as § 1983 actions, would govern these situations. *See, e.g.*, Menell, *supra* note 29, at 1404 (noting alternatives to injunctive relief, including inverse condemnation, in actions as well as state court remedies); Shubha Ghosh, *Toward a Theory of Regulatory Takings for Intellectual Property: The Path Left Open After* College Savings v. Florida Prepaid, 37 SAN DIEGO L. REV. 637, 665-66 (2000). *See generally* Paul J. Heald & Michael L.Wells, *Remedies for the Misappropriation of Intellectual Property by State and Municipal Governments Before and After* Seminole Tribe: *The Eleventh Amendment and Other Immunity Doctrines*, 55 WASH. & LEE L. REV. 849 (1998). Moreover, there is also the possibility that a state would consent to suit since there are reported cases where states are defendants in infringement suits. *E.g.*, Genentech, Inc. v. Regents of the Univ. of Cal., 143 F.3d 1446, 1448-49 (Fed. Cir. 1998).

155. Indeed, the defendant in the case in which the Supreme Court declared that state sovereign immunity was not abrogated in the context of patent infringement suits was a state university. *Florida Prepaid*, 527 U.S. at 630 (noting that College Savings, the plaintiff, "sued the State of Florida" for patent infringement).

156. *See infra* note 208 and accompanying text (discussing experimental use since *Madey v. Duke*, 307 F.3d 1351 (Fed. Cir 2002)).

157. *Florida Prepaid*, 527 U.S. at 628. In response to the Supreme Court decision, the GAO commissioned a report concerning state infringement, which provides an exhaustive catalog of data concerning intellectual property infringement. Robert T. Neufeld, *Closing Federalism's Loophole in Intellectual Property Rights*, 17 BERKELEY TECH. L. J. 1295, 1310-11 (2002); *see also* GAO, INTELLECTUAL PROPERTY: STATE IMMUNITY IN INFRINGEMENT ACTIONS, REP. NO. 01-811 (2001), http://www.gao.gov/new.items/d01811.pdf (last visited Feb. 25, 2005).

158. Although some states are merely providing consumers with information to import their own drugs, other states, such as Illinois, seem to favor buying drugs for at least some of their citizens. *E.g.*, Pam Belluck, *Maine and One of Its Tribes Look to Buy Canadian Drugs*, N.Y. TIMES, Oct. 1, 2004, at A12 (noting that Illinois, Minnesota, New Hampshire, North Dakota, and Wisconsin have set up websites to link consumers to Canadian pharmacies); Marilyn Werber Serafini, *The Other Drug War*,

2. TRIPS

State immunity from patent infringement poses possible problems under TRIPS. In the case of state use of patented inventions, or importation of patented vaccines, there seems to be a clear facial violation of the Article 28 right to exclude under TRIPS.[159] The only issue then would be whether state immunity can be excused under one of the exceptions. The limited commentary available on possible TRIPS noncompliance thus far has focused primarily on Article 31, probably since this is the provision that is commonly associated with compulsory licensing.[160] However, since Article 31 technically only applies to use that is outside the scope of Article 30, this part briefly addresses Article 30 first.

a. Article 30

As explained in the Canada-Generic Medicines case, Article 30 requires that the deviation from the standard patent rights be a "limited exception," in addition to two other separate inquiries. It is difficult to conceive of an argument that state sovereign immunity is "limited" – especially in the context of the Canada-Generic Medicines case holding that Canada's actions were not limited. In particular, the WTO Panel found that Canada's stockpiling provision that enabled generic manufacturers to make and stockpile patented drugs during the last six months of the patent term was not adequately limited where there were no limits on the quantities of patented product that could be made. In contrast, there are no temporal or quantity limits to state immunity – rather, under present law, states can infringe as much as they want for the entire duration of the patent.[161] Moreover, unlike the case before the WTO, state sovereign immunity allows infringement of *any* patented invention by the state, rather than a more focused subset of inventions. Based on the Canada-Generic Medicines case, this would seem to clearly fail the "limited" exception requirement, such that the other two parts of the Article 30 analysis need not even be addressed.

NAT'L J., Mar. 20, 2004 (noting that Illinois governor Blagojevich had suggested importing drugs for state employees, as well as for the state corrections systems and mental hospitals). In addition, there seems to be a growing impetus behind importing drugs. *E.g.*, Robert Pear, *Bush Hints at Policy Shift on Canadian Drug Imports*, N.Y. TIMES, Oct.12, 2004, at A20 (noting that there may soon be an official change in policy towards importation of drugs).

159. As noted earlier, TRIPS requires that all member states provide patent rights that enable patent owners to have the ability to exclude all others from making, using, selling, or importing the patented invention, subject to falling within the stated exceptions to patent rights under Articles 30 and 31. *See supra* note 24 and accompanying text.

160. *See supra* note 92 and accompanying text (discussing procedural requirements for obtaining an exception to exclusion rights).

161. However, it is possible that a state could be enjoined from infringement under the *Ex parte Young* doctrine or be liable under state-based theories. *See supra* note 154 and accompanying text.

b. Article 31

State sovereign immunity from patent infringement also seemingly fails to fall within the parameters of Article 31. Although Article 31 is occasionally noted as a potential TRIPS problem because of state immunity, there has been little detailed discussion.[162] However, a quick review of a few provisions of Article 31 shows that state immunity is probably not justified under this exception.[163] For example, state immunity does not mandate initial negotiation with the patent holder before compulsory use. Although Article 31 provides for some situations where the negotiation may be waived, there must be a "national emergency" or other situation of urgency. In addition, even in those cases, the patent owner must be informed. Current state immunity doctrine imposes no requirement that the patent owner is ever informed that his/her patent is being used without authorization, and there is no requirement to consider whether a national emergency exists.

Even if protecting the doctrine of state immunity were somehow justified as an issue of extreme emergency, none of the other requirements of Article 31 seem to be satisfied. For example, there is no consideration of individual cases on their own merits; rather, in all cases where the state is involved, a compulsory license is always permissible. Similarly, there seems to be no judicial review of "authorization of use" since there is no authorization that actually even needs to take place. Also, there is no clear system of adequate remuneration to the right holder. Although the Supreme Court asserted that there were possible monetary remedies for patent holders, the Court was contemplating possibilities *outside* the scope of patent law. It is questionable whether such remedies – to the extent they even exist – would be sufficient to fit the adequate remuneration provision.

3. Federal Government

At present, there is no general statutory provision or doctrine that enables the federal government to use all patented inventions without qualification. However, there are two specific statutory exceptions that do give the federal government substantial leeway in using patented inventions. The first statutory exception/provision is a patent provision created under the Bayh-Dole Act, while the second exception is established in the judicial code.

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162. For example, without analyzing every element of Article 31, Professor Menell stated that the remaining "hodge podge of potential remedies" available to patent owners under state law in the wake of *Florida Prepaid* affirmatively "would fall below . . . Article 31 criteria." Menell, *supra* note 29, at 1452.

163. Probably the only Article 31 requirement that is met with state sovereign immunity is the requirement that it not be a use permitted under Article 30. *See* TRIPS, *supra* note 24, at art. 31; *see also* Part III.A.2.a. (describing why Article 30 does not provide an exception from liability).

a. Bayh-Dole – Government License

Under the Bayh-Dole Act, the federal government may obtain rights to use inventions that are entirely or partially funded by a federal agency. In particular, as a result of the Bayh-Dole Act, those who receive such federal money[164] are generally permitted to "take title," i.e., own the invention,[165] subject to providing a license to the federal government to use the invention.[166] Specifically, for all inventions made in the course of federally-funded research, the government retains a "nonexclusive, nontransferable, irrevocable, paid up license" to use the invention, or have it used "for or on behalf of the United States."[167] Essentially, this enables the federal government to use any patented technology that it funded, without regard to the type of technology or the amount of government funding. Similarly, the use is permitted regardless of whether the patent is subsequently assigned to a university or even a corporate entity.

The statutory framework of Bayh-Dole does not seem to create any major TRIPS issues. In particular, because the statute provides that a license should issue

164. 35 U.S.C. § 202 (2000). Although the statute refers only to nonprofits and small business firms, it has been extended to cover essentially all entities, including large businesses. *See* Patents; Temporary Regulation, 48 Fed. Reg. 16,254 (Apr. 15, 1983) (to be codified at 41 C.F.R. ch.1) (providing for extension of act "beyond small businesses and non-profit organizations"); Executive Order No. 12,591, 52 Fed. Reg. 13,414 (Apr. 10, 1987) (further extending scope to businesses of any size); 15 U.S.C. § 1501; 35 U.S.C. § 210(c). However, the original drafters of the Bayh-Dole Act specifically rejected attempts to include large businesses within the scope of the provisions. Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1695-96 (1996).

165. There are certain procedural requirements that must be satisfied. For example, the claim to title must happen two years from when the entity discloses the invention to the federal agency. 35 U.S.C. § 202(c)(2) (2000). Otherwise, the federal agency receives title to the invention. *Id.* In addition, the statute provides that in "exceptional circumstances" the government maintains the right to deny title to the invention. *Id.* § 202(a). However, it appears that this has only been utilized once. NATIONAL CANCER INSTITUTE SOLICITATION, MOLECULAR TARGET LABORATORIES, *reprinted in* COM. BUS. DAILY, Feb. 24, 2000, *available at* 2000 WL 8961813.

166. When it was enacted in 1980, the Bayh-Dole Act was intended to promote widespread utilization of inventions funded with federal money by eliminating a Byzantine system of procedures that previously were required before contractors could take title. In particular, the sponsors of the legislation believed that patent ownership would help motivate private investors to transform the results of government research into commercial products. 35 U.S.C. § 200 (2000); *see also* Kenneth Sutherlin Dueker, *Biobusiness on Campus: Commercialization of University-Developed Biomedical Technologies,* 52 FOOD & DRUG L.J. 453, 461 (1997); David Halperin, *The Bayh Dole Act and March-In Rights* (May 2001), http://ott.od.nih.gov/Meeting/David-Halperin-Attorney-Counselor.pdf (last visited Feb. 25, 2005); GAO, TECHNOLOGY TRANSFER: AGENCIES' RIGHTS TO FEDERALLY SPONSORED BIOMEDICAL INVENTIONS, GAO-03-536, at 3-4 (2003) [hereinafter GAO TECH. TRANSFER], http://www.gao.gov/new.items/d03536.pdf (last visited Feb. 25, 2005). Although Bayh-Dole has generally been hailed as effective in promoting patents and furthering commercial development of federally funded inventions, some have questioned whether the balance should be fine-tuned, at least in the case of upstream innovations. *E.g.*, Arti K. Rai and Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289, 291 (2003).

167. 35 U.S.C. § 202(c)(4) (2000).

to the United States, this should be consistent with the TRIPS rights to exclude all *unauthorized* users from the patented invention.[168] Although it may have some of the "feel" of a compulsory license, the situation is in fact the reverse – the right to patent ownership is provided as more of a gift to the contractor to spur innovation, subject only to the small license provided to the United States. Since the grant of the patent is made subject to the license, the relationship is contractual rather than an involuntary license.

b. Limited Federal Immunity – 28 U.S.C. § 1498

There is a statutory provision within the judiciary code rather than the Patent Act that enables the federal government, as well as its government contractors, to essentially infringe patents at will without fear of injunction.[169] In particular, the federal government and those working for it have an absolute right to use, without any possibility of being enjoined,[170] subject only to having to pay "reasonable and entire compensation" afterwards if the patent owner brings a suit for such compensation.[171] Although the government may have to provide some compensation for its use (unlike the use of patents funded from federal money under Bayh-Dole), there is no liability pursuant to a typical patent infringement action. Rather, the only recourse for a patent owner is to sue in the appropriate forum for compensation after the injury has occurred.[172]

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168. *See* TRIPS, *supra* note 24, at art. 28 (noting that the right to exclude only applies to third parties "not having the owner's consent").

169. Most authorities assume that this provision is based on eminent domain principles. *E.g.*, Hughes Aircraft Co. v. United States, 86 F.3d 1566, 1571 (Fed. Cir. 1996); Leesona Corp. v. United States, 599 F.2d 958, 966 (Ct. Cl. 1979); *see also* Daniel R. Cahoy, *Treating the Legal Side Effects of Cipro: A Reevaluation of Compensation Rules for Government Takings of Patent Rights*, 40 AM. BUS. L.J. 125, 139-40 (2002) (asserting that the provision is "primarily a jurisdictional statute" that waives government immunity from private suit). However, at least one commentator has suggested that whether the Takings Clause covers patents is "technically, an unsettled question." Robert C. Wilmoth, *Toward a Congruent and Proportional Patent Law: Redressing State Patent Infringement After* Florida Prepaid v. College Savings Bank, 55 S.M.U. L. REV. 519, 564 (2002); *see also* Odetics, Inc. v. Storage Technology Corp., 14 F. Supp. 2d 785, 793 n. 22 (E.D. Va. 1998) (noting that "infringement by the government *is more akin to a taking*") (emphasis added). In addition, although there is a case that specifically states that this provision is not an eminent domain proceeding, it nonetheless notes that it has a similar theoretical basis and does not question that there is authority for its enactment. De Graffenried v. United States, 29 Fed. Cl. 384, 386-89 (1993) (noting that section 1498 cannot constitute an eminent domain proceeding in a technical sense because the United States has not taken any property).

170. *E.g.*, Trojan, Inc. v. Shat-R-Shield, Inc., 885 F.2d 854, 856 (Fed. Cir. 1989) (noting that "[a] supplier or potential supplier of an infringing product *for the government* is 'immune' from injunctive relief") (citing W.L. Gore & Assoc. v. Garlock, Inc., 842 F.2d 1275, 1281-82 (Fed. Cir. 1988)); *Garlock*, 842 F.2d at 1283 (noting that "[t]hough injunctions may seem to say that making for and selling to the government is forbidden, injunctions based on patent rights cannot in reality do that because of 1498(a)").

171. 28 U.S.C. § 1498(a) (2000).

172. *Id.*

The actors who are potentially covered by this provision are quite broad since the statute refers to unauthorized use "by or for the United States."[173] Use by the federal government includes various government agencies,[174] contractors, and subcontractors.[175]

This provision is not limited to any particular type of invention or specific use and there are also no procedural requirements that must precede government use. Accordingly, when former Secretary of the Department of Health and Human services, Tommy Thompson, announced during the anthrax scare that the United States had the authority to "break" the Cipro patent and produce generic versions without Bayer's permission,[176] he was in fact correct under this law.[177]

Even though § 1498 of the Judiciary Code may provide authority under United States law, it is questionable whether this provision complies with either of the TRIPS exceptions to patent rights.[178] As an initial matter, unauthorized use of the patented invention would violate the Article 28 right to exclude. Accordingly, the issue is whether this provision can be justified under Article 30 or Article 31. Although the few commentators that have discussed TRIPS compliance with this provision have assumed that Article 31 is the only exception to apply,[179] Article 31 explicitly states that it only applies to use not covered by Article 30.[180] As with the

173. *Id.*

174. A report by the National Institutes of Health in fact relied upon this provision in stating, "As a government agency, NIH may use and manufacture any patented invention, whether or not developed with federal funds, and authorize its use and manufacture by others for the United States, without a license, subject to liability for 'reasonable and entire compensation' under 28 U.S.C. § 1498." REPORT OF THE NATIONAL INSTITUTES OF HEALTH, WORKING GROUP ON RESEARCH TOOLS (June 4, 1998), http://www.nih.gov/news/researchtools/ (last visited Feb. 25, 2005).

175. 28 U.S.C. § 1498. The origin of this provision was to relieve government contractors entirely from potential patent liability in the context of an ongoing war when this provision was enacted in 1918. Richmond Screw Anchor Co. v. United States, 275 U.S. 331, 345 (1927); Robishaw Engineering, Inc. v. United States, 891 F. Supp. 1134, 1140 n.10 (E.D. Va. 1995) (noting that the provision was enacted in response to difficulties encountered by military officials in procuring necessary goods from private manufacturers). *See also* 48 C.F.R. § 27.104(c) (2003) (noting that "by appropriate contract clauses" the government authorizes and consents to such use of inventions in performing government contracts "even though the inventions may be covered by U.S. patents . . .").

176. Carroll & Winslow, *supra* note 14.

177. 28 U.S.C. § 1498; *see also* Memorandum from Al Engelberg, *supra* note 7 (providing extensive legal analysis regarding authority for compulsory licenses of Cipro under 28 U.S.C. § 1498).

178. Indeed, this issue was occasionally raised as a potential problem in the context of the anthrax scare.

179. *See infra* notes 181-84 and accompanying text. Some discussions do not even clearly articulate which provision of TRIPS would be relevant. For example, one recent report by the Chemical & Biological Arms Control Institute (CBAI) provided an extensive discussion of legal issues necessary to develop a national vaccine strategy, but only discussed a possible TRIPS problem in passing. BIODEFENSE ROAD MAP, *supra* note 15, at 32-33 (noting that "[t]he government does have the right to use patents with a license [and] this goes against the spirit of . . . TRIPS.").

180. TRIPS, *supra* note 24, at art. 31.

TRIPS analysis of state sovereign immunity, the Article 30 exception will be analyzed first.

(i) Article 30

Limited Exception

The threshold question for Article 30 analysis is whether § 1498 constitutes a "limited exception." As previously discussed, the sole WTO Panel to address the definition of this provision specified that a limited exception must be limited in scope. This provision presents a similar problem to state sovereign immunity with respect to the fact that there is no limit to the duration of infringement or quantity of infringing product. Given that the stockpiling provision was held impermissible under Article 30 for failing to be sufficiently limited even when its scope was confined to the last six months of the patent term, the lack of *any* temporal limits on § 1498 would not appear sufficiently limited. It could be argued, however, that the stockpiling comparison is not entirely apt since there was no compensation provided in the case of stockpiling, whereas § 1498 does explicitly provide for some compensation, thus making the provision arguably more limited. It is still difficult to reconcile the broad scope of § 1498 with the Panel requirement that this be applicable to "small" exceptions. However, assuming this could be justified as limited, the next two prongs of Article 30 will be analyzed.

Unreasonable Conflict with Normal Exploitation?

As with the "limited exception" requirement, what constitutes "normal exploitation" of a patent is difficult to determine because the Panel ruling was fact-specific. Normal exploitation in the Canada-Generics Medicines case involved a de facto extension of patent monopoly. However, here the issue would likely be whether normal exploitation would include having the government or one of its contractors use the patented invention at will, subject only to paying a royalty after the fact. In addition, the Panel did not define what constitutes an unreasonable conflict. Although this provision is probably not met, there is also no dispositive answer, such that the final provision of Article 30 – whether there is unreasonable prejudice to the legitimate interests of the patent owner – will be considered.

Unreasonable Prejudice to Legitimate Interests of Patent Owner, Taking into Account Third Party Interests

As with the "normal exploitation" language, there remains the question of what constitutes a legitimate interest of the patent owner. Legitimate interest in the Canada-Generics case seems not to include having the same effective term of patent protection as other patented inventions; however, this does not seem to be an issue with respect to § 1498. The patent owner's interests in making the best

commercial use of the invention would seem to be prejudiced here. Whether the patent owner's interests are *unreasonably* prejudiced is difficult to determine. Also, it is unclear whether third party interests change the analysis. Unlike the case of patent protection of pharmaceuticals, government use under § 1498 would not provide any immediate consumer benefit. It could be argued that § 1498 ensures that monopoly-like prices are not charged for government projects that involve patented inventions. However, this could nonetheless constitute unreasonable prejudice.

(ii) Article 31

A quick review shows that § 1498 is unlikely to comply with all the requirements of Article 31.[181] The explicit language of § 1498 seems to be a close fit for the types of situations governed by Article 31; in particular, Article 31 addresses use by "government or third parties authorized by the government," which is very similar to the language and intent of § 1498.[182] However, with respect to the procedural conditions that must be met before granting an authorized compulsory license under Article 31, § 1498 does not come close. In contrast to Article 31's requirements of consideration of the individual merits of the invention, as well as a limited duration of use, the loose language of § 1498 provides for "no waiting period . . . no formalities . . . no notice to the patent holder . . . no hearing."[183] Although Article 31 does permit use without the patent owner's permission in some situations, those situations are limited to cases of emergency or national urgency, neither of which is required by § 1498.[184]

4. Limited Exceptions for All Actors

Whereas the previous two sections focused on exceptions that only apply to either state or federal government, this section discusses two exceptions that apply

181. Not surprisingly, some commentators have already stated that § 1498 fails to comply with TRIPS Article 31. *E.g.*, James Thuo Gathii, *The Structural Power of Strong Pharmaceutical Patent Protection in U.S. Foreign Policy*, 7 J. GENDER RACE & JUST. 267, 281-82 (2003) (arguing the United States has used its power for strong patent protection, thereby limiting the capability of developing nations to treat their citizens); Paul Janicke, *Current State of U.S. Patent Law Regarding Infringement of Drug Patents by the Government* (2001), *at* http://www.law.uh.edu/healthlawperspectives/Food/011207Current.html (last visited Feb. 27, 2005) (noting that § 1498 is in "full force and effect," despite its apparent contradiction to Article 31). In addition, the fact that § 1498 fails to comply with Article 31 has been noticed by at least one member state of the WTO. *See, e.g.* EUROPEAN COMMISSION, REPORT ON UNITED STATES BARRIERS TO TRADE AND INVESTMENT, (Dec. 2003), *available at* http://trade-info.cec.eu.int/doclib/html/115383.htm (last visited Feb. 27, 2005) (discussing the failure of the United States to comply with Article 31).

182. *Compare* TRIPS, *supra* note 24, at art. 31 *with* 28 U.S.C. § 1498.

183. Janicke, *supra* note 181.

184. *Compare* TRIPS *supra* note 24, at art. 31 *with* 28 U.S.C. § 1498. Moreover, even where use is permitted without initial consultation of the patent owner, the patent owner must be notified as soon as possible – another condition that is not required under the United States statute. *Id.*

to all actors. In general both of these exceptions are much more narrow than the ones that presently exist for government actors. They are nonetheless of great importance to non-governmental actors who have no recourse from liability under the other provisions. In addition, even for governmental actors, these provisions may prove to be highly relevant to the extent that the present governmental exceptions or immunities are eliminated, either by judicial action or because of problems with TRIPS.

a. March-In Rights

The first exception is part of the Bayh-Dole Act, which, as previously discussed, provides the government with a right to use patented inventions funded with federal money.[185] In addition to the compulsory license to the federal government, there is an additional exception from patent liability for non-governmental actors in some instances. The federal agency that funded the invention has the right to grant a non-exclusive license to a "responsible applicant or applicants" on terms that are "reasonable under the circumstances" if one or more conditions exist that would require protecting the public's interest.[186] The rights that the federal agency may grant are commonly referred to as "march-in" rights and are intended to prevent abuses of rights provided by the Bayh-Dole legislation. In particular, because Bayh-Dole was intended to "promote the utilization of inventions arising from federally supported research or development,"[187] the march-in provisions were designed to "ensure that the Government . . . protect[s] the public against nonuse or unreasonable use of inventions."[188] There are two primary provisions that may trigger march-in rights: (1) where the contractor or assignee "has not taken, or is not expected to take within a reasonable time, effective steps to achieve *practical application of the subject invention,*" or (2) "*to alleviate health or safety needs* which are not reasonably satisfied by the contractor, assignee, or their licensees."[189]

185. *See supra* notes 164-67 and accompanying text.

186. 35 U.S.C. § 203 (2000). In particular, the statute provides that the federal agency can require the grant of reasonable licenses to third parties if it finds (1) that the contractor failed to take effective steps in a reasonable amount of time to achieve practical application of the invention; (2) that a license is needed to alleviate health and safety needs which are not reasonably satisfied by the contractor; (3) that a license is needed to meet requirements for public use specified by federal regulations which are not reasonably satisfied by the contractor; (4) that a license is needed to insure that the invention is substantially manufactured in the United States. *Id.*

187. 35 U.S.C. § 200.

188. *Id.*

189. 35 U.S.C. § 203 (emphasis added). Although there are two additional provisions that may technically trigger march-in rights, the referenced provisions are the ones that have been repeatedly cited in the actual petitions. The other provisions are more procedural issues and do not specifically implicate public health and safety. *See id.*

Although there has been scholarly commentary suggesting that march-in rights could be more aggressively used to address health care costs,[190] the NIH has yet to grant a petition for march-in rights.[191] The first petition for march-in rights was filed by CellPro in 1997, on the basis that the patent holder had failed to take effective steps to ensure practical application of the invention since CellPro was the only one to be selling an FDA-approved device within the scope of the patent claims.[192] The NIH denied the petition,[193] which allegedly contributed to the bankruptcy of CellPro,[194] and prompted discussion of the march-in rights legislation.[195] Some commentators have expressed optimism for the potential utility of march-in rights, based on the fact that *CellPro* involved some unique circumstances, such as the fact that the march-in request was made after CellPro had both turned down an opportunity to license the invention, and been found to willfully infringe.[196]

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190. *E.g.*, Peter S. Arno & Michael H. Davis, *Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed upon Patents Deriving in Whole or in Part from Federally Funded Research*, 75 TUL. L. REV. 631, 659-67 (2001); Jerome H. Reichman, Testimony Before NIH Public Hearing on March-in Rights under the Bayh-Dole Act (May 25, 2004), http://essentialinventions.org/drug/nih05252004/ (last visited Feb. 25, 2005).

191. Indeed, it may be that march-in rights have never been granted by any federal agency. GAO TECH. TRANSFER, *supra* note 166, at 5 (noting that it is believed that the government has never invoked march-in rights).

192. *See* Johns Hopkins Univ. v. CellPro, 978 F. Supp. 184, 189 (D. Del. 1997) (noting that CellPro obtained FDA approval for its system in December 1996, before any of the licensees of the Johns Hopkins University); Avital Bar-Shalom & Robert Cook-Deegan, *Patents and Innovation in Cancer Therapeutics: Lessons from CellPro*, 80 MILBANK Q. 637, 638, 652 (2002) (noting that CellPro was the first time any federal agency was petitioned to march in to compel licensing).

193. Harold Varmus, National Institutes of Health, Determination in the Case of Petition of CellPro, Inc. (Aug. 1, 1997), http://www.nih.gov/news/pr/aug97/nihb-01.htm (last visited Feb. 25, 2005).

194. Luke Timmerman, *Biotech Patent Policy Muscled Away Future of Once-Bright CellPro*, SEATTLE TIMES, Jan. 5, 2003, at F1 (discussing CellPro's case as an example of problems with patent law); Bar-Shalom & Cook-Deegan, *supra* note 192, at 638 (discussing the CellPro bankruptcy).

195. *E.g.*, Bar-Shalom & Cook-Deegan, *supra* note 192; Barbara M. McGarey & Annette C. Levey, *Patents, Products, and Public Health: An Analysis of the CellPro March-in Petition*, 14 BERKELEY TECH. L.J. 1095, 1108-09 (1999); Peter Mikhail, Hopkins v. CellPro*: An Illustration that Patenting and Exclusive Licensing of Fundamental Science is Not Always in the Public Interest*, 13 HARV. J. L. & TECH. 375 (2000); Tamsen Valoir, *Government Funded Inventions: The Bayh-Dole Act and the* Hopkins v. CellPro *March-in Rights Controversy*, 8 TEX. INTELL. PROP. L.J. 211 (2000). *See also* Gretchen Dunbar, Comment, *'Real as Pro Wrestling':* Johns Hopkins University v. CellPro *and the Federal Court's Power of Review in Patent Infringement Actions*, 18 SANTA CLARA COMPUTER & HIGH TECH. L.J. 275 (2002) (focusing on the impact of court review of jury verdicts on the CellPro case).

196. Moreover, at the time the NIH decided the march-in petition, there was no injunction on CellPro's sales of the infringing devices; rather the court had stayed imposition of a permanent injunction until there was an alternative device sold on the market. Johns Hopkins Univ. v. CellPro, Inc., No. 94-105-RRM (D. Del. July 24, 1997); *see also* Bar-Shalom & Cook-Deegan, *supra* note 192, at 645 (describing the complex situation surrounding CellPro's infringement, including its belief on the advice of legal counsel that the patents at issue were invalid); McGarey & Levey, *supra* note 195, at 1108-09.

The NIH, however, has recently dashed hopes that march-in rights could help alleviate soaring health care costs by denying two separate petitions. In July 2004, the NIH denied the march-in petition by a non-profit company, Essential Inventions, to manufacture the drug Ritonavir.[197] The NIH rejected the contention that Abbott Laboratories's 400 % price increase on the cost of the drug, also called Norvir, constituted a denial of health needs that justified march-in rights.[198] Rather, the NIH considered march-in rights to be an "extraordinary remedy" that "is not an appropriate means of controlling drug prices."[199] By characterizing the petition as an "issue of drug pricing" the NIH suggested that the issue was one that extended beyond march-in rights and had "global implications," such that it should be "appropriately left for Congress to address legislatively."[200] The NIH took similar action in September 2004 with respect to a petition to utilize march-in rights for Xalantan, which is priced higher in the United States than other countries.[201] The NIH reiterated the position that march-in rights are extraordinary remedies for drug prices and that the issue should be left to Congress.[202]

b. Experimental Use

As stated by the Federal Circuit, the typical court of last resort in patent litigation cases, the common law doctrine of experimental use in the United States is "truly narrow."[203] Contrary to lay perceptions, there is no general exception for experimentation on patented compounds.[204] Courts have repeatedly declared the doctrine unavailable when there is any connection with a commercial enterprise. For example, experiments to determine whether the patented invention works[205] as

197. According to its petition, Essential Inventions is a "private, not-for-profit corporation" that was organized in January 2004 to "support the creation of and access to Essential Inventions, including medicines." Petition to Use Authority Under Bayh-Dole Act to Promote Access to Ritonavir, Supported by National Institute of Allergy and Infectious Diseases Contract No. AI27220 2 (Jan. 29, 2004) [hereinafter Essential Inventions Petition], http://www.essentialinventions.org/legal/norvir/norvir-29jan04petition.pdf (last visited Feb. 25, 2005).

198. Elias A. Zerhouni, National Institutes of Health, Determination in the Case of Petition of Essential Inventions 5-6 (July 29, 2004) (on file with the Journal of Health Care Law and Policy).

199. *Id.*

200. *Id.* at 6.

201. Elias A. Zerhouni, National Institutes of Health, Determination in the Case of Petition of Xalantan (Sept. 17, 2004), http://ott.od.nih.gov/NewPages/xalatan.pdf (last visited Feb. 25, 2005).

202. *Id.* at 5-6.

203. Roche Products, Inc. v. Bolar Pharmaceutical Co., 733 F.2d 858, 863 (Fed. Cir. 1984).

204. For example, the Federal Circuit in *Madey v. Duke Univ.* noted that there are few cases evaluating experimental use and that the lower court could have been led astray by at least one other opinion that improperly analyzed the scope of experimental use. 307 F.3d 1351, 1362 (Fed. Cir. 2002) (noting that the district court's reliance on Ruth v. Stearns-Roger Mfg. Co., 13 F. Supp. 697, 713 (D. Colo. 1935) was inconsistent with prior Federal Circuit precedent).

205. Pitcairn v. United States, 547 F.2d 1106 (Ct. Cl. 1975); Eyal H. Barash, Comment, *Experimental Uses, Patents, and Scientific Progress*, 92 NW. U. L. REV. 667, 687-88 (1997).

well as experiments to improve on the patented invention have been deemed infringement.[206] An oft-quoted characterization is that the experimental use exception only covers experiments conducted "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."[207] Accordingly, any use of a patented invention remotely related to development of a commercial vaccine, even if at an early stage of development, would be unlikely to fall within the parameters of this narrow exception.

Contrary to a long-held belief by many university administrators, experiments conducted on the campuses of non-profit educational institutions are not per se immune from patent infringement, as the Federal Circuit recently clarified in the case *Madey v. Duke University*.[208] The Federal Circuit did not completely dismiss the relevance of an institution's status as a non-profit institution, but in finding that the district court had placed undue reliance on this factor,[209] the Federal Circuit also provided further limitations that could negate the possibility of experimental use in most cases. The boundaries of experimental use seem further restricted by the court's announcement in *Madey* that:

> [R]egardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is *in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical* inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense.[210]

In this particular case, the court opined that as a major research university, even experiments with "arguably no commercial applications whatsoever" may still fail to be within the parameters of experimental use to the extent that they "further the institution's legitimate business objectives."[211] Specifically, the court considered such objectives to include educating students and faculty, as well as

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206. *E.g.*, Embrex, Inc. v. Service Engineering Corp., 216 F.3d 1343, 1348-50 (Fed. Cir. 2000) (limiting the scope of the Bolar exception under 271(e)(1) to only apply to experiments conducted specifically for FDA approval, but not covering experiments to identify the best drug candidate to submit for future clinical testing for eventual FDA approval).

207. *Roche*, 733 F.2d. at 863; *see generally Madey*, 307 F.3d 1351.

208. 307 F.3d 1351 (Fed. Cir. 2002); Katherine J. Strandburg, *What Does The Public Get? Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81, 85 (2004) (noting that "*Madey* contradicted a belief widespread in the research community . . . that all nonprofit research was exempt from infringement liability."); GAO TECH. TRANSFER, *supra* note 166, at 11-13 (noting that although some researchers believed that use of patented technology for "purely scientific endeavors" was exempt from patent infringement and that patent owners reported a "gentleman's agreement" not to pursue such research for infringement, the *Madey v. Duke Univ.* decision may undermine prior belief that scientific research was exempt). But if the educational institution is a *state* university, the immunities previously discussed would be relevant. *See supra* notes 152-58 and accompanying text.

209. *Madey*, 307 F.3d at 1362.

210. *Id.* (emphasis added).

211. *Id.*

increasing the status of the institution and luring "lucrative research grants, students and faculty."[212]

Although the scope of experimental use under common law is now incredibly narrow, there are at least no substantial TRIPS issues. In particular, although experimental use would technically be an impermissible infringement of Article 28 rights, it is likely justified under Article 30. Commentators have long assumed that Article 30 covered experimental use, however defined by individual countries.[213] Moreover, although the Canada-Generic Medicines case technically did not rule on this issue, it did suggest that this type of use would be permissible under Article 30.[214]

B. Other Limitations to Patent Liability

This final section addresses possible limitations to patent liability that may be relevant if none of the exceptions discussed in the previous section are applicable. Whereas the prior section discussed specific common law and statutory exceptions to infringement, this section discusses potential limitations to full patent liability. For instance, the first example discussed is a limited equitable practice of not imposing injunctions for patent infringement when doing so would be contrary to public health needs. As discussed in this section, this is subject to the discretion of individual judges, which represents a less reliable means of minimizing patent liability than any of the exceptions discussed in the foregoing section. In addition, this section also considers the possibility of new statutory limitations based on past Congressional action as well as present obligations under TRIPS. Although there is no pending legislation that would create exceptions to patent liability with regard to biodefense vaccines in particular, this section provides a brief sketch of domestic and international issues that should be considered if such exceptions are seriously contemplated.

1. Infringement without Injunction

The first type of limitation does not provide immunity from patent infringement charges, but does provide a possible limit to the extent of liability with respect to damages. In particular, the Patent Act explicitly states that in cases of unauthorized infringement, the patentee shall be awarded damages that provide at least a "reasonable royalty."[215] Accordingly, if none of the exceptions discussed

212. *Id.*

213. *See* CANADA-GENERICS, *supra* note 54, at ¶ 4.37. In addition, prior drafts of Article 30 explicitly suggested the inclusion of experimental use. GERVAIS, *supra* note 25, at 241.

214. CANADA-GENERICS, *supra* note 54, at ¶ 4.37.

215. 35 U.S.C. § 284 (2000) (stating that "[u]pon finding for the claimant the court *shall* award the claimant damages adequate to compensate for the infringement, but *in no event less than a reasonable royalty* for the use made of the invention by the infringer . . . .") (emphasis added).

in the previous section are applicable, a court *must* impose some type of monetary damages.

However, a court *does* have discretion within its equity powers to decide whether to impose an injunction on infringing activity where it finds a defendant to be infringing a patent.[216] The possibility that an injunction may not be imposed could be very important if a patented invention is used for widespread vaccination that could be halted by imposition of a preliminary or permanent injunction.

This possibility, however, is fairly remote in most cases. Although there is some precedence for courts to decline to impose such injunctions, recent cases typically assert that a permanent injunction should be part of the patent owner's right once infringement is established.[217] The cases in which courts decline to impose injunctions are rare, typically requiring a situation where imposition of an injunction would cause actual public harm;[218] however, economic harm to a defendant is not considered to be a public harm.[219] In addition, because those cases

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216. *See* 35 U.S.C. § 283 (2000) (providing that courts "*may* grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable") (emphasis added).

217. Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1247 (Fed. Cir. 1989) (noting that "[i]t is the general rule that an injunction will issue when infringement has been adjudged, absent a sound reason for denying it."); KSM Fastening Systems, Inc. v. H.A. Jones Co., 776 F.2d 1522, 1524 (Fed. Cir. 1985) (noting that "injunctive relief against an infringer is the norm"). *See also* Smith Int'l, Inc. v. Hughes Tool Co., 718 F.2d 1573, 1577-78 (Fed. Cir. 1983) (noting that without the right to exclude, the express purpose of "the Constitution and Congress, to promote the progress of the useful arts, would be seriously undermined").

218. There are two famous but very dated cases that are oft-cited for this point. Vitamin Technologists, Inc. v. Wis. Alumni Research Found., 146 F.2d 941, 945 (9th Cir. 1944) (declining to issue an injunction where it would have resulted in higher incidence of rickets); Milwaukee v. Activated Sludge, Inc., 69 F.2d 577, 593 (7th Cir. 1934) (denying injunctive relief where requested relief would have closed the city sewage plant and resulted in the dumping of raw sewage into public areas, resulting in a clear public health hazard). *See also* Continental Paper Bag Co. v Eastern Paper Bag Co., 210 U.S. 405, 424-30 (1908) (declining to rule on whether a court might be justified in withholding relief by injunction in "view of the public interest"). The fact that there are no recent cases underscores their exceptionality. This is particularly true since the Federal Circuit was created after these decisions and it has created precedence for a stronger presumption of permanent as well as preliminary injunctions. *See, e.g., Smith International*, 718 F.2d at 1581 (holding that where patent has been found valid and infringed, irreparable harm is presumed for purpose of issuing preliminary injunction); *see also* MERGES & DUFFY, PATENT LAW, 1056-57 (2003) (noting that the creation of the Federal Circuit has substantially increased the number of preliminary injunction motions granted, such that the number granted now exceeds 60%).

219. *See, e.g.*, Polaroid Corp. v. Eastman Kodak Co., 641 F. Supp. 828, 1985 U.S. Dist. LEXIS 15003, at **5 (D. Mass. 1986), *aff'd*, 789 F.2d 1556 (Fed. Cir. 1986) (granting an injunction against infringer, without regard to fact that the injunction would result in job loss to 800 full-time and 3,700 part-time employees, as well as result in substantial financial losses to the defendant). In addition, even if an injunction will put a defendant out of business, it is not considered a public policy problem. *E.g.*, Windsurfing Int'l, Inc. v AMF, Inc. 782 F.2d 995, 1003 n.12 (Fed. Cir. 1986) (refusal of district court to grant injunction because it might put the defendant out of business was abuse of discretion); Johns Hopkins Univ. v. CellPro, 978 F. Supp. 184, 196 (D. Del. 1997) (trebling the damages for patent infringement even though defendant was relatively small company).

are dated, a present court may be disinclined to follow what may represent antiquated precedent. However, there is some recent authority for courts to deny preliminary injunctive relief or to temporarily stay the imposition of a permanent injunction in the interests of public health if the infringing product is the only available product. [220] Often in these cases courts will allow the injunction to be stayed not only until a new product is available, but also for an additional small period of time to enable patients to transition to a new product.[221]

2. Explicit New Exceptions

In addition to the foregoing exceptions, there is the possibility that Congress could exercise its legislative authority to minimize patent barriers to the creation of vaccines for biodefense. The Constitutional basis for the patent system grants Congress the right to decide what, if any, patent system shall exist. Congress may at any time limit or even eliminate patents pursuant to this authority. As discussed earlier, because the United States is subject to international agreements that now mandate the existence of a patent system with some minimum requirements, regardless of Constitutional authority, Congress should not reduce patent protection below these levels without subjecting the United States to possible noncompliance with TRIPS.

As TRIPS is now the minimum level below which patent protection cannot fall, a re-cap of TRIPS requirements is pertinent to examining what possible adjustments to patent protection could be made in the interest of reducing patent barriers to the development of biodefense vaccines. As discussed earlier, there are two possible ways that patent rights can be modified under TRIPS – either by

220. For cases in which a court declined to issue a preliminary injunction, see Hybritech, Inc. v. Abbott Labs., 4 USPQ2d 1001, 1015 (C.D. Cal. 1987), *aff'd*, 849 F.2d 1446 (Fed. Cir. 1988); Scripps Clinic & Research Found. v. Genentech, Inc., 666 F. Supp. 1379, 1401 (N.D. Cal. 1987), *on motion for reconsideration*, 678 F. Supp. 1429 (N.D. Cal. 1988), *further opinion*, 707 F.Supp. 1547 (N.D. Cal. 1989), 724 F. Supp. 690 (N.D. Cal. 1989), *aff'd in part, rev'd in part, vacated in part & remanded*, 927 F.2d 1565 (Fed. Cir. 1991); American Cyanamid Co. v. U.S. Surgical Corp., 833 F. Supp. 92, 134 (D. Conn. 1992) (the accused infringer's product, an absorbable suture, "has spurred interest from numerous hospitals and doctors, who see it potentially as an innovative product with advantages over the previously existing products").

221. The CellPro case is one example. Johns Hopkins Univ. v. CellPro, 978 F. Supp. 184, 189 (D. Del. 1997); *see also supra* note 192 and accompanying text; Schneider (Europe) AG v. SciMed Life Systems, Inc., 852 F. Supp. 813, 850-51, 861-62 (D. Minn. 1994), *aff'd*, 60 F.3d 839 (Fed. Cir. 1995), *cert. denied*, 516 U.S. 990 (1995) (granting permanent injunction with a one-year transition "to allow an efficient and non-disruptive changeover for those institutions and physicians who now employ the [infringer's product] exclusively"); Ethicon Endo-Surgery v. U.S. Surgical Corp., 855 F. Supp. 1500, 1517 (S.D. Ohio 1994) (noting that to suddenly withdraw the infringing devices with which a large number of surgeons are "unquestionably" familiar and have been trained to use "could have a serious disruptive effect on surgical practice"); Shiley, Inc. v. Bentley Labs., Inc., 601 F. Supp. 964, 971 (C.D. Cal. 1985), *aff'd*, 794 F.2d 1561 (Fed. Cir. 1986) (granting an injunction against defendant's sale of an infringing blood oxygenator, but delaying the injunction for six months to minimize negative impacts on hospitals and surgery candidates).

reducing the scope of patentable subject matter or by creating exceptions to patent rights. Each will be discussed in turn.

a. Limits to Patentable Subject Matter

While theoretically possible, proposed limits to patentable subject matter are likely to face serious opposition in Congress. The United States Supreme Court has taken an expansive view of patentable subject matter and repeatedly stated that Congress can limit the laws if it sees fit.[222] However, proposals to limit patentable subject matter have thus far not been politically viable. In particular, although there have been proposals to deny patentability to controversial subject matter ranging from transgenic animals to products of human cloning, so far, no such legislation has been passed.[223] There have also been indirect attempts to limit the scope of patentable subject matter. For example, a recently-passed appropriations bill proposes to disallow the PTO from using government funds to issue patents on inventions that are "directed to . . . a human organism."[224] Although TRIPS clearly permits some exclusions from patentability, in light of the unlikely passage of such subject matter exclusions due to existing judicial precedent and political limitations, a TRIPS analysis seems unnecessary.[225]

b. Limits to Patent Rights/Exceptions to Patent Infringement

Based on past history, it may be easier for Congress to enact exceptions to patent rights than to create new exclusions for patentable subject matter. For

222. Diamond v. Chakrabarty, 447 U.S. 303, 315 (1980); J.E.M. AG Supply, Inc., v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124 (2001).

223. *E.g.*, S. 2600, 107th Cong. (2002); *see also infra* note 226 and accompanying text (concerning enacted law to limit remedies for infringement of patented medical procedures, rather than proposed legislation to eliminate such technology from the scope of patentable subject matter). Similarly, Congress has declined to enact legislation to impose moratoriums on patentability of controversial subject matter. *See, e.g.*, S. 387, 103rd Cong., § 3 (1993) (proposing two-year moratorium on the patenting of animals); S. 2169, 101st Cong., § 2 (1990) (proposing five-year moratorium on patenting of genetically modified animals).

224. Consolidated Appropriations Act of 2004, Pub. L. No. 108-199, § 634, 118 Stat. 3, 100 (codified as amended in scattered sections of 7 U.S.C., 12, U.S.C., 15 U.S.C., 22 U.S.C., 28 U.S.C., 49 U.S.C) (prohibiting the PTO from using government funds to "issue patents on claims directed to or encompassing a human organism"). However, because it is in an appropriations bill, it will automatically expire after the fiscal year, unless renewed. In addition, it is notable that the Weldon amendment was passed after a more direct attempt to amend the Patent Act had failed. In particular, Senator Brownback had previously proposed an amendment to a Terrorism Bill (providing for federal funding to insurance companies) that included an amendment to narrow the scope of patentable subject matter. S. 2600, 107th Cong. (2002). Although Brownback's original amendment was blocked, when it was re-drafted as the Weldon amendment to limit funding of the PTO for issuance of similar patents, it was passed.

225. To the extent that exclusions from patentability appear to be a viable option, the same principles discussed earlier concerning TRIPS parameters for subject matter are pertinent. *See supra* notes 55-106 and accompanying text.

example, Congress enacted legislation to allow generic drug manufacturers the ability to use patented inventions during the patent term for the purposes of obtaining FDA approval that would speed the sale of such generics after the patent expires.[226] Congress also enacted legislation that immunizes medical doctors from infringement when using certain patented medical procedures.[227] Interestingly, the exception for medical doctors was enacted instead of proposals to exclude the subject matter from patentability, suggesting that limitations to patent rights may be politically more palatable.[228] Moreover, although this exception was somewhat controversial when enacted, there have since been some proposals that essentially build upon this framework with the intent of expanding the exception to include medical tests.[229]

Although it may be more palatable to enact statutory exceptions to patent rights, compliance with TRIPS remains an important issue. As discussed in the context of the Canada-Generics decision, the interpretation of a limited permissible exception is quite narrow. In addition, although there are presently some United States laws that permit infringement broadly, it is not clear that these would withstand a challenge under the WTO framework. To avoid problems under TRIPS, proposed legislation should probably closely mirror either the procedural provisions of Article 31 or be very narrowly tailored to adequately satisfy the three-part test of Article 30.

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226. 35 U.S.C. § 271(e). Not only was this legislation crafted for public policy reasons, but it was prompted by a Federal Circuit case, *Roche v. Bolar*, that had held that use of a patented invention by generic companies to obtain FDA approval constituted patent infringement. 733 F.2d 858 (Fed. Cir. 1984). The legislative response is not surprisingly called the "Bolar exception." For further discussion of the history behind this provision, as well as the larger Hatch-Waxman Act of which it is a part, see Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived their Usefulness?*, 39 IDEA 389 (1999).

227. 35 U.S.C. § 287(c). The precise parameters of this provision are complex and somewhat unclear since there do not seem to be any cases where this provision has been relied upon as a defense in litigation. Nonetheless, for additional information concerning the perceived scope of this provision, as well as potential international problems, see Cynthia M. Ho, *Patents, Patients, and Public Policy: An Incomplete Intersection at 35 U.S.C. § 287(c)*, 33 U.C. DAVIS L. REV. 601 (2000).

228. *Compare* 35 U.S.C. § 287(c) (providing medical doctors immunity from patent infringement) *with* H.R. 1127, 104th Cong. (1995) (proposing to exclude medical procedures from patentability). In addition, the exemption for medical procedures was included as part of a general appropriations bill, such that some have suggested that the substance of the bill was never actually considered. *See, e.g.*, 142 CONG. REC. S11,843 (daily ed. Sept. 30, 1996) (statement of Sen. Hatch); 142 CONG. REC. H8277 (daily ed. July 24, 1996) (statement of Rep. Moorehead); *id.* at H8279 (daily ed. July 24, 1996) (statement of Rep. Schroder); *id.* at H8278 (statement of Rep. Mollohan).

229. H.R. 3967, 107th Cong. (2002) (proposing to amend the Patent Act to exempt medical practitioners utilizing genetic diagnostic tests from patent infringement remedies); H.R. 3966, 107th Cong. (2002) (conducting study of the impact of federal policies on the innovation process for genomic technologies).

CONCLUSION

As the anthrax scare aptly illustrated, patents can quickly become a compelling issue when they impact effective inoculation against a national terrorist threat. This article provides an important analysis of potential patent pitfalls that must be navigated for successful development of biodefense vaccines. In particular, specific research and development activities of vaccine creation that could raise patent infringement problems have been outlined. This article details potential avenues of avoiding or minimizing patent liability under the present United States patent laws. The potential vulnerability of these laws to either domestic or international challenges have been included as well for a comprehensive approach to the situation. In addition, the extensive TRIPS analysis should also be of practical assistance in the event of Congressional consideration of further legislation to promote vaccine development. The analysis of TRIPS provided in this article can be utilized to help craft legislation that will withstand scrutiny under TRIPS and the WTO. [230]

In addition to the importance of this article to the development of biodefense vaccines, the analytical framework should also have continued value beyond the present issue in the current climate that is infused with fear of terrorism. Regardless of the prevailing public health crisis that may be at issue, the same exceptions to patent liability as well as corresponding TRIPS compliance issues will continue to exist. Accordingly, the analysis outlined here should have enduring value for issues yet to arise at the intersection of patents and public health.

230. Indeed, in the wake of the anthrax scare, there was a Congressional proposal regarding compulsory licensing of patents. H.R. 3235, 107th Cong. (2001) (providing for compulsory licensing for certain patented inventions relating to health); H.R. 1708, 107th Cong. (2001) (same); H.R. 2927, 106th Cong. (1999) (same).