AGAINST THE PLAGUE: EXEMPTION OF PHARMACEUTICAL PATENT RIGHTS AS A BIOSECURITY STRATEGY

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I. INTRODUCTION

Acts of terrorism involve threats to use or use of weapons of mass destruction to kill, maim, or destroy property by individuals, groups, or states mainly on political grounds, and for maximum political effects. Terror attacks are characterized by stealth, indiscriminate violence, and destruction meant to heighten people’s fears and concerns for their lives and property. As terrorism has increased, so have the number of counterterrorism strategies by governments around the world. However, terrorism is as old as mankind.

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1. An early example of a state-sponsored terrorist was the Roman emperor Nero, who ruled by fear, slaughtered many members of the nobility, and has been blamed for the burning of Rome. Cindy C. Combs & Martin Slann, Encyclopedia of Terrorism 201 (2002). Dysfunctional or anarchistic individuals or groups acting alone or in concert can perpetrate terrorist attacks. See Jonathan Glover, State Terrorism, in Violence, Terrorism, and Justice 256, 257-60 (Raymond G. Frey & Christopher W. Morris eds., 1991) (contrasting historical state and independent terrorists, highlighting essential features of state-sponsored terrorism, and explaining why states commit acts of terrorism).

2. Political motivation has been described as “a necessary component to a definition of terrorism.” Combs & Slann, supra note 1, at 211. For examples of statutory definitions of terrorism, see Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA PATRIOT Act) Act of 2001, Pub. L. No. 107-56, § 802, 115 Stat. 272, 376; Security Legislation Amendment (Terrorism) Bill, 2002, c. 5, sched. 1 (Austl.); Anti-Terrorism Act, 2001 S.C., ch. 41, § 83.01 (Can.);

3. See Avraham Bleich, Marc Gelkopf, & Zahava Solomon, Exposure to Terrorism, Stress-Related Mental Health Symptoms, and Coping Behaviors Among a Nationally Representative Sample in Israel, 290 JAMA 612, 612 (2003) (concluding that although “the survey participants showed distress and lowered sense of safety, they did not develop high levels of psychiatric distress, which may be related to a habituation process and to coping mechanism”); Press Release, Harvard Sch. of Pub. Health, Survey Shows Anthrax Incidents Have Impact on People’s Worries and Behaviors in Three Cities Where Bioterrorism Reported (Dec. 17, 2001), available at http://www.hsph.harvard.edu/news/press-releases/2001-releases/press12172001.html (revealing that the 2001 anthrax attacks in the United States had an impact on the behavior of individuals living in the three affected cities); Frontline: Plague War (PBS television broadcast Oct. 13, 1998) [hereinafter Frontline] (“Infectious agents are and will continue to be that mysterious source of great panic . . . [a]nd while bombs clearly can create panic, infectious diseases almost spread it.”).

Terrorism is often excused, for right or for wrong, as a reaction to perceived or actual religious, proprietary, or political subjugation, the desire to be rid of an army of occupation, or a quest for a sovereign state. Ultimately, all acts of terror have political, ideological, economic or religious connotations. However, the borderline between acts of legitimate resistance and terrorism is vulnerable to semantic crisis when considering aspirations for self-determination and socioeconomic justice. Still, terrorism is inexcusable no matter the political, economic, or religious motivations of its perpetrators, and is rightly deplored and criminalized, especially in light of the innumerable non-violent means available for settling grievances and disputes domestically and internationally in contemporary times.

It is moot that no state condones terrorism. In the wake of the September 11, 2001 terrorist attacks on the United States, many countries, including Australia, the United Kingdom, Canada, and the United States, either enacted new anti-terrorism laws, or strengthened existing counterterrorism measures and legislation. For instance, in 2005, the United Kingdom Parliament enacted a new anti-terror measure over strong opposition both from within Parliament and the civil society entitled “The Prevention of Terrorism Bill.”

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5. See Wendy Barnaby, The Plague Makers: The Secret World of Biological Warfare 20-22 (2000) (tracing biological attacks to the ancient world when Persians, Greeks and Romans poisoned their enemies); Victoria Sutton, Law and Bioterrorism 3-10 (2003) (tracing the history of biological attacks to Hammurabi’s code of “an eye for an eye,” and pointing out that the Tartars were the first to use biological weaponry when they allegedly catapulted plague-infected corpses over city walls); George W. Christopher et al., Biological Warfare: A Historical Perspective, in Biological Weapons 17, 17 (Joshua Lederberg, ed., 1999) (arguing that the deliberate use of microorganisms and toxins to harm others has been practiced for centuries, and will likely continue into the future).

6. See Charles W. Maynes, All Political Violence is Not Terrorism, in Terrorism: Opposing Viewpoints 22, 23 (Bonnie Szumski ed., 1986) (arguing that the United States definition of terrorism may be too broad); Martin Oppenheimer, Terrorism is Sometimes Justified, in Terrorism: Opposing Viewpoints, supra, at 87-88 (arguing that some terrorism is born from injustice and oppression, and that if governments acted in a just and humane manner, terrorism would not exist); Jordan J. Paust, Terrorism as an International Crime, in International Cooperation in Counter-Terrorism: The United Nations and Regional Organizations in the Fight Against Terrorism 25, 31 (Giuseppe Nesi, ed., 2006) (addressing whether certain forms of terrorism are permissible under international law and concluding that the use of terrorism in war against enemy combatants could be permissible, but that terrorist attacks against detainees and non-combatants are unlawful).

7. Cf. Maynes, supra note 6, at 22-25 (pointing out that not all violence motivated by these issues is necessarily terrorism).


9. See William McGurn, Terrorism Is Never Justified, in Terrorism: Opposing Viewpoints, supra note 6, at 90-95 (arguing that while violence can be justified in war, terrorism cannot because it deliberately targets innocent civilians, and operates outside of the rules of just warfare).


The proposed legislation would have allowed the British government to place suspected terrorists under house arrest without trial. To justify what he called “difficult issues for any government,” Prime Minister Tony Blair contended that “[t]here is no greater civil liberty than to live free from terrorist attack.”

It has been observed that technology shapes terrorist attacks. While terrorists have traditionally relied on guns and bombs, there is a real possibility that in the future biological pathogens could become the weapons of choice for terrorists looking to inflict maximum civilian casualties. According to Interpol Chief Ronald Noble, the bioterrorism alarm is “real and it is continuing to ring.” The United States believes that Al Qaeda is seeking bioweapons. Documents recovered in Afghanistan in 2001 revealed that Al Qaeda had conducted extensive research into the use of biological weapons, along with other weapons of mass destruction. Experts have frequently warned of the high likelihood of a bioterrorism attack. The theoretical inevitability of bioterrorism is further underscored by the relative ubiquity of modern, cutting-edge biotechnology, necessitated partly by a recent spike in scientific pursuits of cures for infectious diseases. For instance, revolutionary genetic engineering techniques have facilitated the creation of}

12. See id. (noting that there was serious opposition to the plan).
13. See id. (noting that the plans were subjected to additional government criticism).
14. See id. (quoting a politician who accused Blair of “using national security for political point scoring”).
15. BARNABY, supra note 5, at 22-23.
16. See Ronald A. Greenfield et al., Bacteria Pathogens as Biological Weapons and Agents of Bioterrorism, 323 AM. J. MED. SCI. 299 (2002) (noting that terrorists could use bacterial pathogens in bioterrorist attacks and that such pathogens are relatively easy to obtain); Katharine R. Meacham & Jo Ann T. Croom, Tricksters, The Plague, and Mirrors: Biotechnology, Bioterrorism, and Justice, in CROSS-CULTURAL BIOTECHNOLOGY 177, 179 (Michael C. Brannigan ed., 2004) (noting that terrorists may use genetic engineering techniques); Barry Kellman, Biological Terrorism: Legal Measures for Preventing Catastrophe, 24 HARV. J. L. & PUB. POL’Y 417, 427-429 (2001) (discussing the relative ease with which terrorists could perpetrate bioterrorism and the potential risk to civilian populations). This view is underscored by the relative ease with which the 2001 anthrax attacks in the United States were carried out via the postal service. Richard Hollingham, FBI Draws Blank in Anthrax Probe, BBC NEWS, Aug. 5, 2003, http://news.bbc.co.uk/1/hi/world/americas/3125885.stm.
18. See Michael R. Gordon, U.S.: Al Qaeda Was Building Lab for Bioweapons, CHI. TRIB., Mar. 24, 2002, at A6 (noting that documents recovered from Al Qaeda facilities indicated that Osama Bin Laden was pursuing a biological research program).
20. See Frontline, supra note 3 (warning in 1998 that all of the conditions necessary for bioterrorism already existed, including terrorists determined to employ biological pathogens on civilian populations, and that the materials necessary to construct biological pathogens were both readily available and relatively affordable).
superbugs, raising anew the “dual-use” research dilemma and the specter of “black biology” tailored to terror goals.

The dual-use research dilemma inherent in cutting-edge genetic engineering techniques was amply illustrated in 2005, when U.S. scientists at the Center for Disease Control (“CDC”) in Atlanta, Georgia recreated the 1918 influenza virus from its published full genome sequence. Furthermore, in 2003, United States scientists genetically engineered an extremely potent form of mousepox, a family of smallpox virus. Moreover, in 2001, Australian scientists, using bioengineering techniques, inadvertently created a superpox that killed mice by crippling their immune system. In the wake of recent coordinated global terror attacks, there is a real fear that these pathogenic recipes could fall into terrorists’ hands, thus potentially facilitating the concoction of a broad range of “designer diseases” ranging from a monstrous superpox to an engineered influenza virus species that may be impervious to all known vaccines and drugs.

The possibility that potent recombinant viral agents or deadly life forms could be created by accident and even from scratch has heightened the specter of abuse by rogue scientists, who might sell such technology to unscrupulous clients or terrorists.

In 2003, a South African scientist, who had worked at a secret bioweapon facility in apartheid-era South Africa, attempted to sell a cluster of genetically engineered, deadly pathogens to the United States government. According to

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22. See Nat’l Research Council, Biotechnology Research in an Age of Terrorism: Confronting the Dual Use Dilemma 15 (2004) (noting that although molecular biology and genetics have many positives, there is a real “possibility that the technologies could also be used to create the next generation of biological weapons. Biotechnology represents a ‘dual-use’ dilemma in which the same technologies can be used legitimately for human betterment and misused for bioterrorism.”).

23. See Int’l Comm. of the Red Cross, Report on “Biotechnology, Weapons and Humanity” (2003), available at http://www.icrc.org/web/Eng/siteeng0.nsf/swpList515/962391D638B22A29C1256E550035DE0 (noting that many have grave concerns about biological weapon proliferation); Peter Aldhous & Michael Reilly, Bioterror Special: Friend Or Foe?, NEW SCIENTIST, Oct. 14, 2006, at 20, 21 (noting that U.S. academic labs are allegedly engaging in experiments that may incidentally produce bioweapons); Block, supra note 21 (explaining that “Black Biology” is a shadowy science in which microorganisms are genetically modified for the sole purpose of creating novel weapons of terror or “designer diseases” such as “penicillin-resistant anthrax” or “stealth viruses” that can not be countered by known vaccines and antibiotics).

24. Terrence M. Tumpey et al., Characterization of the Reconstructed 1918 Spanish Influenza Pandemic Virus, 310 SCIENCE 77, 77-80 (2005); Andreas Von Bubnoff, The 1918 Flu Virus is Reconstructed, 437 NATURE 794, 794-95 (2005).


28. E.g., David Whitehouse, First Synthetic Virus Created, BBC NEWS, July 11, 2002, http://news.bbc.co.uk/1/hi/sci/tech/2122619.stm (reporting that in July 2002, researchers at the State University of New York at Stony Brook announced that they had created a polio virus from scratch, using the genome sequence for polio).


Washington Post reports, the scientist and his team had promised the U.S. government “scores of additional vials containing the bacteria that cause anthrax, plague, salmonella and botulism, as well as antidotes for many of the diseases. Several strains . . . had been genetically altered, a technique used by weapons scientists to make diseases harder to detect and defeat.” Following the well-publicized U.S. refusal to purchase the engineered pathogens, the South African scientist reportedly told The Washington Post that private individuals had shown interests in acquiring his deadly wares. There is thus a justifiable and growing concern that technologies that could potentially compromise national and international security could be easily obtained by terrorists.

Curbing hostile use of biology is very problematic because the same knowledge serves both legitimate and illegitimate purposes. Some scholars contend that any malign uses of biology could not be simply avoided by allowing the technology to self-regulate via elements of market forces. These scholars were also skeptical of the neo-Luddite clamp-down solution that would stop the biological revolution in its tracks. They proposed national and international regulatory oversight of civil and military biological researches to curb possible abuses. Effective and transparent global regulatory oversight is no easy task and could prove elusive, due to its propensity to become entangled in policy quagmires and the web of mutual distrust that continues to define relations between cold warriors and their allies.

In addition to setting up the National Science Advisory Board for Biosecurity, a bioterror watchdog agency tasked to monitor dual use of biology, the United States’ answer to the dual use and diffusion of biological technology centers on two strategies. First, safeguards and security measures must be established to ensure that research into pathogens is legitimate, as well as to prevent domestic and international terrorists from obtaining them.
Second, information generated by federally-funded research in science, technology and engineering at colleges, universities and laboratories must be classified. 41

Both strategies present huge logistical problems, and are of limited practicality. First, effective policing of all known U.S. biological laboratories is practically impossible. Second, classifying, monitoring, and controlling sensitive research that is either not federally funded or is conducted in private labs outside of the United States, is beyond the United States’ jurisdiction. Third, classified information is still vulnerable to espionage, a prospect that may have prompted the United States’ controversial visa restriction policy on foreign researchers in the wake of the September 11, 2001 terrorist attacks. 42

Internationally, the increasing ubiquity of biological weapons know-how, especially on the Internet, 43 has rekindled a call for viable biosecurity strategies 44 and precipitated stringent measures on chemical and biological agents’ governance in labs across the United States and around the world. 45 It has also engendered concerted international efforts to stem the proliferation and trafficking of weapons of mass destruction, particularly in the Middle East and in the Commonwealth of Independent States composed of former Soviet republics. 46

This Article analyzes the likely large-scale public health crises resulting


42. See Edward Alden & Stephanie Kirchgaesser, Foreign Researchers Face Tight Curbs in U.S., FIN. TIMES, Nov. 25, 2005, at 7 (noting that the United States recently proposed stringent rules and measures that could restrict Chinese and other foreign researchers from engaging in high-level research).

43. See Mark Shwartz, Biological Warfare Emerges as 21st Century Threat, STAN. REP., Jan. 11, 2001, available at http://news-service.stanford.edu/news/2001/january17/bioterror-117.html (concluding that even though recipes for creating deadly pathogens are public knowledge, and are already in the public domain, “[t]he idea that anybody can brew this stuff in their garage vastly overstates the case”).

44. See Matthew Meselson, Averting the Hostile Exploitation of Biotechnology, 48 CBW CONVENTIONS BULL. 16, 19 (2000) (describing practical preventative measures against chemical and biological weapons); James W. Parrett, Jr., A Proactive Solution to the Inherent Dangers of Biotechnology: Using the Invention Secrecy Act to Restrict Disclosure of Threatening Biotechnology Patents, 26 WM. & MARY ENVTL L. & POL’Y REV. 145, 145-146 (2001) (suggesting that as a biosecurity measure, the United States’ Invention Secrecy Act should be used to prevent the disclosure of dangerous biotechnology patents); Susan Wright, Taking Biodefense Too Far, BULL. ATOMIC SCIENTISTS, Nov. – Dec. 2004, at 58, 61-62 (noting that the Bush Administration, in 2002, initiated the $5.6 billion “Project Bioshield” to develop new vaccines and treatments to protect against bioterrorist attacks and setup the National Biodefense Analysis and Countermeasures Center to counter bioterrorism).


from a bioterrorism attack. Due to the overly destructive effects on large civilian population in a comparatively shorter time span, bioterrorism-induced diseases could precipitate public health crises that are relatively grander in scale, and with arguably more debilitating effects on public health infrastructure than naturally occurring infectious diseases such as HIV/AIDS, dengue fever, tuberculosis, or malaria.47

The parallel drawn in this paper, between known incurable, epidemic diseases like HIV/AIDS and bioterrorism-inflicted diseases, should not be construed as a disparagement of the enormous devastation wrought by HIV/AIDS, malaria, and other pandemic diseases. This devastation is evidenced by their great toll on human lives and resources—especially in sub-Saharan Africa48—and the continuing challenge they present to modern medicine and the global public healthcare infrastructure.49 Rather, the comparison between these naturally-occurring pandemic diseases and bioterrorism-induced diseases is drawn both to underscore the dramatic and fundamental differences between the respective diseases in the context of disease onset, infection rate, disease progression and possible or inevitable death. These fundamental differences arguably justify different public health policy responses to the two categories of pandemic diseases.

A critical countermeasure to bioterror attacks is a responsive and viable public health system, an integral element of which is an adequate and timely supply of essential vaccines and drugs. The 2001 anthrax attacks in the United States, which nearly precipitated a run on Bayer’s antibiotic ciprofloxacin,50 demonstrated that the public health care system could fall short of critical medicines to either the infected or stem the spread of infectious pathogens such as smallpox, anthrax and the plague. This is especially so since experts in the United States have said that pre-exposure medical countermeasures—that is, inoculation—for civilian populations is unlikely,51 despite dissenting views that immunizations should ideally be given prior to an attack.52

47. Smallpox is believed to have killed more people than all past and present wars and epidemics. Elias, supra note 29.


49. A new “super strain” of HIV resistant to all known therapies, and with swifter progression from HIV to AIDS was recently discovered, prompting concerns among experts that the disease might become intractable. Jessica Berman, New AIDS Strain Discovered in US, VOA NEWS.COM, Mar. 12, 2005, http://www.voanews.com/english/2005-02-13-voa28.cfm. According to Jay Dobkin, the infectious disease specialist of the State University of New York, “Many of us up here remember the dark days before there was any effective treatment for HIV. And I think the case . . . should be a reminder that those days could come back.” Id.

50. See Keith Bradsher, A Nation Challenged: The Antibiotic; Bayer Insists the Cipro Supply Is Sufficient; Fights Generic, N.Y. TIMES, Oct. 21, 2001, at 1B (reporting that several pharmacies run out of ciprofloxacin despite Bayer’s insistence that the supply was sufficient).

51. BARNABY, supra note 5, at 146-48.

52. Compare Jim Turner et al., A BIODEFENSE FAILURE: THE NATIONAL SMALLPOX VACCINATION
Time is of the essence in getting crucial drugs to victims of bioterrorism attacks to save as many lives as possible, and authorities should be able to mass-produce crucial drugs with minimal delay. Drug stockpiling is of limited practical value since most drugs and vaccines have limited shelf-life, and no one knows for sure when terrorists would strike. Moreover, drug stockpiling is not a feasible bioterrorism policy option for resource-poor countries that, unlike the United States and other wealthy nations, are already overwhelmed by HIV/AIDS, and lack functional public health infrastructures and the resources to stockpile bioterrorism-specific drugs for their populations.

Nevertheless, securing crucial drugs in the shortest time possible for those infected in a bioterrorism attack is no less important than other public health preparedness measures. It would undoubtedly minimize loss of life and effectively contain further spread of diseases and mass hysteria. However, the high propensity for intellectual property rights wrangling—as exemplified by the skirmishes over Bayer’s ciprofloxacin in the wake of the September 11, 2001 anthrax attacks in the United States—could stymie authorities’ efforts to mass produce or parallel import crucial patented drugs within the shortest time possible, especially in resource-poor countries of Africa, Asia, and Latin America. This makes an effective bioterrorism-specific pharmaceutical patent appropriation clause in international and national patent laws bereft of the bureaucratic trappings of the contemporary patent regime, and the TRIPS access to medicines paradigms.

There is a plethora of literature on public health preparedness in

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53. The United States recently discovered that the bird flu vaccines it had stockpiled had lost their strength overtime and that one million fewer people could be inoculated than was originally estimated. Christian Nordqvist, Bird Flu Vaccines Lose Their Strength, MED. NEWS TODAY, Nov. 20, 2006, http://www.medicalnewstoday.com/articles157122.php.


56. Laura Spinney, Terror’s Hidden Ally: In a Climate of Fear, Mass Hysteria Can Lead to Symptoms as Troubling as Real Disease or Poisoning, NEW SCIENTIST, Oct. 2006, at 24, 24.

general, and public health legal preparedness in particular, fostering holistic discourses on counterterrorism and natural disaster countermeasures. Public health legal preparedness has been described as a subtext of public health preparedness. Its rising profile in legal scholarship since the late 1990s has been attributed to the recognition of the integral role of law in securing and enforcing public health preparedness strategies.

While the scope of public health law is not clearly defined, it has been suggested that it could be “any law that has significant consequences for the health of a defined population,” and that “the term may encompass such nominally foreign domains as economic development laws, tax law, and international trade law.” It is axiomatic that public health law encompasses intellectual property rights, especially patents and allied rights that directly regulate ownership of, and access to, critical medicines for public health needs, particularly with regard to bioterrorism-induced diseases. Not the least of which because a lack of access to crucial drugs could have “significant consequences for the health of a defined population.” This is an ongoing, albeit unpleasant, reality for millions in resource-poor countries, arguably

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58. Public health preparedness has been defined as. See Anthony D. Moulton et al., What is Public Health Legal Preparedness?, 31 J.L. MED. & ETHICS 672, 673 (2003) (defining “public health preparedness” as “the readiness of a public health system (of a community, a state, the nation, the world community) to respond to specified health threats. It can also be phrased as a goal, i.e., as attainment by the public health system of a defined benchmark of response to conventional dangers and, specifically, to such emerging threats as Severe and Acute Respiratory Disease (SARS), terrorism, and the next major dangers to follow.”).

59. See id. at 674-76 (discussing initiatives to improve public health preparedness).

60. See id. at 673 (describing the term broadly to include “any law that has significant consequences for the health of a defined population”).


62. Moulton et al., supra note 58, at 673.

63. Id.

64. Since the inception of the TRIPS Agreement in 1994, the question of whether intellectual property rights fall within the purview of public health law is now arguably beyond dispute, as TRIPS provides a direct link between intellectual property rights, especially pharmaceutical patents, and public health law. E.g., Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, art. 8.1, 33 I.L.M. 1125, 1201 (1994) [hereinafter TRIPS Agreement] (allowing members to adopt measures to protect public health and to promote the public interest). Intellectual property rights have been prominently linked to public health in recent institutional discourse, and the body of legal and economic scholarship on the relationship between intellectual property rights and public health continues to grow. See Joan-Ramon Borrell & Jayashree Watal, Impact of Patents on Access to HIV/AIDS Drugs in Developing Countries, (Ctr. For Int’l Dev. at Harvard Univ., Working Paper No. 92, 2002), available at http://www.cid.harvard.edu/cidwp/pdf/092.pdf (summarizing an empirical study of the impact of patents on access to new drug therapies in low and middle income countries); Carlos Maria Correa, Ownership of Knowledge – The Role of Patents in Pharmaceutical R&D, 82 BULL. WORLD HEALTH ORG. 784, 784-790 (2004), available at http://www.who.int/bulletin/volumes/82/10/en/784arabic.pdf (decriing “lax” patent rules which engender myriads of weak or otherwise invalid patents for “minor developments” in pharmaceuticals and arguing that such patents unnecessarily impede competition and raise the bar to access to medicines in resource-poor countries). But see Richard P. Rozek & Ruth Berkowitz, The Effects of Patent Protection on the Prices of Pharmaceutical Products, 1 J. WORLD INTELL. PROP. 181, 181-216 (1998) (finding that in the countries studied, intellectual property protection had little, if any, impact on drug pricing, including those drugs introduced after a change to the patent system).

65. See Moulton, supra note 58, at 673 (establishing criteria for “public health law”).

66. The effect of patents on the price of drugs is highly divisive and expert opinion is often sharply divided between industry and non-governmental organization or developing country perspectives. See Rozek
due, in part, to stronger pharmaceutical patents protection under the aegis of the World Trade Organization’s (“WTO”) TRIPS Agreement. The arrangement has effectively rooted international intellectual property rights governance in international trade rules.

Despite the strong link between pharmaceutical patents and public health, most of the scholarship and regulatory regimes concerning public-health legal preparedness largely glosses over intellectual property law and access to medicines interface discourses, and instead focus mainly on the legal status of voluntary rescuers, public health employees, control of biological agents, civil liberties, and legal liability implications of compulsory quarantine and inoculation. While acknowledging the possible dearth of vaccines and drugs as a potentially critical logistic snag in the bioterror defense strategy, even the few articles that have explored potential patent obstacles sought solutions only within the traditional remit and the familiar ambit of the TRIPS Agreement, as well as national patent law and access to medicine paradigms, whose core is the compulsory licensing regime as circumscribed by the “consistency test.”

This solution is arguably vulnerable to bureaucratic trappings and

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68. Compliance related disputes under TRIPS are adjudicated under the multilateral procedures of the World Trade Organization Dispute Settlement Understanding. CARLOS M. CORREA, INTELLECTUAL PROPERTY RIGHTS, THE WTO AND DEVELOPING COUNTRIES: THE TRIPS AGREEMENT AND POLICY OPTIONS 3-6 (2000) [hereinafter CORREA, IP RIGHTS]. See generally TRIPS Agreement, supra note 64, arts. 63-64 (listing procedures for dispute resolution and settlement).

69. See, e.g., BIOLOGICAL WEAPONS DEFENSE: INFECTIOUS DISEASE AND COUNTERBIOTERRORISM xiii-xv (Luther E. Lindler et al. eds., 2004) (neglecting to mention intellectual property rights or access to medicines interface in discourse on counterterrorism strategies); Sutton, supra, note 5; (focusing on civil rights and liberties issues relating to bioterrorism, quarantine law, tortious liabilities etc., with no discussion on the interface between intellectual property and bioterrorism); Moulton et al., supra note 58, at 674 (noting that public health legal preparedness should support voluntary participation in rescue efforts rather than using coercion which could be counterproductive, but not mentioning intellectual property rights). See generally United States Public Health and Bioterrorism Preparedness and Response Act of 2002, Pub. L. 107-188, 116 Stat. 594 (promulgating legal obligations, duties, rights and limitations on the rights of health workers, victims of terror, etc.).

70. See generally Grace K. Avedissian, 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, 286-88 (2003) (recommending that the United States implement compulsory licensing for prescription drugs as a counterterrorism measure to boost global access to generic drugs). The downside of the compulsory licensing solution is that it may be prone to beaurcratic delays and uncertainty in the value of the license, which renders it a last resort remedy, making it unsuitable for an extraordinary bioterrorism emergency. Id.

71. Article 8.1 of the TRIPS Agreement stipulates that “Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.” TRIPS Agreement, supra note 64, art. 8.1. Even measures aimed at curbing abuse of intellectual property rights by right holders must pass consistency muster. Id.
II. UNDERSTANDING BIOLOGICAL AGENTS AND BIOTERRORISM: THE SCALE OF THE PROBLEM

Biological weapons involve the use of disease-causing micro-organisms and other replicative entities, including viruses, infectious nucleic acids, and prions.75 Bioterrorism is the deliberate use of biological weapons by terrorists to inflict death and destruction in pursuit of political, religious or ideological objectives.76

Biological weapons are unique in terms of affordability, ability to reach intended targets, ability to cause limited collateral damage, and ability to achieve the desired outcome.77 A United States government analyst once said...
that “$1500 of nuclear killing power would set an anthrax assailant back by only a penny.” In other words, biological weapons are at once cheap and fatally effective.

Biological weapons are aptly described as weapons of mass destruction, whose potential for causing mass death can only be surpassed “…by the most powerful nuclear weapons, i.e. H-bombs.” This view is reinforced by a 1993 U.S. Congressional Office of Technology Assessment (“OTA”) study, which posited that a nuclear weapon comparable in size to the Hiroshima bomb has an explosive power equivalent to 12.5 kilotons of TNT, 300 kilograms of sarin nerve gas or 30 kilograms of anthrax spores. The bomb could kill between 23,000 and 80,000 people, the sarin could kill 60 to 200 people, and the anthrax could kill 30,000 to 100,000 people. Anthrax’s potential fatality figures outstrip and are potentially double that of a bomb of comparable explosive power. Moreover, anthrax (a biological agent) outclasses sarin (a chemical agent) in terms of probable causalities. The real danger, however, is that anthrax, smallpox, and the plague are much cheaper and relatively easier to acquire than a hydrogen bomb, and could be deployed with greater stealth and swiftness to maximize civilian casualties.

In the context of simulated worse-case scenarios, the following paragraphs will briefly review three potent and weaponizeable biological agents: the plague, anthrax, and smallpox. The possible public health crises scenarios occasioned by bioterrorism are juxtaposed with those resulting from naturally occurring epidemic diseases such as HIV/AIDS, tuberculosis, and malaria. This Article will then adduce reasons why the TRIPS access to medicine package and the exceptions in contemporary patent regimes are unsuitable for bioterrorism-induced diseases and are inadequate as a biodefense strategy. While there are more biological agents than those discussed here, discussions will be limited to the plague, anthrax, and smallpox for the following reasons: (1) space constraints preclude an extensive analysis of all known pathogens; (2) this discourse is not so much about epidemiological analysis, clinical prognosis of biological pathogens, or clinical management of exposed patients, as it is on the pathogens’ inherent virulence.

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78. Id.
79. BARNABY, supra note 5 at 31.
80. Id. (citing U.S. CONG., OFFICE OF TECH. ASSESSMENT, PROLIFERATION OF WEAPONS OF MASS DESTRUCTION: ASSESSING THE RISKS 53 (1993)).
81. Id.
83. The post September 11th, 2001 anthrax attacks in the United States demonstrated the ease with which terrorists can deploy bioagents. See Victoria V. Sutton, A Precarious “Hot Zone” – The President’s Plan to Combat Bioterrorism, 164 MIL. L. REV. 135, 135-36 (2000) (noting inter alia that biological weapons are more flexible than conventional weapons).
85. Others include, for example, brucellosis, tularemia, botulism, viral encephalitides, and viral hemorrhagic fevers. Id.
86. A scientific analysis of biological pathogens is not only beyond the scope of this article, but also requires technical knowledge and expertise which the author does not possess.
in bioterrorism context, and a case for developing a legal framework for accessing critical drugs and vaccines in the advent of their willful and negative deployment; and (3) the choice of the three pathogens in the foregoing discourse is informed by their relative availability, accessibility, weaponizability, and pliability to terrorist use.87

A. The Plague

The plague is an infectious, zoonotic disease caused by the Yersinia pestis bacterium, commonly carried by rodents and fleas.88 People usually become infected with the plague by being bitten by fleas that live on rats hosting Yersinia pestis.89 A swollen and very tender lymph gland on the neck, the bubo gland, is the typical sign of infection that gives the plague the alternate name of “bubonic plague.”90 Other symptoms of bubonic infection include fever, chills, headaches and extreme exhaustion.91 If bubonic plague is left untreated, the bacterium can invade the bloodstream, spreading fatal infection, with a case fatality of 30–60%.92 Bubonic plague is otherwise known as “the black death.”93 Bubonic plague is transmissible through the bite of an infected flea or exposure of skin wounds to an infected material.94

However, when the Yersinia pestis bacterium invades the lungs, rather than the bloodstream, it causes severe respiratory problems, specifically pneumonic plague.95 Its symptoms include “high fever, cough, bloody sputum and difficulty in breathing.”96 Thus, the Yersinia pestis bacterium causes two diseases: pneumonic plague and bubonic plague.97 Pneumonic plague could be spread through an aerosol attack; it is infectious and can manifest within one to six days after an attack.98 Pneumonic plague is a Category A critical biological agent that can easily be disseminated.99 The plague can be treated

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87. See Tucker, supra note 82, at 57 (stating the weight for weight potency of microbial pathogens makes them an ideal terrorist weapon).
90. Id.
91. Id.
95. Id.
96. Id.
97. Id.
98. CDC Plague FAQ, supra note 88, at 1-2.
with modern antibiotics such as streptomycin and gentamicin, although there are concerns about the increasing level of the disease’s resistance to drugs. 100 Scientists in the United Kingdom have also experimented with the plague vaccine for their military, using genetic engineering techniques. 101 However, the World Health Organization (“WHO”) recommends that vaccines should not be used for immediate protection in outbreak cases, but only “as a prophylactic measure for high-risk groups (e.g. laboratory personnel who are constantly exposed to the risk of contamination).” 102

The plague is still very common in some parts of Africa, Asia, and Central America. 103 According to the WHO, nine countries reported 2118 plague cases and 182 deaths in 2003. 104 On the average, there are 1000 to 3000 cases of the plague each year. 105 In 1997, a WHO modeling scenario predicted that the release of fifty kilograms of Yersinia pestis over a city of 5 million people could cause about 150,000 cases of the plague and result in 36,000 deaths. 106 Neither HIV/AIDS nor malaria could wreak as much havoc as the plague in the same period of time. The plague is weaponizable as an aerosol, the expected mode of delivery in any biowarfare or terrorist attacks. 107

B. Anthrax

Anthrax is a bacterium derived from B. anthracis, which resides naturally in soil. 108 The organism enjoys a dual existence. In the infected host, it is a vegetative bacillus. 109 In the environment, it is a spore. 110 Anthrax spores would only form in the infected host if the body tissues are exposed to air. 111 The spores are resilient, and can survive adverse environmental conditions, having the potential to last for decades. 112 Although it exists naturally in soil, anthrax can be grown in any microbiology laboratory. Anthrax spores were weaponized by the United States in the 1950s and 1960s before its biological

100. CDC Plague FAQ, supra note 88.
102. WHO, Plague, supra note 92.
104. WHO, Plague, supra note 92.
105. CDC Plague FAQ, supra note 88, at 2.
107. See CDC Plague FAQ, note 88, at 1 (arguing that the aerosol form of Yersinia pestis should be considered a biological weapon).
108. Franz et al., supra note 84, at 401.
109. Id.
110. Id. As a spore-forming microbe, the bacillus, when exposed to the proper conditions, curls “itself up in a tiny ball and builds around its outer surface a capsule that amounts to a hard hide. Such spores [are] known to be remarkably stable and resistant to the destructive influences of light and heat, and they could remain that way, with no loss of virulence, for a period of many years.” ED REGIS, THE BIOLOGY OF DOOM 11 (1999).
111. Franz et al., supra note 84, at 401.
112. Id.
weapon program was terminated. The former Soviet Union and Iraq have also experimented with the offensive use of anthrax.

Anthrax spores infect animals such as cattle, sheep, goats, and horses, usually while grazing. Humans get infected by skin-to-skin contact with infected animals. This is known as cutaneous anthrax, and it is rampant among workers who process raw goat hair into garment interlining. For instance, a forty-four-year-old New York man contracted respiratory anthrax from untreated animal hides in February 2006. Human infection is also possible by ingestion and by inhalation. If anthrax spores are dried and milled, they turn into a lethal, powdery white substance that is “ounce per ounce, more deadly than any explosive—and ‘smarter’ than the most expertly programmed smart bomb.”

The aforementioned 1993 OTA study estimated that a hypothetical dispersal of 100 kg of anthrax by a small plane could kill one to three million people in a three-hundred-square mile area around Washington D.C. The hydrogen bomb, by comparison, could only kill 570 thousand to 1.9 million people.

The only drug approved by the United States Food and Drug Administration (“FDA”) that is specifically labeled for the treatment of inhaled anthrax is Bayer’s antibiotic ciprofloxacin. However, in 1997, the United States Military began inoculating National Guardsmen in the Armed Forces and certain Ministry of Defense civilian contractors with anthrax vaccine absorbed (“AVA”). The program was temporarily halted on October 27, 2004, when the United States District Court for the District of Columbia ruled that the involuntary inoculation of National Guardsmen and civilian contract employees of the Department of Defense was illegal because the anthrax vaccine being used was an investigational drug prohibited by Congress. The court found further that in the absence of a presidential waiver, the

114. Franz et al., supra note 84, at 401.
115. Id.
116. Id.
119. BARNABY, supra note 5, at 34-35.
120. OSTERHOLM & SCHWARTZ, supra note 77, at 9.
121. OSTERHOLM & SCHWARTZ, supra note 77, at 9; U.S. CONG., OFFICE OF TECH. ASSESSMENT, supra note 80, at 54.
122. OSTERHOLM & SCHWARTZ, supra note 77 at 9.
123. See Kathleen Pender, Cipro Had Big Boost From U.S.: U.S. Tests Led to OK for Anthrax Use, S.F. CHRON., Oct. 25, 2001, at D1 (noting that the FDA and the CDC in 1998 selected ciprofloxacin, under a presidential directive, to treat exposure to advanced biological weapons, including anthrax).
125. Id. at 19. An earlier Preliminary Order had been granted on December 22, 2003 in favor of the plaintiffs. Id. at 16. The Preliminary Order was based on Plaintiffs’ Motion for a Preliminary Injunction enjoining the defendants from inoculating them without their consent, in the absence of a Presidential waiver. Doe #1 v. Rumsfeld, 297 F. Supp. 2d 125 (D.D.C. 2003).
plaintiffs could not be inoculated without their consent.126

This ruling ostensibly prompted the December 10, 2004 determination by the Department of Defense that there was a heightened risk of anthrax attacks against United States military personnel.127 The Department of Defense’s determination led to the U.S. Secretary of Health and Human Services’ January 14, 2005 declaration of emergency, justifying the authorization of emergency use of AVA,128 and clearing the way for the FDA’s January 27, 2005 authorization of emergency use of anthrax vaccine.129 In October 2006, the U.S. Department of Defense announced that it would “resume mandatory anthrax vaccinations for more than 200,000 troops and defense contractors within 60 days.”130 It should be noted, however, that in 2002, the FDA had approved resumption of anthrax vaccine production.131 This implies that a reliable alternative to ciprofloxacin could soon be available to protect against anthrax outbreaks in civilian population.

C. Smallpox

Smallpox is a naturally occurring disease that often starts with a low fever.132 Its scientific name is Variola, a Spanish word for “blotchy pimples.”133 The virus only infects humans, and has two subspecies: Variola minor and Variola major.134 The former is a weaker strain and rarely kills its victims.135 However, the latter kills up to 45 percent of infected people who are not immune to it.136 Variola major has no cure, and usually bestows its trademark pockmark-scars on lucky survivors.137 A smallpox outbreak occurred in the United States over fifty years ago138 and another in former Yugoslavia in 1972.139 It showed up again in Somalia in 1977140 and claimed

128. Id.
132. OSTERHOLM & SCHWARTZ, supra note 77, at 15-19.
134. Id. at 482.
135. Id.
136. Id.
137. OSTERHOLM & SCHWARTZ, supra note 77, at 17.
138. Id.
139. Id. at 18.
its last known victim in England in the summer of 1978. Smallpox was declared eradicated by the WHO in 1980. In the last century, approximately five-hundred million people reputedly died of smallpox worldwide. The number of deaths caused by smallpox dwarfs the estimated 320 million combined deaths from the 1918 swine flu pandemic, HIV/AIDS, and all military and civilian casualties of twentieth century warfare.

The WHO has expressed concern that smallpox “can easily be produced in large quantities in the laboratory and freeze-dried and its virulence thus preserved for months or years.” Officially, the U.S. CDC in Atlanta and the Russian State Research Center for Virology and Biotechnology are the only two WHO-approved repositories for smallpox in the world. However, there are reputed, clandestine stockpiles in obscure laboratories around the world, raising the fears that samples could get into the hands of terrorists.

In 2001, there were official simulated smallpox terror attacks in the United States. Christened “Dark Winter,” the scenario featured three large smallpox laden aerosol clouds infecting one thousand shoppers each in Oklahoma City, Atlanta, and Philadelphia. The initial simulated attacks occurred during December 1st, and by the 22nd, about 16,000 residents had been infected across twenty-five states, while one thousand people had already died. Under this simulation, by early February, three million U.S. residents would have been infected and about one million would have died. The nation’s smallpox vaccine was inadequate, leaving panicking citizens no choice but to scramble across shuttered Canadian and Mexican borders. Additionally, the possible fatalities of smallpox attacks on civilian populations were reinforced in a chilling 2002 BBC docudrama. In the docudrama, a “suicide patient” in New York City triggered a global smallpox infection.

Some commentators have attacked the two scenarios cited above as being overboard and exaggerated. Nevertheless, a comparison of the 2005 38.6 million global HIV infections, (which dated back to the 1980s), with the possible casualties in the simulated smallpox attack scenarios shows

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140. Richard Preston, The Demon in the Freezer 77.
141. Id.
142. Franz et al., supra note 84, at 404.
143. Osterholm & Schwartz, supra note 77, at 17.
144. Id.
145. Franz et al., supra note 84, at 404.
146. Id.
147. Id.
149. Id. at 20.
150. Id. at 16, 41.
151. Id. at 43.
152. Id.
154. Id.
155. Enserink, supra note 52, at 1592-93.
dramatically higher disease progression, infection rates, and casualty figures in the comparatively shorter time span of bioterrorism-induced diseases. Moreover, the global figure for AIDS deaths in 2005 alone was an estimated 2.8 million. This figure is dwarfed by the 3 million total smallpox infections and 1 million smallpox deaths in the United States within two months of the “Dark Winter” simulated smallpox attacks. The difference in death figures is further underscored by the obvious fact that those 2.8 million, who died of AIDS in 2005, were not infected with the HIV virus in 2005. The stark difference in disease onset, disease progression, disease timeline, and infection rates between bioterrorism-specific smallpox attacks and HIV/AIDS is put in a clearer perspective by Richard Preston in the following passage:

It has taken the world twenty years to reach roughly fifty million cases of AIDS. Variola (smallpox) could reach that point in ten or twenty weeks. The outbreak grows not in a straight line but in an exponential rise, expanding at a faster and faster rate. It begins as a flicker of something in the straw in a barn full of hay, easy to put out with a glass of water if it’s noticed right then. But it quickly gives way to branching chains of explosive transmission of a lethal virus in a virgin population of nonimmune hosts. It is a biological chain reaction.

A re-enactment of “Dark Winter” in a resource-poor country would arguably result in greater casualties in large measure due to a lack of critical drugs and vaccines. This is exemplified by a recent study on the estimated potential global deaths from an influenza pandemic. Of the fifty-one to eighty-one million estimated potential influenza deaths, 96% were from poorer countries in the developing world. This figure is due in part to the endemically parlous public health system, exemplified by the chronic drug shortages, dearth of competent health care professionals, and blighted public-health infrastructure. It is evident that, while wealthy nations like the


157. Id.

158. Dark Winter, supra note 148.

159. See Nat’l Inst. of Allergy and Infectious Diseases, The Evidence That HIV Causes AIDS (Feb. 27, 2003), http://www.niaid.nih.gov/factsheets/evidhiv.htm (noting that the HIV virus infection is believed to lead to AIDS over a period of time, depending on access to antiretroviral treatment). HIV’s progression from infection to full-blown AIDS to death is arguably slower than anthrax or smallpox. Id.

160. Preston, supra note 140, at 48.


163. Id. at 2215. Endemic poverty was in part responsible for the huge discrepancy between potential influenza deaths in developed and developing countries. Id.

164. See Colin D. Mathers & Dejan Loncar, Projections of Global Mortality and Burden of Disease from 2002 to 2030, 3 PLoS MED. 2011, 2021-22 (2006), available at dx.doi.org/10.1371/journal.pmed.0030442 (discussing a recent WHO-sponsored study that showed that poorer countries have the highest rate mortality and bear the greatest burden from diseases).
United States are restructuring their public health care systems and experimenting with and stockpiling anthrax and smallpox vaccines as part of a comprehensive biodefense strategy, resource-poor nations who are equally vulnerable to bioterror attacks are materially challenged to cope with bioterrorism-induced public health crises.

Securing adequate supplies of critical vaccines and drugs in the wake of bioterror attacks is imperative for all nations, rich and poor. This need was amply demonstrated by the 2001 “Dark Winter” simulated smallpox attacks, where inadequate smallpox vaccines aggravated the spread of the virus in the United States. In light of the foregoing analysis, it is clear that access to critical medicines could be compromised if patented drugs or vaccines cannot be mass-produced or parallel-imported within a short period to combat bioterrorism-induced diseases.

The danger of inadequate supplies of vaccine or shortages of critical drugs in the wake of a bioterrorism attack, as noted earlier, was exemplified by the well-publicized skirmishes over Bayer’s antibiotic ciprofloxacin (Cipro) in Canada and the United States in the wake of the 2001 anthrax attacks. If the anthrax attacks had persisted and become widespread in the United States, then U.S. Health Secretary Tommy Thompson could have undoubtedly made good on his threat to override Bayer’s patent and mass-produce ciprofloxacin.

165. Although there is still much to be done, major progress has been made in bioterrorism public health preparedness under “Project Bioshield,” which includes: coverage of 89% of the U.S. population by the Centers for Disease Control and Prevention emergency communications networks; bioterrorism plans in varying degrees of progress in all fifty states; and preliminary laboratory equipment, facilities, and staffing upgrades. SHELLEY A. HEARNE ET AL., READY OR NOT? PROTECTING THE PUBLIC’S HEALTH IN THE AGE OF BIOTERRORISM EXECUTIVE SUMMARY 2 (2003), available at http://healthyamericans.org/state/bioterror/Bioterror-execsum.pdf. In addition, the U.S. government set up a Bio Watch program to protect major U.S. cities by monitoring the air for biological agents that could be released by terrorists. Sean Spicer, A Few Facts About Homeland Security and Economic Security, INSIGHT MAGAZINE, June 15, 2004, available at http://www.insightmag.com (archives available to subscribers only).

166. See generally United States Public Health and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, § 121, 116 Stat. 594, 612 (establishing a strategic stockpile of various drugs, vaccines, and biological products). Following the 2001 anthrax attacks in the United States, the Bush Administration asked Congress for $1.5 billion in biodefense funding which Congress increased to $2.5 billion. Wright, supra note 44, at 58-61. With Congressional approval of $7.45 billion in biodefense funding in 2005, bioterrorism defense funding has increased 1,500% since 2001. Id.

167. See Frederick M. Abbott, The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO, 5 J. INT’L ECO D claration ] (noting that the state of public health care in developing world is “a continuing catastrophe”).

168. DARK WINTER, supra note 148.

169. The impact of patents on developing countries’ access to crucial drugs has been well documented. E.g., Padmashree Gehl Sampath, India’s Product Patent Protection Regime: Less or More of “Pills for the Poor”? 9 J. WORLD INTELL. PROP. 694, 694 (2006).


When asked about the prospects of the United States government applying compulsory licensure to facilitate generic production of ciprofloxacin, the Health Secretary at the time replied “[we] are looking at the patent issue very closely.”

Similarly, Canadian authorities announced that they had overridden Bayer’s patent on ciprofloxacin, without prior consultations with Bayer or permission from the Canadian Commissioner for Patents as required by section 19(1) of the Canadian Patent Act. Although Canada later reversed its decision to override the ciprofloxacin patent, the haste with which the decision was made without due compliance with the procedures in the Canadian Patent Act underscores the extraordinary urgency that characterizes bioterrorism-induced public health crisis. In justifying the measure, a Canadian health official was quoted as saying that “Canadians expect and demand that their government will take all steps necessary to protect their health and safety.”

Had the spread of anthrax assumed epidemic proportions, a decision overriding Bayer’s patent in ciprofloxacin by U.S. and Canadian authorities would, in retrospect, be considered an ethical and necessary public-health policy measure, important enough to trump pharmaceutical proprietary rights.

Recently, a repeat of Bayer’s ciprofloxacin patent imbroglio loomed large amidst global avian flu pandemic fears. There were great global apprehensions that the bird flu virus could jump the species barrier and mutate into a transmissible human flu virus, akin to the 1918 global influenza pandemic that claimed at least 20 million lives. With barely enough Tamiflu (oseltamivir...
phosphate) for 2% of the world’s population being supplied by Roche. Taiwan reportedly vowed to make a generic version of Roche’s Tamiflu without Roche’s consent and in breach of Roche’s patent. Similarly, United States Senator Charles E. Schumer called on Roche to reach an agreement that would allow at least five U.S. companies to manufacture Tamiflu within a month or face legislation that would strip the company of its patent.

However, Senator Schumer’s ultimatum to Roche appears moot because U.S. patent law’s compulsory licensure provision has specific, narrow and limited applications and is rarely used for patented pharmaceuticals. Additionally, the United States is reluctant to derogate from pharmaceutical patents rights in large part because its pharmaceutical industry reputedly derives about forty percent of its income from exports. In 2003, the U.S. pharmaceutical industry was reportedly responsible for $63.9 billion in real output, for a total of $172.7 billion, including economic ripple effects. Furthermore, the U.S. pharmaceutical industry reputedly has an average annual turnover of nearly US$200 billion; much of it derived from patents. Consequently, overriding Roche’s patent in Tamiflu would weaken and undermine the U.S. global drive for stronger pharmaceutical patents rights and protection. It was most certain that the United States would not invoke the TRIPS compulsory licensure provision to mass produce Tamiflu, notwithstanding Senator Schumer’s ultimatum to Roche.

Nevertheless, Senator Schumer’s threat was not without significance. While it did not represent the official position of the U.S. government, Senator Schumer’s ultimatum arguably mirrored the general sentiments of a nation enthralled by the avian flu pandemic prospects, and the imperative of stopping the pandemic by any means. It was also reminiscent of the United States’

184. Id. at 6.
187. Kaufman, supra note 181. This decision, made under the auspices of the compulsory licensing regime in Articles 30 and 31 of TRIPS, was necessary to give members who lack manufacturing capacity, an opportunity to import pharmaceutical products. TRIPS Agreement, supra note 64, arts. 30-31; see also General Council for Trade-Related Aspects of International Property Rights, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health Decision, WT/L/540 (Aug. 30, 2003) (clarifying obligations under a compulsory license pursuant to TRIPS).
188. The public’s support for Senator Schumer’s threat to strip Roche of its patent was reminiscent of
and Canada’s 2001 battles for Bayer’s ciprofloxacin, and Brazil’s 2001 compulsory licensure threat to Roche’s Nelfinavir, all of which ended in negotiated price reductions and promises of adequate supplies.\textsuperscript{189} Given the antecedence of successful open threats and ultimatums in the face of looming public health pandemics, Roche’s ostensible capitulation to the Taiwanese and the U.S. Senator’s threats was inevitable, as evidenced by the company’s subsequent announcement that it was ready to license its Tamiflu patent under negotiated terms.\textsuperscript{190} It has thus become a standard practice to coerce drug companies into allowing generics of critical drugs by threatening a breach of their patents.\textsuperscript{191} While there is arguably the luxury of time for licensing negotiations in a looming pandemic scenario, there is precious little time for coaxing, cajoling, or haggling over mutually agreeable terms of license and royalty in a bioterrorism-induced public health crisis scenario.

This is amply demonstrated by the haste with which the Canadian government initially overrode Bayer’s patent before eventually backpedaling.\textsuperscript{192} This makes having a definitive legal framework for automatically overriding pharmaceutical patents imperative in the face of highly probable bioterrorism crises. The absence of such a law presently renders patents overridden as an effective, self-help, emergency public health policy measure; however, as a response it is largely ad hoc, perfunctory, and vulnerable to patent-grab criticisms.\textsuperscript{193} This Article calls for the enactment of a definitive legal framework for pharmaceutical patent rights derogation, and its operational paradigm in bioterrorism situations.

Against this background, the following section will critically examine the dynamics of the pharmaceuticals and patents interface in general. Special focus will be on the propriety of the TRIPS compulsory licensure and access to
essential medicines regime for bioterrorism induced-public health crises, and the prospects for a special, bureaucracy-free, bioterrorism appropriation clause in patent laws.

III. STRONG MEDICINE: THE PATENTS AND PHARMACEUTICALS ENIGMA

The debate about pharmaceutical patents and access to medicine is an enduring subject of legal, economic and political discourse. Although there were minor skirmishes over drugs pricing between the pharmaceutical industry and AIDS activists in the United States in the mid 1980s, the pharmaceutical patents and access discourse was effectively ushered into the public domain, and imprinted in the public’s psyche by the well-publicized spat between the pharmaceutical industry and the South African government. The latter sought to invoke the compulsory licensure provision of its patent law, via the 1997 Medicine Act, to facilitate cheap imports of anti-retroviral drugs for the nation’s 4.2 million HIV/AIDS sufferers. The 1997 Medicine Act empowers the South African health minister to revoke any pharmaceutical patents if he perceives any associated medicines to be too expensive. The 2002 Act also permits parallel importation of medicines and empowers the health minister to overrule regulatory decisions on the registration and safety of medicines.


200. The Medicines and Related Substances Control Act s. 13 (S. Afr.).
arguably responsible for forcing a rethinking of the interface between patent and public health issues by the WTO, and striking a political bargain aimed at addressing the public health crisis in resource-poor countries in the November 2001 WTO/TRIPS Doha Ministerial Declaration. It also helped swell an army of anti-corporatization and globalization activists from the streets of Seattle to Genoa, culminating in a disastrous blackening of the pharmaceutical industry’s image. The incident also became a standard reference point in noisy discourse on the north/south knowledge divide, and the acceptable modalities for fair trading rules, knowledge access, and technology transfer. It was, undoubtedly, a public relation disaster for the pharmaceutical industry, which quickly abandoned the South African lawsuit, while some of its members retreated quickly into damage-control strategies, including the selling of antiretroviral drugs to resource-poor countries at discounted prices in order to soothe tensions.

While it may appear that the pharmaceutical industry went too far in challenging South African law, the economics of pharmaceutical research and development justified industry opposition to the South African cheap drugs initiative. The pharmaceutical industry is one of the most research-intensive industries and, empirically, the most patent-dependent of all capital-intensive industries.

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206. See Robert L. Ostergard, Jr., The Development Dilemma: The Political Economy of Intellectual Property Rights in the International System 97 (2003) (noting the pharmaceutical industry’s attempts to repair its image by distributing free drugs to developing countries); Steve Sternberg, AIDS Drug Costs Hurt Africa: New Discounts Mean Little in Poor Nations, USA Today, Mar. 15, 2001, at 7A (noting that Bristol-Myers Squibb and Merck & Co. were the first drug companies to announce discount sales of antiretroviral drugs to poor African countries). See Drozdiak & Blustein, supra note 193 for a critical view of the pharmaceutical industry’s ad hoc approach for access to low cost drugs in developing countries.

207. Rik Van Reekum, Intellectual Property and Pharmaceutical Innovation: A Model for Managing the Creation of Knowledge Under Proprietary Conditions I (1999); Pharm. Research &
intensive, high-technology industries. The odds of a new prescription drug entering the market are one in five thousand. Even then, only 30% of the drugs in the marketplace produce revenue that exceeds their cost of development. Moreover, it is axiomatic that millions of dollars of private research and development funding are sunk into the industry in pursuit of innovative and blockbuster drugs.

In the United States, advancement of a potential new medicine from “a research idea to treatment” averages ten to fifteen years, and costs $800 million. Similarly, a controversial 2003 report by Bain & Company put the costs of developing a single new drug at $1.7 billion. Although the actual cost of pharmaceutical research and development is a highly controversial topic—especially with the pharmaceutical industry’s estimated research and development cost estimates constantly attacked as being exaggerated—there is no denying the significance of patents to the pharmaceutical industry. The patent system ensures that the pharmaceutical industry can recoup its huge financial investments, by keeping out competitors during patent pendency.


210. Id.


214. Opponents contend that the pharmaceutical industry’s research and development figures were exaggerated and did not take into account the amount that the U.S. government spends on the National Institute of Health and other health related agencies such as the FDA, CDC, DOE, etc. Most recently, Representative Sherrod Brown called on the Bush Administration to investigate the actual cost of pharmaceutical research & development. Rep. Brown Asks White House for Study of Drugs R&D Costs, DRUG INDUSTRY DAILY, Apr. 26, 2005, available at http://www.fdanews.com/newsletter/article?issueid=7484&articlenumber=71492; Letter from James Love, Dir., Consumer Project Tech., to the Dep’t of Commerce, Int’l Trade Admin. (Jul. 1, 2004), available at http://www.cptech.org/ip/health/rndtf/drugpricestudy.html; see also MARCIA ANGELL, THE TRUTH ABOUT THE DRUG COMPANIES: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT, 37-51 (2005) (debunking the pharmaceutical industry’s estimate of $802 million in research and development costs per drug, and accusing the industry of concealing the real costs of about $100 million after taxes).


This is otherwise known as patent exclusivity, and is conferred on all patentable inventions by Article 28 of the TRIPS Agreement. In the Canada-Patent Protection of Pharmaceutical Products ("Canada-Patent Protection") case, the WTO Panel Report highlighted the significance of TRIPS’ Article 28 as follows:

The normal practice of exploitation by patent owners, as with owners of any other intellectual property right, is to exclude all forms of competition that could detract significantly from the economic returns anticipated from a patent’s grant of market exclusivity. . . . Patent laws establish a carefully defined period of market exclusivity as an inducement to innovation, and the policy of those laws cannot be achieved unless patent owners are permitted to take effective advantage of that inducement once it has been defined.

The above quote affirms the twin functional values of patents embodied in the reward and prospects doctrines. Primarily, the societal quid pro quo for patent exclusivity is the expected concomitant rise in research and development investments, and public disclosure of the patented invention, which, in turn, assures conditions for competitive, innovative and beneficial products.

The pharmaceutical industry is, however, highly vulnerable to cheap imitations and piracy because chemicals are easily replicable. It is estimated that about 6% of world global trade in medicines is lost due to counterfeits.

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217. TRIPS Agreement, supra note 64, art. 28.
219. The reward doctrine posits that patents are rewards given to inventors who contribute to economic and technological progress of a nation that give them incentive to keep working. NUNO PIRES DE CARVALHO, THE TRIPS REGIME OF PATENT RIGHTS 1-8 (2005) The prospect doctrine posits that patents are certificates that grant inventors the power to prospect the market for commercial opportunities. Id. The prospect doctrine thrives on the apparent weakness of the reward theory that most patents are never worked and that it is impossible to know the full potential of a patent when it is granted. MICHAEL PERELMAN, STEAL THIS IDEA: INTELLECTUAL PROPERTY RIGHTS AND THE CORPORATE CONFISCATION OF CREATIVITY 59-63 (2002) (giving specific examples specific examples of patents that were never worked or developed). However, Nuno Pires de Carvalho argues that both the Reward and Prospect doctrines are flawed because they do not offer a complete systematic explanation of the patent system as a whole. PIRES DE CARVALHO, supra, at 1-8. Nevertheless, the two theories do highlight some of the practical functions of the patent system. Edmund W. Kitch, The Nature and Function of the Patent System, 20 J.L. & ECON. 265, 266 (1977).
221. Abbott, Doha Declaration, supra note 167, at 472-73 (noting the pharmaceutical industry’s argument that patents are indispensable to continual funding of research and development of innovative pharmaceuticals).
223. Association of the British Pharmaceutical Industry, The Trade in Counterfeit Medicines (July 2003),
Empirical study has established that cheap imitations of original products could adversely affect incentives for further innovation. This is one of the reasons the pharmaceutical industry is ever keen on promoting stronger patent protection for pharmaceuticals and fending off production of cheaper generics prior to expiration of patents. Companies have employed tactics like collusive agreements with competitors in clear breach of anti-competition rules. They have also used infringement lawsuits as barriers, and have crafted perennial patent monopoly rights via new patents on slightly modified process or product pharmaceutical patent claims. This is exemplified by ongoing patent disputes between Novartis and Indian pharmaceutical companies in a Chennai court. The former sought patent protection for Glivec, a modified form of its leukemia drug, under the Indian 2005 Patent Act, while the latter contended that the modified cancer drug constituted mere “incremental innovations,” and suffered from prior publication, lack of inventive step, and insufficient description, and did not represent a significant improvement on the original off-patent leukemia drug, therefore making it ineligible for protection under the Indian Patent Act. Significantly, the Indian generic version of Glivec retailed only “for about a tenth of the $2,600 that Novartis charge[d] for a month’s course of treatment.” Novartis’ challenge to Indian Patent law was premised on its alleged non-compliance

224. See Edwin Mansfield, Mark Schwartz & Samuel Wagner, Imitation Costs and Patents: An Empirical Study, 91 ECON. J. 907, 907, 915 (1981) (surveying firms, including pharmaceutical companies, and determining that about half of their patented innovations would not have been introduced if patent protection were not available).  
230. Gentleman, supra note 228, at C5.
with TRIPS. 231

Pharmaceutical patents are so crucial to the pharmaceutical industry’s survival that many nations have drafted special legislation to extend the term of pharmaceutical patents beyond the standard twenty years. 232 For instance, in the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 (“Hatch-Waxman Act”) 233 permits limited extensions for pharmaceutical patents to make up for time lost during the marketing approval process conducted by the FDA. Similarly, the European Union and Australia have conditional pharmaceutical patent term extension provisions in their patent laws. 234

Apart from patents, the pharmaceutical industry often resorts to trademarks 235 and trade secrets or know-how 236 to protect their brands from generic competition. Such plus-patent protection is especially crucial for off-patent drugs. This is more so for trademark, which is as effective as patent in blocking parallel importation of generics even when brand names are off-patent. 237 The know-how component of pharmaceutical production is protected by laws guaranteeing exclusive rights on clinical drug test data, which are indispensable for securing marketing rights in most countries. 238

235. S. CALLENS ET AL., CHAPTERS ON PHARMACEUTICAL LAW 100 (2000). It is theoretically possible to use trademark or trade dress to protect expired patents provided the mark or dress is not claimed in the expired patent and has no functional value. See, e.g., TrafFix Devices, Inc. v. Mktg. Displays, Inc., 532 U.S. 23, 29 (2001) (using the functionality doctrine to scuttle an alleged product design trade dress infringement suit).
236. See Ian Dodds-Smith, DATA PROTECTION AND ABRIDGED APPLICATIONS FOR MARKETING AUTHORIZATIONS IN THE PHARMACEUTICAL INDUSTRY, in PHARMACEUTICAL MEDICINE, BIOTECHNOLOGY AND EUROPEAN LAW 93, 93 (Richard Goldberg & Julian Lonbay eds., 2000).
237. Glasgow, supra note 227, at 252-54.
238. Notwithstanding the grant of a patent, clinical testing data is required before drugs are allowed to be marketed in most countries. In the United States, the FDA monitors clinical trials of new drugs in order to ensure public health safety. Information for Clinical Investigators, http://www.fda.gov/cder/about/smallbizclinical_investigator.htm (last visited Oct. 27, 2007). In Europe, medicines for humans must be approved before they can be sold, which involves submission of clinical test data for the drug for which approval is sought. Council Directive 65/65, art. 4, 1965 O.J. 369 (EEC). Approval of the Medicine Evaluation Agency for market authorization is validated by certificates issued to that effect. Aaron Xavier Fellmeth, Secrecy, Monopoly, and Access to Pharmaceuticals in International Trade Law: Protection of
For instance, Article 39.3 of the TRIPS Agreement enjoins WTO members to preserve the confidentiality of clinical drug test data submitted for marketing approval, except in cases of overriding public interest.\footnote{TRIPS Article 39.3 provides: Members, when requiring, as a condition of approving the marketing of a pharmaceutical or of agricultural or chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except when necessary to protect the public, or unless steps are taken to ensure the data are protected against unfair commercial use. TRIPS Agreement, supra note 64, art. 39.3.} Similarly, in the United States,\footnote{Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585. The FDA as a matter of law, will not entertain a generic manufacturer’s application for marketing approval without the prior approval of the initial registrant (brand manufacturer). 21 U.S.C. § 355(c)(3)(E)(ii) (2000).} Canada,\footnote{Food and Drugs Act, C.R.C., ch. 870 (1985), amended by § C. 08.004.1, 129 C. Gaz. 2494 (Can.).} and European Union,\footnote{Council Directive 2001/83/EC, art. 10, 2001 O.J. (L 311) 75.} generic-drug manufacturers may not rely on clinical drug test data submitted by brand manufacturers for marketing approval, until five to ten years after initial marketing approval.\footnote{243. TRIPS Agreement, supra note 64, art. 39.3.}

However, there are exceptions to the panoply of legal protection for pharmaceuticals. In the context of intellectual property rights in general, these exceptions are generally hinged on the imperatives of balancing the conflicts among intellectual property rights, unbridled technology diffusion, and competition or antitrust policy.\footnote{Although the TRIPS Agreement does not expressly address competition law, its Article 40(1) notes that “some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade.” TRIPS Agreement, supra note 64, art. 40(1). Article 40(2) states that nothing in TRIPS prevents members from specifying “licensing practices or conditions that may in particular case constitute abuse of intellectual property rights having an adverse effect on competition in the relevant market.” TRIPS Agreement, supra note 64, art. 40(2). Article 31 is an important provision in the context of pharmaceuticals as it allows non-exclusive compulsory licensing. TRIPS Agreement, supra note 64, art. 31; see infra Part IV.} In the context of the TRIPS Agreement, the significance of the interplay between intellectual property and competition policy was underscored by the constitution of the WTO Working Group on the Interaction between Trade and Competition Policy at the December 1996 Singapore Ministerial Conference.\footnote{World Trade Organization, Singapore Ministerial Declaration, WT/MIN(96)/DEC, ¶ 20 (1996), available at http://www.wto.org/english/tratop_e/minist_e/min96_e/singapore declaration96_e.pdf. The Working Group has since discussed topics including the objectives of intellectual property and their relationship to competition policy, the optimal treatment of intellectual property licensing agreements and the implications of the territorial segmentation of intellectual property protection in the context of competition policy. See, e.g., WTO, Working Group Set Up by Singapore Ministerial http://www.wto.org/english/tratop_e/minist_e/min99_e/english/about_e/16comp_e.htm (last visited Oct. 24, 2007). For discussion on the adequacy of the TRIPS competition policy, see Fredrick M. Abbott, Are the Competition Rules in the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights Adequate, in REFORMING THE WORLD TRADING SYSTEM: LEGITIMACY, EFFICIENCY, AND DEMOCRATIC GOVERNANCE 317, 317-34 (Ernst-Ulrich Petersmann & James Harrison, eds., 2005) (concluding that there are no compelling grounds for change, but see infra Part IV.)}
particular, derogations from patent exclusivity are often anchored on public policy underpinnings for public health protection. A good example of such derogation from patent exclusivity is the “Bolar” exception rule in the United States that allows the use or sale of a patented invention, if such dealings are reasonably related to the development and submission of information under a federal law governing the manufacture, use, or sale of drugs or veterinary biological products.246 A comparable Canadian provision247 was held compatible with Article 30 of the TRIPS Agreement by the WTO Dispute Settlement Understanding (“DSU”) Panel on March 17, 2000 in the Canada-Patent Protection case.248

Similarly, the European patent regime recognizes particular249 and general250 exceptions to bio-pharmaceutical patent exclusivity. William Cornish and David Llewellyn noted that general exceptions cover both private and experimental use.251 While private use covers private and non-commercial acts, experimental use covers all non-commercial experimental activities in relation to the subject matter of the invention.252 The experimental use exception is especially controversial in the context of successful blockbuster drugs.253 However, recent trends in the European Patent Convention countries show increasing acceptance of the commercial experimental use exception.254 For instance, while accepting the Bolar-type exception rule, the German

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246. 35 U.S.C. § 271(e)(1) (2000). Section 271(e)(1) was enacted following a Federal Circuit decision in Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858, 863-64 (Fed. Cir. 1984), which held that clinical data testing was not within the purview of the common law experimental use doctrine.

247. Patent Act, R.S.C., ch. P-4, § 55.2(1) (2001) (Can.) (“It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product.”).


249. Particular exceptions include “extemporaneous” preparations by pharmacists from prescriptions provided by the Council Agreement Relating to Community Patents 89/695, art. 27(c), 1989 O.J. (L 401) 1, 14 (EEC), and the “farming” use exception in conformity with the Council Directive 98/44, art. 11, 1998 O.J. (L 213) 13, 19 (EC). For discussion, see WILLIAM CORNISH & DAVID LLEWELYN, INTELLECTUAL PROPERTY: PATENTS, COPYRIGHT, TRADE MARKS AND ALLIED RIGHTS 245-47 (5th ed., 2003).

250. CORNISH & LLEWELYN, supra note 249.

251. Id. at 245.

252. Acts by governmental, educational, or charitable organizations might not be commercial, but would not likely be regarded as private use. Id.


254. CORNISH & LLEWELYN, supra note 249, at 249.

255. Id.
Federal Supreme Court held in the 1995 case of *Boehringer Ingelheim Int. GmbH* vs. *Dr. Rentschler Arzneimittel GmbH and others* that “it is not contrary to the permissibility of clinical tests that the Defendants are carrying out or supporting these with the further aim of licensing the laws relating to pharmaceuticals.” Moreover, the European Parliament gave a fillip to the Bolar-type exception in a resolution dated April 16, 1996 supporting the measure.

Other possible exceptions to pharmaceutical patent exclusivity include: international exhaustion of intellectual property rights (on which Article 6 of TRIPS is mute), the limited exceptions under Article 30 of TRIPS, the compulsory licensing provisions of Article 31 of TRIPS, and the TRIPS-Doha Declaration on Public Health for leveraging access to critical medicines in resource-poor countries. The following paragraphs will critically review the propriety and efficacy of these exceptions for securing crucial drugs for bioterrorism-induced diseases in the context of attendant extraordinary public health crises.

IV. THE PROPRIETY OF TRIPS PROVISIONS AND OTHER EXCEPTIONS TO PATENT EXCLUSIVITY FOR BIOTERRORISM-INDUCED DISEASES

The following examines TRIPS Article 6 on the exhaustion of intellectual property rights, TRIPS Article 30 on limited exception to patentees’ rights, TRIPS Article 31 on compulsory licensing provisions, the TRIPS-Doha Declarations on Public Health, and other general exceptions to patents exclusivity as they affect pharmaceutical patents rights in relative detail. The discourse will primarily draw on these patent-limiting provisions of TRIPS and the patent laws of the United States, the European Union, Canada, and other Anglo-American jurisdictions for comparison. This Part will argue that the existing exceptions are inadequate for bioterrorism-induced public health crises.

A. TRIPS Provision on Exhaustion of Rights and Implications for Parallel Importation of Pharmaceuticals for Bioterrorism-Induced Diseases

In principle, especially within the territory covered, intellectual property rights are exhausted after first sales by the right owners or with the right owners’ consent. However, the law concerning international exhaustion of

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257. *id.* at 79.

258. Paragraph 17 of the European Parliament 1996 Resolution provides as follows: Measures should be introduced which enable pharmaceutical companies to begin, in advance of patent or supplementary protection certificate (SPC) expiry, such laboratory experiments and regulatory preparations as may be required only for the registration of generic pharmaceuticals developed in the EU, to be available on the market immediately, but only after the expiry of a patent or SPC for a proprietary product.

intellectual property rights is not as settled, since intellectual property rights are inherently territorial, and national intellectual property rights can still be used to bar the importation of goods sold abroad by national rights owners, or sold abroad with their consent. The significance of international exhaustion of pharmaceutical rights policy lies in its dual use to allow or forbid cross-border importation of cheap medicines. In the European Union, for example, cross-border parallel importation of medicines is an established practice, rooted in the common-market principle and validated by the European Court of Justice in numerous cases.

Article 6, the key provision of the TRIPS Agreement on exhaustion, states, “For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.” In principle, patentees can use their national rights to bar cross-border importation of goods originally sold abroad by them or with their consent. In the context of the TRIPS Agreement however, patentees’ right to bar cross-border importation of goods is ostensibly constrained by Article 6 of the TRIPS Agreement, which excludes exhaustion of intellectual property rights from within its ambit in dispute settlement situations. In other words, there can be no justiciable complaint against parallel importation of patented products under Article 6 of TRIPS. This position is reinforced by paragraph 5(d) of the November 2001 Doha Declaration on the TRIPS Agreement and Public Health, which states, “The effect of the provisions of the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge subject to the MFN and national treatment provisions of...
Articles 3 and 4."  

Significantly, paragraph 5(d) of the Doha Declaration neither adds anything substantial to Article 6 of TRIPS, nor radically changes its scope. The main provision of TRIPS that pertains to exhaustion is Article 6, and, arguably, it already tacitly allows Members to decide their exhaustion regime. Therefore, paragraph 5(d) of the Doha Declaration is no more than a reassuring restatement of the law as provided under Article 6 of TRIPS. According to Carlos M. Correa, although paragraph 5(d) "does not add substantively to the TRIPS Agreement, it certainly reassures Members wishing to apply an international exhaustion principle that it would be legitimate and fully consistent with the Agreement to do so."  

Theoretically, this is bound to detract from TRIPS’ ability to rein in parallel importation of patented, cheap pharmaceuticals. It is axiomatic that TRIPS’ reticence on exhaustion of intellectual property rights is not a proactive endorsement of anti-parallel importation policy, but rather some passive neutrality designed to gloss over a highly controversial subject that divided negotiators and scholars into pro- and anti-international intellectual property rights exhaustion camps. 

It is noteworthy however that, while TRIPS is reticent on exhaustion of intellectual property rights, it does not forbid member countries from embracing a national intellectual property rights exhaustion policy. In fact, as noted earlier, paragraph 5(d) of the Doha Declaration expressly endorses such a right. For instance, the United States, like the European Union and Japan, operates a national patents rights exhaustion policy. To ensure the viability of its patent law in this regard, the United States consistently seeks cooperation with its trade partners in shoring up supports for national intellectual property rights exhaustion policy, especially for pharmaceuticals. This arguably explains the ubiquitous anti-international intellectual property rights exhaustion clause in the intellectual property chapters of the United States’  

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269. Some negotiating parties, led by Australia, Brazil, Hong Kong, India and New Zealand, favored the inclusion of international exhaustion of intellectual property rights. GERVAIS, supra note 266, at 112-113. Other negotiating parties, including the United States, Canada and the European Union preferred national exhaustion. Id. Under international exhaustion, once a product has entered the market with the right holder’s consent anywhere in the world, all intellectual property rights in that product are exhausted. Id. Under national exhaustion, intellectual property rights are marked by territoriality. Id. Right holder’s authorization would be required prior to exploitation of rights outside of the territory where the product first entered the market. Id.  
The pertinent question is whether TRIPS’ reticence on intellectual property rights exhaustion could avail a member to parallel import critical pharmaceuticals in a bioterrorism related public health crisis? Theoretically, members could employ Article 6 of TRIPS to parallel import crucial drugs for bioterrorism-induced ailments. While such an action may not constitute a justiceable complaint by an aggrieved member under the TRIPS DSU, legal remedies outside of TRIPS’ DSU regime, (such as alleged breach of intellectual property components of bilateral trade agreements) are not entirely foreclosed. TRIPS’ ambivalence on international exhaustion of intellectual property rights provides no legal basis for cross-border parallel importation of drugs, and may not avail a member who seeks to do so.

Moreover, political pressures and threats of economic sanctions from aggrieved members with the requisite clout may render any decision to parallel-import crucial drugs for bioterrorism-related diseases under paragraph 5(d) of the Doha Declaration obtuse or even imprudent. Furthermore, a WTO member may not avail itself of Article 6 of TRIPS to parallel import crucial drugs to meet a bioterrorism crisis if it is obliged by a bilateral free trade agreement to the contrary. Singapore’s position best illustrates this point. Prior to signing a bilateral free trade agreement with the United States in August 2003,


275. Countries where pharmaceutical manufacturing contributes significantly to the GDP, such as the United States and the European Union, are keen to ensure enforcement of international intellectual property protection for pharmaceutical and chemical products. E.g., Trade Act of 1974, 19 U.S.C. § 2242(b)(1) (2000) [hereinafter Special 301] (authorizing the use of trade sanctions under by the Office of the United States Trade Representative (“USTR”). Special 301 empowers the USTR to categorize a country as a “priority foreign country” if (i) the country’s acts, practices and policies are the most onerous to U.S. industry; and (ii) the country is not in good faith multilateral or bilateral negotiations to provide adequate and effective intellectual property protection. Id. Special 301 has been used, with a relative degree of success, to persuade countries to protect the intellectual property rights of U.S. businesses in pre- and post- TRIPS dispensions. E.g., Judith H. Bello & Alan F. Holmer, “Special 301”: Its Requirements, Implementation, and Significance, 13 FORDHAM INT’L L. J. 259, 261 (1989-1990); Stefan Kirchanski, Comment, Protection of U.S. Patent Rights in Developing Countries: U.S. Efforts to Enforce Pharmaceutical Patents in Thailand, 16 Loy. L.A. Int’l & Comp. L.J. 569, 587-90 (1994); Arthur Wineburg, U.S. Trade Threats Spur Asian Laws on Intellectual Property, Nat’l L.J., July 13, 1992, at 29.

276. It is not clear whether such a member could resort to the public health provisions of the TRIPS agreement, without first declaring a public health emergency, and seeking a compulsory license to manufacture or import such drugs. See Declaration on the TRIPS Agreement and Public Health, supra note 267, ¶ 5 (providing grounds for compulsory licenses and the determination of national emergencies).

Section 66(2)(g) of the Singapore Patent Act 1994 allowed for international exhaustion of patents rights in all patented processes and products. However, the 2003 United States-Singapore Free Trade Agreement excluded pharmaceuticals from the scope of Section 66(2)(g), by specifically foreclosing parallel importation of patented pharmaceutical products without the authorization of the patent owner. A fortiori, the provisions of paragraph 5(d) of the Doha Declaration and Article 6 of the TRIPS Agreement’s reticence on exhaustion of intellectual property rights are of little practical use for parallel importation of crucial drugs in bioterrorism-induced public health crises situations, or any public health emergency for that matter.

B. The Propriety of Article 30 of the TRIPS Agreement for Bioterrorism-Induced Diseases

Article 30 of the TRIPS Agreement allows for derogation from patent exclusivity on grounds of “exceptional use” by imposing three distinctive, but cumulative, exceptions on Article 28(1) of the TRIPS’ patents exclusivity: (1) the exceptional use must be limited; (2) the exceptional use may not unreasonably conflict with the normal exploitation of the patent; (3) the exceptional use may not unreasonably prejudice the legitimate interests of the patentee, taking into account the legitimate interests of third parties.

The pertinent question is whether Article 30 of TRIPS could be used in sourcing crucial drugs and vaccines in bioterrorism-induced public health crises. The negotiating history of Article 30 and the Canada-Patent Protection case offer some insights into the scope and usefulness of Article 30 in this context.

278. Section 66 (2)(g) of Singapore’s 1994 Patent Act provides that an act is not infringing if: (I) it consists of the import, use or disposal of, or the offer to dispose of, any patented product or any product obtained by means of a patented process or to which a patented process has been applied, which is produced by or with the consent (conditional or otherwise) of the proprietor of the patent or any person licensed by him, and for this purpose “patent” includes a patent granted in any country outside Singapore in respect of the same or substantially the same invention as that for which a patent is granted under this Act and “patented product,” “patented process” and “licensed” shall be construed accordingly.


280. Article 30 of TRIPS provides that “members may provide limited exceptions to the exclusive rights conferred by a patent provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.” TRIPS Agreement, supra note 64, art. 30.

281. See Canada-Patent Protection, supra note 218 (noting the historical antecedence of Article 30 in...
respect. The Canada patent case will be analyzed in detail due to the significant light it sheds on the prospect of Article 30 being used as a tool for the procurement of critical drugs in a public health pandemic or bioterrorism crisis.

The negotiating history of Article 30 of TRIPS indicates that it was originally designed to accommodate a wide range of specific, authorized exceptions. This included prior users’ rights; private and non-commercial acts; experimental acts; manual preparation by pharmacists and medical doctors in accordance with a prescription, or acts performed with a medicine so prepared; acts done in reliance upon such acts not being prohibited by a valid claim as initially granted in a patent, but subsequently prohibited by a valid claim of that patent as amended; and governmental acts performed for government uses. Apparently, these specific exceptions never made it to the final provisions of Article 30 as it is presently construed.

In the Canada-Patent Protection case, the European Community challenged the consistency of Sections 55.2(1) and 55.2(2) of the Canadian Patent Act with Articles 27.1, 28, 30, and 33 of TRIPS. Section 55.2(1) of Canada’s Patent Act provided that a patent shall not be infringed if the patented invention is used or sold for uses that reasonably relate to the development and submission of information required under any Canadian law. This is otherwise known as the “regulatory review exception,” which is akin to the United States’ Bolar exception in the Hatch-Waxman Act. However, Canada’s patent law went beyond the Bolar exception in Section 55.2(2), by authorizing third parties to manufacture and stockpile patented pharmaceuticals during regulatory review processes, six months prior to the expiration of the patent term. The WTO panel report examined the validity of the twin exceptions in Sections 55.2(1) & (2) of Canada’s Patent Act vis-à-vis Article 30 of TRIPS. The panel found that Section 55.2(1), which embodied the regulatory review Bolar-type exception, was consistent with Articles 27.1 and 28.1 of TRIPS because it was authorized by Article 30 of TRIPS.

In effect, the WTO panel sanctioned acts of manufacturers and suppliers of active pharmaceutical components, as well as producers of generic pharmaceuticals, provided such acts were reasonably related to marketing approval of a generic pharmaceutical product. The WTO panel, however,
found that the stockpiling exception under section 55.2(2) of the Canadian Patent Act ran afoul of Article 28.1 of TRIPS because it was outside of the ambit of allowable exceptions under Article 30 of TRIPS. Therefore, Article 30 was narrowly construed.

The WTO panel’s ruling, severing the stockpiling exception from the regulatory review exception of Canada’s patent law, demonstrates the narrow ambit of the limited exceptions allowable under Article 30 for the production of generic pharmaceuticals. It also unequivocally demonstrates that Article 30 of TRIPS is improper for the challenges of bioterrorism emergency situations; drug stockpiling, though of limited practical use, is arguably an integral logistical measure of bioterrorism preparedness.

Although the “limited exceptions” provision was narrowly construed, the precise parameters were left undefined by the WTO panel ruling, rendering it vague and vulnerable to semantic arguments. While any number of patent-limiting provisions could theoretically fit into its narrow confines, in practice, only those that are less threatening to patented inventions, like the experimental use exception as opined by the WTO panel in the Canada-Patent Protection case, would pass muster.

The inappropriateness of Article 30 for bioterrorism emergencies is further underscored by the cumulative nature of its three conditions. Non-compliance with any of the three provisions contravenes Article 30 as a whole. The following paragraphs will examine conditions two and three in an attempt to shed more light on their usefulness for securing crucial medicines in any bioterrorism context.

1. Conflict with Normal Exploitation of a Patent

The second condition of Article 30 of TRIPS requires that exceptions to the rights conferred should not unreasonably conflict with a normal exploitation of the patent. While TRIPS does not define “normal exploitation,” the WTO panel in the Canada-Patent Protection case defined “normal” as “a normative standard of entitlement” and “what is common within a relevant community.” The Panel went on to define “exploitation” as the “commercial activity by which patent owners employ their exclusive patent rights to extract economic value from their patent.”

291. Id.
292. Id. ¶ 7.30 (“The term ‘limited exceptions’ must therefore be read to connote a narrow exception—one which makes only a small diminution of the rights in question.”).
293. See Nordqvist, supra note 53 (noting that the U.S. government recently had to restock its flu vaccine stockpiles due to the vaccines’ loss of strength).
294. See generally Canada-Patent Protection, supra note 218 (declining to precisely define “limited exceptions”).
295. See id. ¶ 4.30 (discussing the limited character of the experimental use exception).
296. See infra Part IV.B.1.
297. Id.
298. TRIPS Agreement, supra note 64.
300. Id.
summed up what it perceived as the essence of the second leg of Article 30 of TRIPS by stating that “[t]he normal practice of exploitation by patent owners, as with owners of any other intellectual property right, is to exclude all forms of competition that could detract significantly from the economic returns anticipated from a patent’s grant of market exclusivity.”

The panel’s construction of the second prong of Article 30 was arguably too restrictive. Without a doubt, patent owners would love to exclude all forms of competition and breach stringent anti-competitive rules. However, the TRIPS Agreement does not envisage an unbridled patent monopoly as evident in Article 31(k), which enjoins against anti-competitive practice and would avail the grant of a compulsory license to loosen up any anti-competitive gridlock. If anything, the second condition of unreasonable conflict with normal patent exploitation under Article 30 of TRIPS makes it nearly impossible to employ the Article to acquire needed drugs in bioterrorism emergencies. Such a use would no doubt be an extreme measure vis-à-vis the stockpiling provision of section 55.2(2) (now repealed) of the Canadian Patent Act which the panel found invalid under Article 30 of TRIPS.

Furthermore, applying the second prong of Article 30 to the acquisition of crucial drugs for bioterrorism attacks could be complicated by a lack of a understanding of critical terms like limited exceptions, normal exploitation, or unreasonable conflict. The panel’s proposition in this respect is too descriptive and very pro-patent. For instance, it is very unlikely that a WTO member could successfully parallel import crucial drugs for bioterrorism attacks via the second prong of Article 30. If Canada could fail to retain its drug stockpiling exception during the generic pharmaceuticals regulatory review process, any urgent measure aimed at securing crucial medicines for victims of bioterrorism attacks outside of the TRIPS systemic-bound provisions would be doomed to invalidity under Article 30 for unreasonably conflicting with the normal exploitation of the pharmaceutical patent in question.

2. **Legitimate Interests of Patents Owner and Third Parties**

The third part of TRIPS Article 30 requires that any exception to patent exclusivity should not unreasonably prejudice the legitimate interests of the patent owner. It ostensibly seeks to maintain a balance, however, by

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301. *Id.* ¶ 7.55.
302. Article 31(k) of TRIPS provides:

   Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur.

   TRIPS Agreement, supra note 64, art. 31(k).
303. TRIPS Agreement, supra note 64, art. 30.
305. TRIPS Agreement, supra note 64.
It is pertinent at this juncture to analyze the implications of the requirement of “the legitimate interests of third parties” on the effectiveness of the third limb of Article 30 for critical drug procurement in bioterrorism emergencies.

Article 30 of TRIPS coincides with Articles 13, 17, and 26(2) of TRIPS on general exceptions to the exclusive rights of copyright, trademark, and industrial designs. It is reminiscent of Article 9(2) of the Berne Convention on literary and artistic works, with its time-honored three-step tests. However, Articles 17, 26(2), and 30 of TRIPS on trademark, industrial designs, and patents, respectively, differ from the Berne Convention’s Article 9(2) and TRIPS Article 13 on Copyright by the additional requirement that legitimate interests of third parties should be considered. Daniel Gervais views this as a broadening of the scope of the exceptions to industrial property exclusive rights.

Is it a coincidence that only the industrial property rights provisions of TRIPS contain the additional requirement for consideration of the legitimate interest of third parties? The answer is, arguably, “no.” This is underscored by the absence of such a requirement under Article 13 of TRIPS dealing with derogation from copyright exclusivity. The significance of this differential treatment between industrial property on the one hand (trademarks in Article 17; industrial designs in Article 26(2); and patents in Article 30) and copyright on the other hand (Article 13) arguably lies in the former’s association with technical products and capital-intensive goods and services of comparatively greater economic value than products traditionally protected by copyright.

306. Id.
307. Article 13 of TRIPS provides a general exception to copyright exclusivity, stating “[m]embers shall confine limitations or exceptions to exclusive rights to certain special cases which do not conflict with a normal exploitation of the work and do not unreasonably prejudice the legitimate interests of the right holder.” Id. art. 13. Article 17 of TRIPS provides a general exception to trademark exclusivity, stating “[m]embers may provide limited exceptions to the rights conferred by a trademark, such as fair use of descriptive terms, provided that such exceptions take account of the legitimate interests of the owner of the trade mark and of third parties.” Id. art. 17. Article 26(2) of TRIPS on industrial designs provides:

Members may provide limited exceptions to the protection of industrial designs, provided that such exceptions do not unreasonably conflict with the normal exploitation of the protected industrial designs and do not unreasonably prejudice the legitimate interests of the owner of the protected design, taking into account the legitimate interests of third parties.

Id. art. 26.
308. See Berne Convention for the Protection of Literary and Artistic Works, Sept. 9, 1886, 828 U.N.T.S. 222 (amended Sept. 28, 1979) (“It shall be a matter for legislation in the countries of the Union to permit the reproduction of such works in certain special cases, provided that such reproduction does not conflict with a normal exploitation of the work and does not unreasonably prejudice the legitimate interests of the author.”).
309. Id. Article 30 of TRIPS was taken from Article 9(2) of the Berne Convention. JACQUES J. GORLIN, AN ANALYSIS OF THE PHARMACEUTICAL-RELATED PROVISIONS OF THE WTO TRIPS AGREEMENT 28 (1999). The addition of consideration for the legitimate interest of third parties was clearly deliberate, although no special reason was offered for its inclusion. Id.
310. GERVAIS, supra note 266, at 241.
311. TRIPS Agreement, supra note 64, art. 13.
312. This is the case notwithstanding that copyright law is now the basis for digital rights management in the burgeoning information society. PETER DRAHOS & JOHN BRAITHWAITE, INFORMATION FEUDALISM: WHO OWNS THE KNOWLEDGE ECONOMY? 169-186 (2003); Pamela Samuelson, Copyright and Freedom of Expression in Historical Perspective, 10 J. INTELL. PROP. L. 319, 326-27 (2003); Alan Story, Don’t Ignore
Since we live in an increasingly technology-dependent era, societal stakes in industrial property rights-related inventions are undoubtedly very high. Third parties, comprising the society at large, naturally have legitimate interests in the methodology for patented pharmaceutical technology dissemination, diffusion, and access. While patent owners have legitimate interests in securing their ownership rights, society has equally legitimate interests in accessing the protected inventions. However, whether third parties could couch the need for access to crucial drugs in bioterrorism situations as “legitimate interests” under the third prong of Article 30 remains an open question, and arguably doubtful, due to the narrow and limited construction by the DSU Panel in the Canada-Patent Protection case.\textsuperscript{313}

The term “legitimate interests” appears to be the operating force in the third prong of Article 30 of TRIPS. Again there are no clues from TRIPS on the exact meaning of “legitimate interests.” However, the panel on pharmaceuticals described “legitimate interests” as interests that “... are supported by relevant public policies or other social norms.”\textsuperscript{314} The panel then alluded to experimental use of patented products for scientific experimentations, throughout the duration of patents, as an example of legitimate interests.\textsuperscript{315} Both patent owners and society have legitimate interests in using the patent for the advancement of science and technology.

Arguably, this is an integral element of patent policy fundamentals. The patentee trades his patent specifications and workings for a limited monopoly. The societal quid pro quo in this seemingly mutually beneficial arrangement is the knowledge revealed in the disclosed patent. Herein resides the critical mass for the parties’ respective legitimate interests, alluded to by the panel on pharmaceuticals.\textsuperscript{316}

It is, however, doubtful whether the legitimate interests of pharmaceutical patent owners and the legitimate interests of third parties could be mutually consistent in the context of a need to mass-produce crucial drugs to aid victims of bioterrorism. Under this scenario, the pharmaceutical patent owner would claim to have legitimate interests in excluding the third party from mass-producing the required drugs, while the third party would claim to have legitimate interests in doing so. Article 30 is ill-suited to handle this conflict of rights due to its narrow construction by the WTO panel in the Canada-Patent Protection case.

It is significant that, although the panel endorsed the scientific experimental use exception as properly within the ambit of any legal construct or analysis of the third leg of Article 30, the panel cautioned that it did not draw any conclusions about the correctness of any such exception in national
The panel would not speak to the validity of experimental use exceptions to patent exclusivity under Article 30 of TRIPS. The panel’s reticence is understandable, lest national authorities seize onto it to validate definitive experimental use under Article 30 of TRIPS.

It is significant, however, that the panel only cited the experimental use exception as an example of a third party’s legitimate interest. It was one of the original specific exceptions proposed during the negotiation of Article 30. It is arguably also the least patent-threatening activity relative to other original exceptions, such as government use, which could be more effective in parallel importing or mass producing drugs in the event of a pandemic or bioterrorism crisis.

The European Community suggested a liberal interpretation of Article 30 in a 2002 paper submitted to the Council of TRIPS. This was to facilitate the implementation of Paragraph 6 of the 2001 TRIPS/Doha Declaration on Public Health, for exporting of pharmaceuticals to WTO members with or without limited manufacturing capacity. Despite support for the proposal by developing countries, the United States was resolutely opposed to using Article 30 in this way, on the grounds that it would be prejudicial to the rights of WTO members, under the TRIPS Agreement. A fortiori, the cumulative limited exceptions of Article 30 are ill-suited to meeting the challenges of securing crucial patented drugs under the extreme emergency situations of a pandemic or bioterrorism crisis.

C. Compulsory Licensure Regime: Is Article 31 of the TRIPS Agreement Fit for Bioterrorism-Induced Public Health Crises?

The provisions of Article 31 of the TRIPS Agreement incorporate conditions under which a WTO member could use patented technologies without the authorization of the right holders. This power is known as the “compulsory licensure regime.” This raises a couple pertinent questions.

317. Id.
318. Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, supra note 282, § 2.2.3.
319. See Canada-Patent Protection, supra note 218, ¶ 5.6 (discussing the purposes behind the government use exception).
322. EC to WTO Communication, supra, note 320, ¶ 5.
323. A group of developing nations supported a similar interpretation of TRIPS Article 30 to the one advanced by the European Community. Council for Trade-Related Aspects of Intellectual Property Rights, Paragraph 6 of the Ministerial Declaration on the TRIPS Agreement and Public Health, ¶ 8, IP/C/W/355 (June 24, 2002).
325. TRIPS Agreement, supra note 64, art. 31.
How might Article 31 of the TRIPS Agreement be used to facilitate access to crucial patented medicines in bioterrorism crises, and what are the prospects for such use in the context of Article 31’s concomitant conditions? The following paragraphs examine these questions in the context of recent literature, case law, and a comparative analysis of relevant national patent laws.

1. Article 31(a): Authorization of Use Shall Be Considered on its Individual Merits

Article 31(a) provides that the use by any government or authorized third party of a compulsory licensure shall be considered on its individual merit. Article 31(a) arguably implies that the grounds for invoking compulsory licensure are subject to oversight in order to determine their meritorious propriety. While not specifying or delimiting the grounds for compulsory licensure (with the exception of semi-conductor technology), Article 31(a) suggests that it may not be granted on frivolous grounds.

The pertinent question is whether a compulsory licensure for the production of critical generic drugs in the event of a bioterrorism attack pass the merit muster. Ostensibly, it should, as an indisputable public health crisis incident generally cognizable under Article 7 and Article 8.1 of the TRIPS Agreement. However, Article 31(a) of the TRIPS Agreement has conceptual and definitional lacunas that could pose serious interpretational problems, and potentially undermine its use in bioterrorism scenarios. First, the TRIPS Agreement is reticent on the question of who should assess the grounds for compulsory licensure. This lacuna arguably accommodates a number of possible scenarios. Is the merit assessment role incumbent on the third-party beneficiary of such a governmental

327. TRIPS Agreement, supra note 64, art. 31.
328. Article 27.1 of TRIPS appears to prohibit compulsory licensing of patented products or services on grounds of a lack of local working or manufacturing:
   Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether
   products or processes, in all fields of technology, provided that they are new, involve an inventive step
   and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article
   70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without
   discrimination as to the place of invention, the field of technology and whether products are imported
   or locally produced.
   Id. art. 27.
329. Article 7 of TRIPS provides:
   The protection and enforcement of intellectual property rights should contribute to the promotion of
   technological innovation and to the transfer and dissemination of technology, to the mutual advantage
   of producers and users of technological knowledge and in a manner conducive to social and economic
   welfare, and to a balance of rights and obligations.
   Id. art. 7. Article 8.1 provides:
   Members may, in formulating or amending their laws and regulations, adopt measures necessary to
   protect public health and nutrition, and to promote the public interest in sectors of vital importance to
   their socio-economic and technological development, provided that such measures are consistent with
   the provisions of this Agreement.
   Id. art. 8.1.
authorization? Or, is it the pharmaceutical patent right holder, the TRIPS Council, or the entirety of the stakeholders mentioned above? These questions harbor a practical problem which allows any number of stakeholders or interested parties to interfere with the use of a compulsory licensure by raising its meritorious propriety, even in cases of proven public health emergency crises such as a bioterrorism attack. The obvious downside to this scenario is the likelihood of flimsy objections questioning the merit of compulsory licensure grounds, and the inevitable delay that could result from wrangling over the merits of a compulsory licensure in procuring critical drugs for victims of bioterrorism. The authorities could ill-afford a delay in the context of bioterrorism crises.

Moreover, the possible delay could be exacerbated by the absence of any guidance from Article 31(a)—or any other provisions of the TRIPS Agreement—on the timeframe for challenging the grounds adduced for a compulsory licensure invocation. In this circumstance, the meritorious propriety of the grounds for granting compulsory licensure could, as a justiceable ground, stall the compulsory licensure process in possible lawsuits or administrative challenges by the right holder or any interested party. However, a lawsuit or administrative challenge to compulsory licensure could still be pursued after the grant of a compulsory licensure, and should consequently not pose a genuine obstacle to the production or procurement of critical drugs for bioterrorism victims. Nevertheless, to the extent that challenging compulsory licensure prior to procuring critical medicines could not be entirely precluded under Article 31(a) of the TRIPS Agreement, its effectiveness in the bioterrorism context is questionable. Article 31(a) of the TRIPS Agreement provides fodder for disputes over grounds for compulsory licensure that could delay the critical timeline required for manufacture, importation, and distribution of crucial drugs to the victims of bioterrorism attacks. Time is of the essence in containing the spread of pathogenic agents such as anthrax, the plague, or smallpox.

2. Article 31(b) of the TRIPS Agreement: Evidence of Prior Authorization on Reasonable Commercial Terms Required

Article 31(b) provides that prior to the invocation of compulsory licensure, the would-be licensee must seek a negotiated license from the patent right holder on reasonable commercial terms and conditions. Additionally,
efforts at a negotiated voluntary license on reasonable commercial terms must have failed within a “reasonable period of time.” These terms pose definitional and conceptual obstacles that could potentially hamstring the effectiveness of Article 31(b) in the context of bioterrorism. Significantly, the TRIPS Agreement provides no clues on the meaning of both “reasonable commercial terms and conditions” and “reasonable period of time.” This leaves these concepts open to any number of disparate interpretations, potentially fueling disputes and making litigation inevitable.

The term “commercial,” however, connotes business and profits. The Longman Dictionary of Contemporary English defines “commercial” as “related to the ability of a product or business to make a profit.” The phrase “reasonable commercial term and conditions” presupposes that both parties are expected to negotiate and agree on a mutually acceptable reasonable royalty that is concomitant with the market value of the goods in question. In fact, Article 31(h) of TRIPS Agreement requires that “the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization.” While both “reasonable commercial terms and conditions” and “adequate compensation” imply value recompense for compulsory licensure, the parameters for delineating their full compensatory imports remain unclear. The process is fraught with potential disputes as patentees could refuse to deal or resort to litigation if they thought a royalty unreasonable or inadequate. An incident from India in the late 1960s exemplifies this. The Indian government’s attempt to negotiate a compulsory license for a patented drug got mired in endless negotiations and ended in a stalemate when the patentee demanded a royalty of 25%. Four years after commencement of negotiations, the parties agreed to a 10% royalty. It is sacrosanct that compensational disputes are potential stumbling blocks to compulsory licensure in any bioterrorism scenario. The real obstacle, however, is not compensational disputes, but the delay such disputes could create in securing critical medicines within the shortest time possible for bioterrorism victims. Compensational disputes for patent takings are, in practice, deferred to national courts. National patent laws would have to be used to determine compensation for compulsory licensure.

*Id. art. 31(b).*

32. *Id.*


34. TRIPS Agreement, *supra* note 64, art. 31(h).


36. See DHAR & GOPAKUMAR, *supra* note 229 at 22 n.38 (discussing an incident in India where negotiation costs were excessive and forced the abandonment of an important project).

37. *Id.*

38. *Id.* 10% was still higher than the 5% the Indian government sought. *Id.*

39. *E.g.*, TRIPS Agreement, *supra* note 64, art. 31(j).
However, national judicial compensatory awards would have to conform to the tenets of the TRIPS Agreement. 340 In the United States, the Fifth Amendment of the U.S. Constitution requires just compensation for any private property taken by the government for public use.341 Otherwise known as eminent domain, this concept is rarely employed by the United States for appropriating pharmaceuticals patents. 342

In addition, the term “reasonable period of time” is inherently ambiguous, and any clarifications are absent in the TRIPS Agreement. Parties are expected to prove that they failed to agree on terms of voluntary license within a “reasonable period of time” before compulsory licensure could be invoked. 343 Nuno Pires de Carvalho opines that WTO members regard a “reasonable period of time” as ranging from ninety days to six months. 344 He suggests that “the ultimate criterion should be left to the market practices and to the assessment of the parties’ real intention.” 345 However, the problem is, for the meaning of “reasonable period of time,” there are no standard or customary market practices. To expect a WTO member faced with a critical shortage of drugs in a bioterrorism crisis to wait for three to six months to agree to “reasonable commercial terms and conditions” before invoking compulsory licensure would be preposterous. Furthermore, either party—right holder or licensee—could seize on the inherent ambiguity in “reasonable period of time or conditions” to justify its reasons for blocking or seeking compulsory licensure through a lawsuit or an administrative challenge. 346

3. Waiver of Patentees’ Prior Authorization Due to National Emergency or Other Circumstances of Extreme Urgency or Public Non-commercial Use

The requirement for prior authorization from patent right holders before the grant of compulsory licensure may be waived by a WTO member in the event of a “national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.” 347 Therefore, a WTO member faced with a bioterrorism crisis could seek refuge under the waiver provision by characterizing its problem as a national emergency or a situation of extreme urgency. Moreover, if the drugs in question would be given gratuitously to the

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340. Id. art. 45 (authorizing award of adequate damages to the right holder to compensate for the injury occasioned by infringement, as well as reimbursement of the right holder for incidental fees such as attorney’s fees).

341. U.S. CONST. amend. V (providing inter alia that no one shall be deprived of their private property for public use without just compensation).

342. See Daniel R. Cahoy, Patent Fences and Constitutional Fence Posts: Property Barriers to Pharmaceutical Importation, 15 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 623, 672-73 (2005) (discussing the viability of a suit against the government on eminent domain rather than patent infringement grounds); Cahoy, Legal Side Effects, supra note 186, at 139-146 (arguing that under the current statutory scheme, unauthorized government appropriations of private rights should be treated as eminent domain takings).

343. TRIPS Agreement, supra note 64, art. 31(b).

344. PIRES DE CARVALHO, supra note 219, at 234.

345. Id.

346. For instance the right holder might contend that compulsory licensing was premature because a “reasonable period of time” for the discussion of an adequate royalty or compensation had not elapsed.

347. TRIPS Agreement, supra note 64, art. 31(b).
A major impediment to the effective use of the consent waiver provisions characteristically centers on the susceptibility of key terms to semantic and interpretational problems. For instance, while it might seem obvious, it is not inconceivable that a reluctant pharmaceutical right holder could contend that a bioterrorism attack was no more than a normal or non-extreme urgency public health crisis. A WTO General Council Decision of August 30, 2003 granted resource-poor nations who lack manufacturing capacity for pharmaceuticals the right to import essential medicines for public health needs, via the compulsory licensure regime.

Given the TRIPS Agreement’s generous latitudes for pharmaceutical patent rights derogation—as exemplified by the national emergency, circumstances of extreme urgency, and the public health crises exceptions highlighted above—the case for a pharmaceutical patent appropriation clause in national and international patent regimes for bioterrorism crises situations would appear obtuse. However, the seemingly generous terms in which the “national emergency or circumstances of extreme urgency” exceptions are crafted arguably belie the concomitant conditionality and lurking political and economic externalities that are guaranteed to frustrate their usefulness in any bioterrorism scenario.

a. Key Grounds for Waiver of Prior Authorization are Susceptible to Definitional and Interpretational Problems

A major impediment to the effective use of the consent waiver provisions characteristically centers on the susceptibility of key terms to semantic and interpretational problems. For instance, while it might seem obvious, it is not inconceivable that a reluctant pharmaceutical right holder could contend that a bioterrorism attack was no more than a normal or non-extreme urgency

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348. This would be without prejudice to patentees’ right to adequate compensation as required by Article 31(h) of the TRIPS Agreement. Id. art. 31(h).
349. Id. arts. 27-28.
350. See Declaration on the TRIPS Agreement and Public Health, supra note 267.
351. Id. ¶ 4.
352. Id. ¶ 5.
353. The General Council’s decision was made pursuant to paragraph 6 of the WTO Doha Ministerial Declaration on the TRIPS Agreement and Public Health. Id. at ¶ 6. Paragraph 6 recognizes the difficulties that WTO members with insufficient or non-existant pharmaceutical manufacturing capacity face in making effective use of TRIPS’ compulsory licensing regime. Id.
situation, and that invocation of compulsory licensure for procurement of critical medicines without prior consultation or authorization was premature. Furthermore, the usefulness of the “public non-commercial use” exception is equally dicey in the bioterrorism context, where it could only be availing if drugs were given gratis to victims. Even then, the possibility of elements of “commercial use” creeping into the transaction is very high indeed. This would be especially true if authorities used paid private contractors to distribute drugs to the populace, with a view to easing the burdens on public health officials and institutions or accelerating the distribution process in order to save as many lives as possible as quickly as possible. In such a scenario, the right holder could contend that it was not a “public non-commercial use” and that prior consent or negotiation was mandatory before the invocation of compulsory licensure, albeit in the bioterrorism context. Thus, the scenario allows “national emergency” or “circumstances of extreme urgency” and “public non-commercial use” exceptions to coalesce with tangled and complicated legal results. For example, authorities faced with a bioterrorism crisis, and intent on waiving prior authorization of pharmaceutical right holders, would have to decide whether to inform the right holders “as soon as reasonably practicable” (as required by the “national emergency” or “extreme urgency” exception) or “promptly”, (a la “public non-commercial use” grounds). These legal uncertainties could potentially hamstring the use of compulsory licensure for a bioterrorism-induced public health crisis.

b. Economic and Political Expediencies as Impediments to the Usefulness of the Consent-Waiver Provisions of Article 31(b) of the TRIPS Agreement

Another significant impediment to the propriety of the compulsory licensure regime in a bioterrorism context is the complex politics underpinning the political economy of international intellectual property rights. The knowledge-based economy, which has ridden the back of a strong

354. See TRIPS Agreement, supra note 64, art. 31(b) (defining public non-commercial use as “where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government”).

355. See id. (requiring a potential user of a patented product to first attempt “to obtain authorization from the right holder”).

356. See id. Article 31(b) requires that when prior authorization is waived on grounds of a “national emergency or other circumstances of extreme urgency” the right holder shall be “notified as soon as reasonably practicable.” Id. However, when prior consent is waived on grounds of “public non-commercial use,” then right holders “shall be informed promptly.” Id. This is further complicated by TRIPS’ failure to define “as soon as reasonably practicable” and “shall be informed promptly.” See id. (providing no definition of the terms). These are crucial timelines that a would-be compulsory licensee could have difficulty complying with. This would be so especially where the right holder or patentee is outside of the would-be licensee’s jurisdiction or where the patentee’s whereabouts are not immediately known.

357. Id.

358. Analysts believe that the idea of incorporating intellectual property rights in TRIPS was seeded by intense lobbying of corporate interests in the United States, Europe, and Japan. DUNCAN MATTHEWS, GLOBALIZING INTELLECTUAL PROPERTY RIGHTS: THE TRIPS AGREEMENT 7-45 (2002).

359. See generally DRAHOS & BRAITHWAITE, supra note 312, at 39-60 (explaining that knowledge is “the
intellectual property protection regime to a roaring success, see e.g., MASKUS, supra note 195, at 169 ("Industrialized countries, which have strong systems of intellectual property protection remain the overwhelming sources of new invention and artistic creation.").


366. Knock It Off! A Row Is Brewing in America over Generic Drugs, ECONOMIST, Feb. 24, 2007, at 76. The pharmaceutical industry invented a variant of generics known as “authorized generics” that are promoted by owners of the patents for the original branded drugs rather than by generic manufacturers. Id. The aim of “authorized generics” is to compete against genuine generics and mitigate financial losses arising from drugs going off patent. Id. at 77. The U.S. Congress has launched a legislative bid to crack down on authorized generics. Id. It remains to be seen if Congress will succeed given the pharmaceutical industry’s economic and political clout.

367. Utilitarianism is one of the dominant theories justifying intellectual property rights protection. Utilitarianism posits that creativity would decline in the absence of incentives in the form of monopoly rights.
of rights, or rights derogation as a campaign against innovation\textsuperscript{368} or unsound public policy.\textsuperscript{369}

This strand of scholarship or argument resonates well with the fundamentals of free market economies and underscores the apparent reluctance of the U.S. authorities to use compulsory licensing for Bayer’s ciprofloxacin,\textsuperscript{370} despite the presence of compulsory licensure provisions in the Orphan Drug Act of 1983.\textsuperscript{371} It is safe to say that authorities in the United States are more apt to use their eminent domain powers to appropriate land for real estate developers\textsuperscript{372} than pharmaceutical patents to secure affordable medicines for Americans.\textsuperscript{373} For instance, only eight out of more than two thousand new eminent domain cases filed in 2003-2004 involved intellectual property rights.\textsuperscript{374}

Governments around the world have attempted to use compulsory licensure or have attempted to regulate pharmaceutical pricing.\textsuperscript{375} However, in the post-TRIPS era, such attempts are bound to be heavily criticized and met with stiff resistance from the pharmaceutical industry.\textsuperscript{376} For instance, in the pre-TRIPS era (1969-1987), Canada reined in drug prices and famously had some of the cheapest medicines in industrialized world for patented pharmaceuticals.\textsuperscript{377} The strategy purportedly saved the country an estimated

\textsuperscript{368} Sidney Taurel, The Campaign Against Innovation, in ETHICS AND THE PHARMACEUTICAL INDUSTRY, supra note 197, at 326, 326-28.


\textsuperscript{370} See Shankar Vedantam & Terence Chea, Drug Firm Plays Defense in Anthrax Scare, WASH. POST, Oct. 20, 2001, at A4 (noting that the U.S. government’s reluctance to override Bayer’s patent on Cipro, due in part to the signal such an action would send to the international community).


\textsuperscript{373} See David Malakoff, NIH Declines to March in on Pricing AIDS drug, 305 SCI. 926 (2004) (discussing the National Institute of Health’s rejection of a plea to use its power to rein in the spiraling cost of an AIDS drug).

\textsuperscript{374} Aaron S. Kesselheim, Biomedical Patents and the Public’s Health: Is There a Role for Eminent Domain?, 295 JAMA 434, 435 (2006).

\textsuperscript{375} See Crater Corp. v. Lucent Tech., 255 F.3d 1361, 1368 (Fed. Cir. 2001) (reaffirming the power of the federal government to use compulsory licensing for technology acquisition and holding inter alia that 28 U.S.C. § 1498 grants the government the authority to use compulsory licensure for patented technologies); Abbott, Action and Reaction, supra note 365, at 29-30 (noting that imposition of price controls was the most common regulatory response by governments).

\textsuperscript{376} Abbott, Action and Reaction, supra note 365, at 31-33.

It is extremely doubtful that Canada could re-enact its pre-TRIPS, \textit{laissez faire}, pharmaceutical patent policy in the current regime of patents fencing. The U.S. Congress recently encountered difficulty on May 3, 2001, when it introduced the Affordable Prescription Drugs and Medical Inventions Act, a bill that was quite audacious in its quest to make patented drugs more affordable.\footnote{378} Of note was section 158(d) of the bill, whose six grounds on licensing and remunerative terms for compulsorily licensure would have, if passed into law, revolutionized the drug access paradigm.\footnote{379} Not surprisingly, the bill did not make it past the House of Representatives and never became law.\footnote{380} The House was undaunted, however, and the bill, rechristened the “Public Health Emergency Medicines Act”, was reintroduced in October 2005.\footnote{381} Predictably, the new bill, like its predecessor, failed to become law.\footnote{382}

The pharmaceutical industry’s power transcends the United States, and has been exerted, directly or by proxy, in nations such as Brazil,\footnote{383} South Africa,\footnote{384} Canada,\footnote{385} and the United Kingdom,\footnote{386} to block unfavorable drug policy. In Britain, for instance, compulsory licensure and Crown Use could, in principle, be used to derogate from patent exclusivity.\footnote{387} Great Britain was confronted with the imperatives of a restrictive drug pricing policy option...
when it introduced a national health insurance policy for the first time in 1911.\footnote{See John Abraham, The Political Economy of Medicines Regulation in Britain 230 (2002) (“The Liberal government introduced the 1911 National Health Insurance Act. The aim was to assist people below certain minimum income level to receive medical benefit through a national insurance for sickness funded by statutory contributions from the employer, the government and the employed.”).} By 1951, when free medical care was extended to the entire population, the number of prescriptions under the National Health Service had risen to 200 million, increasing government financial commitments, and precipitating an undue government preoccupation with price regulation, much to the chagrin of the pharmaceutical industry in post-World War II Great Britain.\footnote{Id. at 236.} In the 1960s, the British government’s attempt to grant compulsory licenses to generic-drug manufacturers became mired in litigation and was unsuccessful.\footnote{Cornish, supra note 388, at 24-26 (noting that under the compulsory licensing regime preceding the 1977 Patent Act, food and drug patents could be licensed under conditions set by the Patent Office); see also Dutfield, supra note 216, at 122-26 (noting that Pfizer sued the Department of Health for infringing its patent on tetracycline).} Out of fifty applications submitted by generic manufacturers, only four were successful, due to the difficult legal procedures with which applicants had to comply.\footnote{Dutfield, supra note 216, at 125-26.} A similar situation occurred in Italy, where a constitutional challenge, mounted by the pharmaceutical industry to 1978 Italian legislation overriding pharmaceutical patents, was successfully upheld by the Constitutional Court.\footnote{Id. at 127.}

Thus, while compulsory licensure may be legally and theoretically feasible in bioterrorism contexts, it runs against the grain of the free market and could be scuttled by economic and political expediencies that could potentially hamstring authorities’ political will. An unconditional and unambiguous pharmaceutical patent appropriation clause is clearly necessary not only in the bioterrorism context, but in all situations where public health is threatened.

V. CONFRONTING THE PLAGUE: RATIONALIZING THE CASE FOR THE INCLUSION OF A PHARMACEUTICAL PATENT APPROPRIATION CLAUSE IN THE PATENT REGIME

This Part of the Article uses ethical justifications, overriding public interest, and human rights as bases for the inclusion of an pharmaceutical patent appropriation clause.

A. Ethical Justifications for a Pharmaceutical Patents Appropriation Clause in Bioterrorism Context: Utilitarianism as a Two-Edged Sword.

It is ethically justifiable to have a bioterrorism-specific pharmaceutical patent appropriation clause, despite such philosophical concepts like utilitarianism. Utilitarianism pitches incentive imperatives in an intellectual
property context, and is rooted in philosophical underpinnings exhorting support for rights in tangible and intangible private proprietary holdings.\textsuperscript{394} Utilitarianism holds that moral rules must be oriented towards maximizing human well-being.\textsuperscript{395} By extrapolation, intellectual property protection would incentivize innovative and beneficial inventions, which, in turn, improve the lot of the populace.\textsuperscript{396} Conversely, the absence of intellectual property protection would lead to a downward spiral in intellectual creativity and life-impacting innovation, with concomitant depreciation in societal well-being. The incentive element of utilitarianism resonates well with the general economic-right argument for intellectual property protection,\textsuperscript{397} and is often linked, rightly or wrongly, to John Locke’s labor theory.\textsuperscript{398} While espousing natural law justification for proprietary rights,\textsuperscript{399} Locke posited that objects produced by an individual through the mixing of labor with resources held in common are the property of that individual alone, provided enough is left in common for others,\textsuperscript{400} and that no person takes from the common more than he can use.\textsuperscript{401} However, Locke’s labor theory has been branded ambiguous in the intellectual property context.\textsuperscript{402} For example, Robert Nozick argued that Lockean justification for intellectual property would only be valid if other persons did not suffer net harm.\textsuperscript{403}

\textsuperscript{394} The normative and theoretical bases for individual property rights are the subject of centuries old discourse between philosophers, theologians and economists. Terry L. Anderson & Fred S. McChesney, \textit{Introduction to Part I of Property Rights: Cooperation, Conflict, and Law} 13-19 (Terry L. Anderson & Fred S. McChesney eds., 2003). However, Peter Drahos notes that a distinction is seldom made between real property and intellectual property. Peter Drahos, \textit{A Philosophy of Intellectual Property} 1 (1996). Drahos wonders whether existing theories of property can accommodate intellectual property or whether a distinctive theory of intellectual property is necessary. \textit{Id.}

\textsuperscript{395} See Østergaard Jr., supra note 206, at 17-21 (faulting the utilitarian argument that juxtaposes long-term social development with the short-term drawbacks of exclusive intellectual property, and arguing that intellectual property protection slows the diffusion of technology and can possibly engender monopolistic behavior).

\textsuperscript{396} Id.


\textsuperscript{398} Mayer-Schönberger, supra note 362, ¶¶ 8-14.

\textsuperscript{399} \textit{John Locke, Two Treatises of Government} 101 (Peter Laslett ed., Cambridge University Press 1988) (1690). John Locke’s idea that a person who labors on resources unowned or held in common has a natural property right to the fruits of his labor which must be respected by the State, has been argued to have some correlations with intellectual property, where ideas and subjects of inventions could be part of the public domain. See Justin Hughes, \textit{The Philosophy of Intellectual Property, in Intellectual Property: Moral, Legal, and International Dilemmas} 81, 107 (Adam D. Moore ed., 1997) (discussing the Lockean justification for intellectual property); Sigrid Sterckx, \textit{Can Drug Patents be Morally Justified?}, 11 Sci. Eng’g. Ethics 81, 81-82 (2005) (examining natural rights justification for drug patents). But see Edwin Hettenger, \textit{Justifying Intellectual Property}, 18 Phil. Pub. Aff. 31, 36-40 (1989) (disagreeing with John Locke’s natural property rights theory).

\textsuperscript{400} \textit{Locke}, supra note 399, at 167; see also Carys J. Craig, \textit{Locke, Labour and Limiting the Author’s Right: A Warning Against a Lockean Approach to Copyright}, 28 Queen’s L.J. 1, 11-12 (2002) (discussing the proviso in the context of critiquing the Lockean justification for copyright).

\textsuperscript{401} \textit{Locke}, supra note 399, at 167.


\textsuperscript{403} Robert Nozic, \textit{Anarchy, State, and Utopia} 178-82 (1974). Net harm in this context means that other people should not be left poorer than they were before the property was acquired. \textit{Id.}
Scholars such as Resnik and De Devile have used utilitarianism, sentimentality, and moral considerations to justify restrictive construction of the U.S. compulsory licensure provision for patented pharmaceuticals. According to Resnik and DeVille, broad and unrestricted use of compulsory licensure for patented pharmaceuticals would be unethical and antithetical to the overall social good. However, as a consequence-based theory, utilitarianism is two-faced, and could equally be used to justify pharmaceutical patent derogation if the majority of the population would be left worse off. Peter Drahos and John Braithwaite shared this perspective by arguing that a “patent system that does not recognize the utility preferences of much of the world’s population when it comes to disease can hardly look to utilitarianism for comfort.” Thus while intellectual property may be justified on utilitarian grounds, there is ample room in utilitarianism to accommodate pharmaceutical patent appropriation in bioterrorism context. To the extent that pharmaceutical patent appropriation policy could facilitate prompt access to critical medicines, it would produce the greatest happiness of the greatest number in the society, making its inclusion in national and international patents regimes morally justified and imperative.

**B. Overriding Public Interest**

The public interest is an integral element of governmental regulatory intervention policy. Carlos Correa opined that public interest could justify governmental actions to achieve public policy objectives of promoting health, education, and socio-economic developments. Mike Feintuck points two two examples in which authorities may intervene on the grounds of public economic interest: (1) market failure; or (2) the imperative of curbing abuse of monopolistic or oligopolistic power via anti-trust or competition rules. While acknowledging the legitimacy of private property rights in market-oriented economies, Feintuck posits that the “untrammeled exercise of private

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405. Id.
406. TOM L. BEAUCHAMP & JAMES F. CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS 340-1 (5th ed., 2001) (defining consequentialism as a label used to describe moral theories that posit that actions are right or wrong according to the balance of their positive and negative consequences); see also, Philip Pettit, Consequentialism, in A COMPANION TO ETHICS 230, 230-32 (Peter Singer ed., 1971) (pointing out that utilitarianism is a type of consequentialism).
408. DRAHOS & BRAITHWAITE, supra note 312, at 15-17.
412. FEINTUCK, supra note 410, at 13-14.
property rights has the potential to cut across the legitimate democratic expectations of others in terms of parity of esteem and the ability to participate fully in society.”

He argues further that “[i]f the activities of private entities in practice result in damage to the democratic fabric of society, by restricting the ability of others to act as citizens, they should expect such activities to be challenged or indeed curtailed and economic forces should not remain unconstrained.”

In the context of intellectual property rights and public health, it has been suggested that public welfare considerations should trump private interests and determine the drug-access paradigm. There is no doubt that it is in the overall public interest that authorities should be able to get critical medicines to bioterrorism victims within the shortest possible time due to the extraordinary nature of the ensuing emergency situation. However, as demonstrated earlier in this Article, such a prompt response is liable to become entangled in inherent bureaucratic gridlocks in the access paradigm of national and international patent regimes. Viewed from this perspective, a pharmaceutical patent appropriation clause in national and international patent regimes is justifiable due to overriding public interests.

C. Human Rights Perspectives

Securing access to life-saving drugs has been described as an issue within the rubric of international human rights law. Since an intellectual property regime is an integral element of the drug-access paradigm, there has been a considerable renewed interest in the interface between intellectual property and human rights. It has been noted by the UN Sub-Commission on Human Rights that there are apparent conflicts between the fundamental tenets of international human rights and the principles of international intellectual property regime as embodied in the TRIPS Agreement.

However, the stance of the UN Sub-Commission on Human Rights on

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413. Id. at 15.
414. Id.
415. Sol Picciotto, Defending the Public Interest in TRIPS and the WTO, in GLOBAL INTELLECTUAL PROPERTY RIGHTS, supra note 67, at 224-25.
416. Zita Lazzarini, Making Access to Pharmaceuticals a Reality: Legal Options under TRIPS and the case of Brazil, 6 YALE HUM. RTS. & DEV. L.J. 103, 117 (2003) (“A careful reader will find no ‘right to access to pharmaceuticals’ in the International Bill of Human Rights or in any subsequent modern human rights instruments. However, such obligation—although not a defined human right itself—is firmly grounded in the implications of existing substantive provisions and in the special needs created by the current circumstances.”).
417. See Peter Prove & Miloon Kothari, Human Rights Bodies Gear Up on TRIPs, BRIDGES, July-Aug. 2000, 13, 13, available at http://www.ictsd.org/English/BRIDGES4-6.pdf (criticizing TRIPS for threatening key human rights, including “the right of everyone to enjoy the benefits of scientific progress and its applications, the right to health, the right to food and the right to self-determination”).
international intellectual property regime is supremely ironic because as a type of property, the ostensible strengthening of intellectual property rights via the TRIPS Agreement should be in conformance with the tenets of international human rights law, reputed for its avowed support for property rights. For instance, Article 17(1) of the Universal Declaration of Human Rights ("UDHR") provides that "Everyone has the right to own property alone as well as in association with others." Most importantly, and in an apparent reference to intellectual property, Article 27(7) of UDHR provides that "Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author." At the regional level, the First Protocol to the European Convention on Human Rights, which is legally enforceable, alludes to intellectual property, in its exhortation of proprietary rights protection. In addition, and more specifically, Article 17(2) of the Charter of Fundamental Rights of the European Union on right to property, which is non-justiceable, provides that "Intellectual property shall be protected." Furthermore, Article 15(1)(c) of International Covenant on Economic, Social, and Cultural Rights, requires signatory states to recognize the right of everyone "to benefit from protection of moral and cultural material interests resulting from any scientific, literary or artistic production of which he is the author." 

If TRIPS is antithetical to the fundamental ideals of human rights law as suggested in the excerpts of the UN-Sub-Commission on Human Rights, how can international human rights law’s apparent support for property rights, including intellectual property, be justified, which the TRIPS appears to promote? In other words, how could international human right law be interpreted to abhor what it promotes? The seeming contradiction is symptomatic of the complex interface between intellectual property and human rights, and is aptly put in context by Audrey Chapman as follows:

The development of a global economy in which intellectual property plays a central role underscores the need for human rights community to claim the rights of the author, creator and inventor, whether individual, a group or a community, as a human right. It is equally important for human rights advocates to protect the moral interests and

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420. Id.
421. Id.
rights of the community to securing access to this knowledge. A third human rights consideration is whether relevant laws identifying rights to creative works and scientific knowledge and determining the subject matter which can be claimed as intellectual property are consistent with respect for human dignity and the realization of other human rights.  

It seems then that the challenge of resolving the apparent conflict lies in finding a balance between intellectual property rights protection and human rights.  

Property rights, like other rights, are neither absolute nor sacrosanct. In the context of public health protection and preservation, intellectual property rights should give way to every human’s right to health and life. It has been argued that whenever terrorism threatens public health, personal and economic rights should give way to public health protection imperatives. Thus, in public health terms, the right to life and health trumps property rights. Viewed from this perspective, a pharmaceutical patents appropriation clause in the context of bioterrorism does not necessarily contravene property rights and is justified by the fundamental right to health and life.

VI. CONCLUSION

This Article proposes the inclusion of a bioterrorism-specific pharmaceutical patents appropriation clause in national and international patent regimes. The thesis is predicated on the impropriety of the current bureaucracy-prone access to medicines paradigms in international and national patent regimes for bioterrorism-induced public health crises situations. Using highly plausible, worst-case scenarios of bioterrorism attacks, this Article argues that vast swathes of the population could become simultaneously vulnerable to deadly bioweapons, exposing millions of people to inevitable deaths, in a comparatively shorter time span than naturally-occurring diseases like HIV/AIDS or tuberculosis. In this circumstance, time is of utmost essence in saving as many lives as possible. This makes it imperative for authorities to override patents on crucial drugs or vaccines without the consent of patent owners.

427. See PERELMAN, supra note 219 at 2-3 (acquiescing to the creativity promotion rationale for intellectual property protection, but railing at the regime’s degeneration into a system which now "threatens to exhaust creative activity").
holders, thus avoiding lengthy negotiations that might be destined for failure. Moreover, this Article deems a bioterrorism-specific appropriation clause in global patents regimes expedient, in light of the pervasive and dominant pro-patents forces intent on a stronger intellectual property regime. This regime rationalizes patent protection solely on utilitarianism, and would cast attempts at proportionality of rights as campaigns against innovation. A fortiori, absent a bioterrorism-specific pharmaceutical patent appropriation clause, authorities could be bogged down by political and economic expediencies of pharmaceutical patent appropriation, fostering indecision that would make securing critical medicines in bioterrorism pandemics situations nigh impossible. This Article justifies the case for bioterrorism-specific pharmaceutical patents appropriation on ethical grounds, overriding public interests, and fundamental rights to health and life.