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A Proactive Solution to the Inherent Dangers of Biotechnology: Using the Invention Secrecy Act to Restrict Disclosure of Threatening Biotechnology Patents

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A PROACTIVE SOLUTION TO THE INHERENT DANGERS OF BIOTECHNOLOGY: USING THE INVENTION SECRECY ACT TO RESTRICT DISCLOSURE OF THREATENING BIOTECHNOLOGY PATENTS

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I. INTRODUCTION

Biotechnology is a rapidly expanding field that the United States should address seriously. This technology, while offering many beneficial advances, also presents a strong threat to national security. Good examples of this threat include genetically engineered crops that compete and can destroy local biodiversity, increased bacterial resistance through overuse of conventional antibiotics, and the overwhelming threat of biological warfare through genetically created and enhanced diseases.[1]

One potential way to address this threat without stifling the advancement of biotechnology is through the United States patent system. The United States Patent and Trademark Office encourages innovation of

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[1] *See Bioterrorism: Our Frontline Response, Evaluating U.S. Public Health and Medical Readiness: Hearing Before the Subcomm. on Pub. Health of the S. Comm. on Health, Educ., Labor and Pensions*, 106th Cong. (1999) (statement of Stephanie B.C. Bailey, M.D., Director, Metropolitan Health Department, Nashville and Davidson County, Tennessee) [hereinafter *Bioterrorism*].

> The potential public threats we all face are growing in number, complexity and severity. Rapid air travel means grave infectious diseases can be spread from one country to another simply when an infected person takes a plane flight. Our food supply has become globalized, and we are more vulnerable to food-borne diseases from imported food than ever before. Insidious bacteria that have mutated so that they are no longer easily treatable with existing antibiotics are multiplying in number. Virulent new viruses, such as hantavirus and Ebola, have emerged. And reports of instances where persons have access to biological weapons are increasing.

Id.

new technologies by granting limited monopolies to the inventors to exclude others from using those technologies for a time.[2] In exchange, the inventors must disclose their new inventions to the public, adding to the field of common knowledge.[3] The Invention Secrecy Act of 1951[4] ("ISA") was enacted to control the disclosure of scientific inventions in which the United States may have a property interest based on the concerns of national security. The ISA allows the Commissioner of the Patent and Trademark Office to keep an invention secret through a government mandated secrecy order while the invention's potential threat is evaluated by the appropriate administrative agency.[5] Originally, concerns for these secrecy orders were for inventions such as those involving rocketry and atomic weapons. While containing broad language that might apply to any type of invention, the ISA did not contemplate the development of biotechnology. The biotechnology industry at the time was at best in its infancy, and patents for living organisms were excluded.[6] As biotechnology grows in national prominence, however, a careful review of its potential effects is warranted. The ISA gives an opportunity to review biotechnology patents and their potential impacts on national security.

Secrecy orders issued under the ISA provide several advantages for the control of potentially harmful technologies, without stifling the incentives for research. While a secrecy order is an obvious prior restraint on the dissemination of information, this restraint allows for an effective evaluation of the invention before it becomes general knowledge. When threats are discovered, a short delay before issuance of the patent would give the United States a head start in preventing future disaster, such as starting work on vaccines to potentially threatening viruses. The secrecy order is also evaluated by the agency best suited to understand the new invention, so that an accurate assessment of the impact of the new technology is made.

This Note argues that, through the use of secrecy orders, biotechnology patents that could potentially affect national security can be evaluated properly by an appropriate technical agency, allowing for control of the technology before it becomes a problem that cannot be

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[2] *See* 35 U.S.C. § 271 (1994 & Supp. V 1999).

[3] *Id.* § 112.

[4] *Id.* §§ 181-88.

[5] *Id.* § 181.

[6] *See* Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 131 (1948). *See also infra* notes 101-114 and accompanying text for a discussion of the standards for patentable subject matter.

contained. Section II of this Note discusses what biotechnology is and how it can present a threat to public health and safety. Section III discusses the current regulation of biotechnology and the statutory controls on dissemination of information. Section IV discusses the United States Patent System and how secrecy orders from the ISA can be used to curtail the public disclosure of inventions that are dangerous to the national security. Section V discusses the constitutional implications of the ISA and other potential problems associated with using the Act. This Note then concludes that use of the ISA allows for a careful review of biotechnology before any information is widely disseminated. This review will allow the government to restrict the disclosure of threatening technologies before they are given a chance to develop into more serious problems.

II. THE NATURE OF BIOTECHNOLOGY

A. *Biotechnology in General*

Biotechnology is a broad term encompassing a variety of different ideas. Biotechnology, however, is normally associated with recombinant DNA technology. Using this technique, genetic material can be inserted into the target's genome from another source to create a modified organism. This technology was largely developed in the 1970s and was facilitated by the discovery of specific enzymes, which allowed for the development of rapid DNA sequencing so that large sections of DNA could be isolated and mapped. [7] In addition, this technology allowed for the creation of cloned cells that are exactly the same as, and carry the identical DNA of, the parent cells.[8] Over time, scientists have adapted

[7] *See generally* HARVEY LODISH ET AL., MOLECULAR CELL BIOLOGY 221-61 (3d ed., 1995) (providing an overview of the techniques and terms of recombinant DNA technology).

> The discovery of two types of enzymes provided the impetus for these recent developments and permit *DNA cloning*. One type, called restriction enzymes, cut the DNA from any organism at specific sequences of a few nucleotides, generating a reproducible set of fragments. The other type, called DNA ligases, can insert DNA restriction fragments into replicating DNA molecules producing recombinant DNA.

Id. at 221.

[8] *Id.*

biotechnology to a variety of uses in many different environments.[9] The natural result of this is that biotechnology is a significant advancement that has the potential to affect everyone across the globe. Given this broad reach, a careful analysis of the benefits and risks associated with biotechnology is warranted.

B. *Genetically Engineered Microorganisms*

One common line of research in the biotechnology field is the creation of new microorganisms. Genetically engineered microorganisms are bacteria that have been artificially manipulated through recombinant DNA technology for some specific purpose. For example, one potential application is to add gene coding for biological pesticides to other organisms to make those organisms resistant to other pests.[10] A different application is to use biological microorganisms to reduce the concentration of toxic chemicals through bioremediation.[11] These organisms could also be modified to remove their plasmid transfer functions in an effort to prevent the strains of that microorganism that are used for pest control from transferring their modified genes to virulent strains of the same bacteria.[12]

There are a variety of concerns about the potential environmental effects of genetically modified organisms. For example:

> A major concern was that organisms would be created with novel genotypes that would have unpredictable or harmful properties that could threaten human health or the environment. Such novel agents, for example, might result in new pathways for the spread of disease or might produce

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[9] For a chronological overview of the development of biotechnology, see LISA YOUNT, BIOTECHNOLOGY AND GENETIC ENGINEERING 93-106 (2000).

[10] *See* Raymond A. Zilinskas, *Analysis of the Ecological Risks Associated with Genetically Engineered Marine Organisms*, *in* GENETICALLY ENGINEERED MARINE ORGANISMS: ENVIRONMENTAL AND ECONOMIC RISKS AND BENEFITS 110 (Raymond A. Zilinkas & Peter J. Balint eds., 1998).

[11] *Id.* at 111.

[12] *See* Maarten H. Ryder & Raymond L. Correll, *Assessing the Potential Benefits and Risks of Introducing Natural and Genetically Manipulated Bacteria for the Control of Soil-Borne Root Diseases*, *in* BIOLOGICAL CONTROL: BENEFITS AND RISKS 211 (Heikki M.T. Hokkanen & James M. Lynch eds., 1995).

> animal tumor viruses that might be introduced into the human intestinal tract, with uncertain results.[13]

In essence, there is a great deal of uncertainty as to what will happen when a new species is introduced into a non-native environment.[14] However, "[t]here are many examples of such damage occurring from the transfer of species to foreign environments. The clogging of African waterways with the South American water hyacinth and the erosion in Australia caused by the introduction of rabbits are two examples."[15] It is also difficult to predict what effect these organisms will have on the other species in the environment into which they are introduced.[16] Of course, a counter argument can be posed that bacteria are constantly exposed to new DNA naturally present within the environment, so genetic manipulation by man is no different than what is taking place in nature. It is worth noting, however, that what mankind does is far more potent than simply speeding up the evolutionary process through direct manipulation.[17] Thus, it would

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[13] David Ozonoff, *Just When You Thought It Was Safe: An Update on the Risks of Recombinant DNA Technology, in* GENETICS AND THE LAW III 467, 469 (Aubrey Milunsky & George J. Annas eds., 1985).

[14] *See* L.E. Ehler, *Planned Introductions in Biological Control, in* ASSESSING ECOLOGICAL RISKS OF BIOTECHNOLOGY 27-28 (Lev R. Ginzburg ed., 1991) (claiming that "every introduction of an exotic species can be expected to have an environmental impact of one sort or another. These impacts may or may not be predictable, and their effects can vary according to a number of factors . . . .").

[15] Klaus Bosselmann, *Plants and Politics: The International Legal Regime Concerning Biotechnology and Biodiversity*, 7 COLO. J. INT'L ENVTL. L. & POL'Y 111, 119 (1996).

[16] *See id.*; *see also* Ehler, *supra* note 14, at 35.

[17] *See* M.J. Day & J.C. Fry, *Microbial Ecology, Genetics, and Risk Assessment, in* RELEASE OF GENETICALLY ENGINEERED AND OTHER MICRO-ORGANISMS 160 (J.C. Fry & M.J. Day eds., 1992).

> Vast numbers of plants, animals, and microbes die daily and, during their decay, present DNA directly to bacteria capable of taking it up. Thus, it is conceivable that DNA exchange occurs routinely in nature. There is a difference, however, between this natural presentation of non-specific DNA and DNA entering the environment within GEMS ["genetically modified organisms"]. DNA derived from GEMs has not been subjected to natural selection for its amplification. At no time during its synthesis did it compete with natural organisms or have natural selective pressures imposed upon it. The GEM DNA, in stable recombinant organisms, will be released into the environment in relatively large amounts. Thus, the evolution of GEMs, which are constructed in the laboratory, does not rely on chance, their fitness or on natural selection.

Id.

be incorrect to argue that this genetic enhancement by scientists is the equivalent of the natural selection process.

An additional concern with genetically engineered organisms is that it may prove difficult to control modified organisms once they are released into the environment, despite any pre-release safeguards placed on them.[18] The inherent uncertainty of what environmental impact the release of genetically engineered organisms will have gives an excellent reason to examine them closely when they are being developed. Initial review of the impact of these organisms while an applicant files for a patent on those organisms would allow their risks to be safely assessed before they are blindly released into the environment to cause unforeseen results.

C. *Biotechnology and Agriculture*

In the late eighteenth century, economist Thomas Malthus predicted that the world's population would reach unsustainable levels as only so much food could be grown.[19] What Malthus could not account for was the fact that technology could create higher yields of food, allowing the population to expand even further.[20] Agriculture is one of the fields that has most benefited from the development of biotechnology.[21] Of course, agricultural biotechnology is nothing new. Scientists have known that they could select the traits they want expressed in plants from as early

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[18] *See* Francis E. Sharples, *Genetic Engineering Raises Environmental Concerns, in* GENETIC ENGINEERING: OPPOSING VIEWPOINTS 40-42 (William Dudley ed., 1990).

> [T]he degree of control afforded by experiments conducted in containment differs from that involved in releases in the field. Once released, modified organisms that find suitable habitats may not only reproduce and spread, but can be expected to evolve in ways that are beneficial to their own survival. The evolution process can allow modified organisms to escape constraints imposed by debilitating them before their release, so that both physical and biological containment may be nullified outside the laboratory.

Id. at 40.

[19] *See* THOMAS ROBERT MALTHUS, AN ESSAY ON THE PRINCIPLE OF POPULATION (Philip Appleman ed., W.W. Norton & Co. 1976) (1798).

[20] *Id.* at xvi.

[21] *See* A. Shinmyo et al., *Gene Regulation in Plant Cells, in* ADVANCES IN PLANT BIOTECHNOLOGY 12 (D.D.Y. Ryu & S. Furusaki eds., 1994).

as the work of Gregor Mendel.[22] With the advent of recombinant DNA technology, however, the ability to alter agriculture is greatly enhanced.

There are many potentially useful agricultural products being developed with biotechnology. Examples include higher yielding crops, herbicide resistant crops, and crops that are engineered to be naturally pest resistant.[23] Applying biotechnology to agriculture can also result in large economic savings, as pesticides may no longer be needed.[24] Proponents of biotechnology claim that with more productive and efficient food sources, we will be able to preserve the Earth's biodiversity.[25] Others counter by claiming that even with advances in agricultural science biodiversity has been historically lost.[26]

Modified agricultural products can also be used to address some of the world's nutritional problems. For example, about 100 million children suffer from Vitamin A deficiency, which can lead to blindness and a decreased immune system.[27] Up to 3.7 billion people, particularly women, suffer from iron deficiency, which can cause anemia and result in children who are stillborn or underweight and who are likely to die shortly after childbirth.[28] Fortunately, scientists have developed a new grain of rice infused with the Vitamin A precursor beta-carotene and iron, which could solve these problems.[29]

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[22] Gregor Mendel is credited with discovering the rules of inheritance in genetics. In the mid-nineteenth century, Mendel conducted experiments on garden pea plants. Through cross-pollination of the plants, he was able to select which traits were expressed in future plant generations, including whether the peas were wrinkled, the height of the plants, and the color of the peas. *See* ROBERT H. TAMARIN, PRINCIPLES OF GENETICS 3-39 (2d ed. 1986).

[23] *See* Henrique Freire de Oliveira Souza, *Genetically Modified Plants: A Need for International Regulation*, 6 ANN. SURV. INT'L & COMP. L. 129, 138 (2000).

[24] *See* Industrial Biotechnology Ass'n, *Genetic Engineering Benefits Agriculture, in* GENETIC ENGINEERING: OPPOSING VIEWPOINTS, *supra* note 18, at 119 (stating that "[g]enetically engineered tomato and tobacco plants have been made resistant to a viral disease that costs farmers as much as $200 million ever year").

[25] *See* Robert B. Horsch & Robert T. Fraley, *Biotechnology Can Help Reduce the Loss of Biodiversity, in* PROTECTION OF GLOBAL BIODIVERSITY 50 (Lakshman D. Grurswamy & Jeffrey A. McNeely eds., 1998).

[26] *See* Bosselmann, *supra* note 15, at 111 (explaining that "[t]he rise of biotechnology, especially in the areas of agriculture and pharmaceuticals, has paralleled the loss of biodiversity").

[27] Gordon Conway, *Food for All in the 21st Century*, ENVIRONMENT, Jan. 1, 2000, at 9.

[28] *Id.*

[29] *Id.*; *see* Trisha Gura, *New Genes Boost Rice Nutrients*, SCIENCE, Aug. 13, 1999, at 994.

The advantages of applying biotechnology to agriculture are not without associated risks. One concern is whether genetically modified food itself is safe to eat.[30] Another concern is that insect resistant crops may become useless if the insects develop a resistance to the toxins used to repel them.[31] It may be possible that through careful planning and regulation of this use of genetically modified agriculture, this risk can be prevented. Given, however, that mutation can arise either spontaneously or in response to some physical or chemical agent,[32] and that insects generally have a short lifespan,[33] the ability for the insects to adapt to the resistant crops is simply a matter of time.

A different, yet equally significant concern with engineered plants is that the plants themselves may become pests within the ecosystem.[34] Modified organisms could compete so successfully within their ecosystem so as to disturb natural balances and dominate their environment.[35] While this may seem like science fiction,[36] a real world example is seen in kudzu. Originally transferred to the United States as an ornamental plant, kudzu is now an agricultural pest in the Southwestern United States.[37] A

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[30] *See* MARTIN TEITEL & KIMBERLY A. WILSON, GENETICALLY ENGINEERED FOOD: CHANGING THE NATURE OF NATURE (1999) (discussing how genetically engineered food products are created and whether they are safe). *See also* Dan L. Burk, *The Milk Free Zone: Federal and Local Interests in Regulating Recombinant BST*, 22 COLUM J. ENVTL. L. 227 (1997) (discussing the safety and regulation of genetically modified milk).

[31] Michael A. Whittaker, *Reevaluating the Food and Drug Administration's Stand on Labeling Genetically Engineered Foods*, 35 SAN DIEGO L. REV. 1215, 1220-21 (1998).

[32] *See generally,* LANSING M. PRESCOTT, MICROBIOLOGY 244-50 (2d ed. 1993) (discussing the biochemical origination of mutations).

[33] As an example, the common fruit fly, *Drosophila melanogaster*, which has historically been used by biology students to study the expression of genetic phenotypes, has a short generation time of twelve to fourteen days. TAMARIN, *supra* note 22, at 59.

[34] *See* David J. Earp, Comment, *The Regulation of Genetically Engineered Plants: Is Peter Rabbit Safe in Mr. McGregor's Transgenic Vegetable Patch?*, 24 ENVTL. L. 1633, 1653-54 (1994).

[35] Bosselmann, *supra* note 15, at 119 (stating that "[e]ven with less-robust species, such as wheat, which are extremely unlikely to escape into the wild, their introduction can change populations of microorganims in the soil and the number and types of insects, birds, and herbivores in the surrounding area").

[36] For an example of this very issue in literature, see ROBERT A. HEINLEIN, STARSHIP TROOPERS 123-24 (Ace Books 1987) (1959).

[37] *See generally* JANET LEMBKE, DESPICABLE SPECIES: ON COWBIRDS, KUDZU, HORNWORMS, AND OTHER SCOURGES 129-54 (1999) (describing the dominance of the invasive plant kudzu within the Southern United States ecosystem).

> Throughout the South, kudzu creeps with stealthy swiftness over brushpiles and fences. It climbs trees and telephone poles and casts its

related consideration is that these modified plants would hybridize with native plant species, potentially making these wild plants more resilient and capable of spreading in their environment much like weeds themselves.[38] Were scientists to introduce a plant species that dominated its ecosystem, or a species that destroyed essential crops like grains, the United States would then be in grave danger. These concerns are significant enough to be relevant to the nation's future. Therefore, a careful review of new agricultural biotechnology patents is warranted due to their potentially serious environmental impacts.

D. *Bioterrorism*

Perhaps the worst danger posed by biotechnology is the use of man-made or modified microbes as agents of terror or warfare. While biological warfare has been used throughout most of recorded history,[39] the ability to modify and enhance naturally occurring diseases to make even more resilient diseases poses a grave danger to society.[40] Diseases

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> soft but heavy net over thickets and hedgerows. It enshrouds abandoned houses, tumbledown tobacco barns, rusted appliances, and junked cars. It sneaks into gardens and plowed fields. Displacing innocent native vegetation, it twines, curls, shoots upward and outward with relentless green insistence. In its wake, power outages occur, and trains have been derailed. By the mid-1990s, kudzu had laid claim to more than 7,000,000 acres—almost 11,000 square miles—of the South. Monstrous roots thrust deep into the earth of at least sixteen states, ropey vines embrace the landscape, and leaves smother it in a big, soft, fuzzy, unbreakable hug. Once the vine invades any location, getting rid of it is well nigh impossible. And it seizes another 120,000 acres every year, a rate that can only increase with the increase in the plant's domain.

Id.

[38] *See* Earp, *supra* note 34, at 1654. A related concern is that these transgenic plants could transfer their enhanced genes to native weeds, in effect creating even tougher weeds. *Id.*

[39] *See* Ronald M. Atlas, *Combating the Threat of Biowarfare and Bioterrorism*, 49 BIOSCIENCE 465 (1999) (describing the historical use of biological agents in warfare).

[40] *See* Harlee Strauss & Jonathan King, *The Fallacy of Defensive Biological Weapons Programmes*, *in* BIOLOGICAL AND TOXIN WEAPONS TODAY 66 (Erhard Geissler ed., 1986).

> Organisms dangerous to human health and welfare, such as influenza virus, dengue virus, Bacillus anthracis and the fungi that produce aflatoxins, already plague human society. There is little doubt, given the fiscal resources available to the military establishments of major industrial nations and the new developments in biotechnology, that new

such as anthrax[41] and smallpox,[42] with their extremely high mortality rates, could spawn global epidemics. For example:

> An attack involving a biologic agent, particularly if released unannounced, will not be evident until individuals feeling ill, probably with flu like symptoms, begin presenting to their physicians' offices, emergency rooms, and health clinics. Because disease undergoes an incubation period, this could be days or even weeks after the attack which would have been colorless, odorless, and soundless. If the agent used causes its victims to become infectious, as does smallpox, and was released in a major city with a major airport, the disease could become pandemic, worldwide, in a matter of a few days. Within

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> variants of these and many other harmful organisms can be generated. Despite their development in the name of national security, the existence of such organisms is likely to increase significantly the risk of their use and decrease national and international security.

Id. For an example of how scientists modify bacteria to make them even more resistant to treatment, see A.P. Pomerantsev et al., *Expression of Cereolysine ab Genes in Bacillus Anthracis Vaccine Strain Ensures Protection Against Experimental Hemolytic Anthrax Infection*, 15 VACCINE 1846, 1850 (1997).

[41] Anthrax is of great concern to the infectious disease community:

> Anthrax causes an illness that looks like flu, followed by shock and death. The mortality rate is about 95% without treatment and 80% with treatment. An estimate of the consequences of a 100 pound release of anthrax spores from a Piper cub over Washington is a mortality substantially higher than the nuclear bomb on Hiroshima. It would, in essence, be a medical disaster in size and scope unlike anything ever seen.

Bioterrorism, *supra* note 1 (statement of John G. Bartlett, M.D., Chief, Infectious Diseases Division, John Hopkins University School of Medicine).

[42] Smallpox is another disease health care providers are concerned about, because:

> [U]nlike anthrax, it is highly contagious. This disease was eliminated from the globe in 1976 under the leadership of D.A. Henderson. Thus, no one has seen a case in 23 years. Smallpox vaccinations have been discontinued so that nearly all persons on earth are now susceptible to the disease. The mortality rate is about 30%. Most of us in the infectious disease community believe that a single case of smallpox in 1999 would terrify the health care system because of the possibility of a global epidemic. An effective response would require hospitalization of all patients in negative pressure rooms, vaccinations of thousands of exposed or potentially exposed persons, and the probable need for quarantine.

Id.

> our own national boundaries, given our highly mobile society, the disease could also spread to several states in mere hours.[43]

Biological agents, because they are generally colorless, odorless, and tasteless, have the unique advantage of being difficult to detect before release.[44] Smallpox and anthrax in particular have "advantages in that they can be grown reasonably easily and in large quantities and are sturdy organisms that are resistant to destruction. They are especially suited to aerosol dissemination to reach large areas and numbers of people."[45] As if these characteristics were not bad enough, scientists have tinkered with these diseases to make them even more resistant to treatment.[46] In sum, these biological agents are the perfect weapons—lethal to the masses while at the same time difficult to counteract and destroy.

Congress has attempted to restrict access to biological weapons through two statutes.[47] The Biological Weapons Anti-Terrorism Act of 1989 seeks to punish those who knowingly create or transfer biological agents or toxins for the purpose of using these items in biological warfare.[48] The Antiterrorism and Effective Death Penalty Act of 1996, which restricted access to biological agents even further, supplemented this law.[49] However, the effect of these laws is diluted by the fact that

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[43] *Bioterrorism*, *supra* note 1 (statement of Michael T. Osterholm, Ph.D., Chairman and CEO, Infection Control Advisory Network).

[44] *Bioterrorism: Domestic Weapons of Mass Destruction, Special Joint Hearing Before the Senate Veterans Affairs Committee and Senate Subcomm. On Labor, Health and Human Services, Education and Related Services of the Senate Committee on Appropriations*, 106th Cong. (1999) [hereinafter *Bioterrorism: Domestic*] (statement of Donald A. Henderson, M.D., director, Center for Civilian Biodefense Studies, the Johns Hopkins University).

[45] *Id.*

[46] *See* Pomerantsev, *supra* note 40.

[47] For a discussion of the current status of federal law concerning biological warfare, see Heather A. Dagen, *Bioterrorism: Perfectly Legal*, 49 CATH. U. L. REV. 535 (2000). *See* Atlas, *supra* note 39 (describing the government's current regulatory scheme).

[48] *See* Biological Weapons Anti-Terrorism Act of 1989, 18 U.S.C. § 175 (1994 & Supp. IV 1998).

[49] *See* Antiterrorism and Effective Death Penalty Act of 1996, Pub. L. No. 104-132, § 511, 110 Stat. 1284. The statute strengthened the Biological Weapons Anti-Terrorism Act of 1989 by expanding the definition of "infectious substance" to "infectious substance, or biological product that may be engineered as a result of biotechnology, or any naturally occurring component or bioengineered component of any such microorganism, virus, infectious substance, or biological product." *Id.* § 511(b). The statute also provided that the Secretary of Health will maintain a list of potentially

individuals must have the intent to use the biological agents. Individuals could escape liability by claiming that they never intended to use the microbes for biological warfare.[50] Short of a planned conspiracy, it would be difficult to show intent without the microbes actually being released into the environment.

Unfortunately, the current public health infrastructure is also unprepared to deal with a bioterrorism event releasing microbial agents into the general public.[51] The frontline response against an outbreak would fall onto local health care providers.[52] These providers, who are currently untrained in how to respond to such an emergency, are themselves at risk of falling to the very disease they would be trying to combat.[53] Were that to happen, it is likely that little could be done to further prevent an epidemic.

This Note does not presuppose that using the patent system to limit access to the information necessary to make more dangerous biological agents would remove the threat of biological warfare and the need for the public health system's preparedness. Strengthening the public health care system through enhanced training and better equipment is essential to fighting any outbreak that may occur.[54] This Note does argue, however,

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dangerous biological agents, further clarifying what counted as infectious agents under the act. *Id.* § 511(d).

[50] The statute provides in relevant part that "[w]hoever knowingly develops, produces, stockpiles, transfers, acquires, retains or possesses any biological agent, toxin, or delivery system for use as a weapon . . ." 18 U.S.C. § 175.

[51] *See Bioterrorism*, *supra* note 1 (statement of Michael T. Osterholm, Ph.D., Chairman and CEO, Infection Control Advisory Network) (asking "[a]re state public health departments ready for such a scenario [as bioterrorism]? The simple answer is no").

[52] *See id.* (statement of Jeffrey P. Koplan, M.D., Director, Centers for Disease Control and Prevention) (commenting that "[t]he initial response to such a biological attack on civilians is likely to be made by the public health community rather than by the military or emergency responders").

[53] *See id.* (statement of Richard L. Alcorta, M.D., State EMS Medical Director for the Maryland Institute for Emergency Medical Services Systems).

> Most vulnerable to a biologic release are the EMS response personnel, the primary health care/family practitioner, and the emergency department physicians and staff. This is the infrastructure of our national health care safety network. Without a real-time identification of a highly infectious biologic organism, this critical cadre of physicians and health care professionals, as well as the health care system will be seriously, if not fatally, crippled.

Id.

[54] *See id.* (statement of Jeffrey P. Koplan, M.D., Director, Centers for Disease Control and Prevention) (stating that "increased vigilance and preparedness for unexplained

that limiting access to biological agents and the information necessary to improve them, combined with a proper response from the health care system, could greatly reduce the effectiveness of bioterrorism. These combined efforts represent the best means of dealing with these potential threats.[55]

III. CURRENT CONTROLS ON BIOTECHNOLOGY

A. *Current Regulation of Biotechnology*

The regulation of biotechnology within the United States is currently a decentralized regime dividing its jurisdiction among a variety of organizations. In 1986, the Office of Science and Technology created the Coordinated Framework for Regulation of Biotechnology.[56] This coordinated framework split responsibility for regulating biotechnology among the Department of Agriculture, the Environmental Protection Agency ("EPA"), the Food and Drug Administration ("FDA"), the National Institute of Health, and the Occupational Safety and Health Administration ("OSHA").[57]

Primary jurisdiction for each of these agencies is based on statutory authority. For example, the Department of Agriculture controls the movement of genetically modified plants under the Federal Plant Pest Act[58] and the Plant Quarantine Act.[59] The EPA similarly claims jurisdiction over genetically engineered organisms based on the Federal

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illnesses is an essential part of the public health effort to protect the American people against bioterrorism").

[55] *See id.* (statement of Margaret A. Hamburg, M.D., Assistant Secretary for Planning and Evaluation, Department of Health and Human Services).

> Measures that will deter or prevent bioterrorism will be far and away the most cost effective means to counter such threats to public health and social order. Among the activities that need to be initiated are efforts to control access to and handling of dangerous pathogens, including proactive measures by the scientific community to monitor more closely the facilities and procedures surrounding the use of such biological agents.

Id.

[56] Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (June 26, 1986).

[57] *Id.*

[58] 7 U.S.C. §§ 150 aa-jj (1994).

[59] *Id.* §§ 151-167. The Department of Agriculture also claims jurisdiction over some veterinary biologics under the Virus Serum Toxin Act, 21 U.S.C. §§ 151-158 (1994).

Insecticide, Fungicide, and Rodenticide Act[60] and the Toxic Substances Control Act.[61] OSHA even claims some jurisdiction under the Occupation Safety and Health Act of 1970.[62] The problem with these various individual statutes, used as the basis for the regulation of biotechnology, is that none of these laws were designed to regulate biotechnology.[63] In addition, due to overlapping jurisdiction of the statutes, it is difficult to determine which agency is actually in control. [64]

An advantage of this coordinated framework is that each agency can have expertise in a very specific area. For example, the EPA is capable of employing experts in the field of pesticide biotechnology products. Additional agencies in control of the decisions also means that it is harder for any one individual to influence all of the agencies, as opposed to lobbying one central agency to further an individual's agenda. In accordance with this principle, additional agencies in control gives individuals more opportunities to be heard in the policy making process.[65]

A decentralized coordinated framework scheme is not without its disadvantages.[66] With power being allocated among a variety of different

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[60] 7 U.S.C. §§ 136-136y.

[61] 15 U.S.C. §§ 2601-2629 (1994).

[62] *See* 29 U.S.C. § 651 (1994).

[63] *See* Valerie M. Fogleman, *Regulating Science: An Evaluation of the Regulation of Biotechnology Research*, 17 ENVTL. L. 183, 234 (1987).

[64] *See id.*

[65] The Administrative Procedures Act requires that "the agency shall give interested persons an opportunity to participate in the rulemaking through submission of written data, views, or arguments with or without opportunity for oral presentation." 5 U.S.C. § 553 (1994). With each agency being required to take comments from interested individuals when promulgating a new rule, an individual has more opportunities to be heard by participating in each agency's individual discussion. Note, however, that the Department of Agriculture uses formal rulemaking under § 556 of the Administrative Procedures Act to regulate biotechnology as opposed to notice and comment rulemaking under § 553. *See* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,352 (June 26, 1986).

[66] Despite the overall controls of the Coordinated Framework, the framework itself envisions that individual agencies will take the lead in regulation. *See id.* at 23,303.

> To the extent possible, responsibility for a product use will lie with a single agency. Where regulatory oversight or review for a particular product is to be performed by more that one agency, the policy establishes a lead agency, and consolidated or coordinated reviews. While this preamble seeks to convey an overview of the coordinated framework it must be noted that the regulatory requirements are highly technical; reliance only on the simplified summary statements herein could be misleading and, thus, the agency policy statements must be consulted for specific details.

agencies, it becomes harder to maintain government oversight over the regulation of biotechnology. Essentially, it becomes difficult to keep track of what each individual agency is doing. A variety of agencies making different decisions on the regulation of biotechnology could also lead to incoherencies and gaps in the doctrine.[67] The framework itself has been criticized as being inflexible due to the variety of regulations involved and its high susceptibility to influence by the Executive Branch.[68] In addition, creating unified policy may be more difficult with additional agencies involved, as it is far easier to lobby a single agency as opposed to several. If a person's agenda is actually beneficial to the science of biotechnology, it may then be a problem to seek approval from all of the various agencies that regulate the different aspects of biotechnology. Thus, this framework may run to the contrary of having an actual uniform government policy on the use of biotechnology that is consistent and predictable.

B. *Statutes Used to Control the Dissemination of Scientific Information*

The United States uses several different statutes to attempt to restrict the flow of information that threatens national security from falling into the wrong hands. These statutes range from having extremely broad prohibitions, such as in the Export Administration Act, which allows for the restriction on the exportation of essentially any materials that could affect national security, to the narrow range of the Atomic Energy Act, which is limited to information concerning the atomic and nuclear sciences. This Note argues that outside of the ISA, which is discussed in detail in Section IV, the other statutes that regulate the dissemination of technical information are generally ineffective in dealing with the problems presented by biotechnology.

1. The Espionage and Sabotage Act of 1954[69]

The Espionage and Sabotage Act ("ESA"), which imposes a very general control over the dissemination of information, is essentially designed to prevent military secrets from being transmitted to foreign

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Id.

[67] *But see id.* (arguing that "[t]he agencies will seek to operate their programs in an integrated and coordinated fashion and together should cover the full range of plants, animals, and microorganisms derived by the new genetic engineering techniques").

[68] *See* Fogleman, *supra* note 63, at 232-36.

[69] 18 U.S.C. §§ 794, 2151-56 (1994).

agents. This statute could apply to biotechnology under a broad interpretation of what is "information relating to the national defense."[70] Unfortunately, the Supreme Court has not clarified whether this broad standard could be applied. In *Gorin v. United States*,[71] the Court defined the national defense as "a generic concept of broad connotations, referring to the military and naval establishments and the related activities of national preparedness."[72] Just what constitutes those activities of preparedness, however, is left for a jury to decide.[73] Thus the application of the ESA is dependent wholly on the factual circumstances, and would be difficult to apply when lay people are asked to evaluate the impact of complex technical information on national security. Certainly a system in which experts evaluate new technologies for potential threats before those technologies are released would be more effective than after the fact judicial controls.[74]

The ESA suffers from several problems when it is applied in the context of dangerous biotechnology. One such problem is the fact that it is limited to transmission of information to foreign countries or agents.[75] Bioterrorism, on the other hand, is also a domestic concern that the Act cannot affect. This statute may also have problems with improvement patents that expand upon an older invention. If an older invention was not restricted, then this act may not affect or notice the potential of any improvements to the older, unrestricted information. Finally, a key element is that there must be an intentional dissemination of the information with a desire to willfully harm the United States.[76] It would be difficult to argue, however, that simply publishing scientific

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[70] *Id.* § 794(a).

[71] 312 U.S. 19 (1941).

[72] *Id.* at 28.

[73] The Court stated that "[t]he question of the connection of the information with national defense is a question of fact to be determined by the jury as negligence upon undisputed facts is determined." *Id.* at 32.

[74] The option of secrecy orders allows evaluation by the appropriate defense agency, encouraging expert review of the technology. *See* 35 U.S.C. § 181 (1994 & Supp. V 1999); *see also infra* notes 167-68 and accompanying text (discussing the designation of other agencies as defense agencies under the ISA).

[75] *See* 18 U.S.C. § 794 (1994).

[76] The statute provides in relevant part that "[w]hoever, with intent or reason to believe that it is to be used to the injury of the United States or to the advantage of a foreign nation, communicates . . ." *Id.*

information in a foreign journal is evidence of intent to harm the United States.[77]

2. The Export Administration Act of 1979[78]

The Export Administration Act ("EAA"), different in scope from the espionage statute, allows control of the nation's exports as necessary for national security. It requires the Secretary of Commerce, in cooperation with the Secretary of Defense and other appropriate agencies, to establish a list of all goods and technologies that should be subject to export controls.[79] Regulations then require that a license be granted by the Secretary of Commerce to export any of these controlled goods or technologies.[80]

Similar to the ESA, the EAA is limited in its scope to the export of technology abroad.[81] This statute, therefore, is fairly ineffective in preventing dangerous technologies from becoming available domestically. Another problem with the EAA is that it requires prior identification of the threatening technology before it can be placed upon the control list. While the Act has means by which technologies are evaluated for their potential impact on national security,[82] there is no stipulation that these advisors search out all new technologies for their impacts. However, when coupled with the advance reviews of the technology from secrecy orders from the ISA,[83] the EAA could be an effective statute to prevent dangerous technologies from falling into the wrong hands.

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[77] It has also been argued that due to the differences in language between sections 794(a) and 794(b), and the omission of the term "publish" from section 794(a), communications to foreign nationals do not include publications. *See* Roger Funk, *National Security Controls on the Dissemination of Privately Generated Scientific Information*, 30 UCLA L. REV. 405 (1982).

[78] 50 U.S.C. §§ 2401-20 (1994 & Supp. V 1999).

[79] *Id.* § 2404(c). This Commodity Control List is subject to quarterly review, with all goods and technology on the list reviewed at least once per year. *Id.*

[80] 15 C.F.R. § 740 (2001).

[81] The regulations do have a broad definition of what an export is. For example, the "release of technology to a foreign national in the United States through such means as demonstration or oral briefing is deemed an export." *Id.* § 730.5. Unfortunately, even these broad definitions are still concerned with foreign nationals and countries, so no consideration is given as to hoe the technology might be used by American citizens. *Id.*

[82] 50 U.S.C. § 2404(h). These Technical Advisory Committees are formed at the request of a producer whose technology is subject to or being considered for an export control. 15 C.F.R. § 730.10(b).

[83] 35 U.S.C. §§ 181-88 (1994 & Supp. V 1999).

3. Arms Export Control Act[84]

The Arms Export Control Act ("AECA") is the other major export measure designed to prevent the exportation of, and foreign contact with, military technology.[85] Like the EAA, the AECA sets forth a list of materials[86] that may not be exported without permission and license of the Secretary of State.[87]

The AECA suffers from the same problems as the EAA does when applied to the context of the proliferation of dangerous biotechnology.[88] The scope of the statute is limited to activities involving foreign nationals and countries, so domestic concerns are not addressed.[89] Though the AECA encompasses technical information,[90] including technical information that is not classified,[91] that technology must have "significant military or intelligence applicability."[92] In addition, information within the public domain is not covered under the AECA.[93] When defining the public domain,[94] basic fundamental research at universities has been

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[84] 22 U.S.C. §§ 2751-2976 (1994 & Supp. V 1999).

[85] *Id.* §2751; 22 C.F.R. § 120.1 (2001).

[86] The compilation was entitled the United States Munitions List, 22 U.S.C. § 2778(a). This list excludes all items that are included in the Commodity Control List as part of the EAA. *Id.*; 22 C.F.R. § 120.4.

[87] 22 U.S.C. § 2778; 22 C.F.R. § 123.2.

[88] The AECA has been recently challenged as unconstitutional on its face. In *Bernstein v. U.S. Dep't of State*, a mathematician challenged the legitimacy of the Act as applied to cryptographic computer source code. 945 F. Supp. 1279 (N.D. Cal. 1996). The district court held that the licensing requirements for speech relating to encryption of computer software was an unlawful prior restraint, but that the scheme of the act as a whole was not overly broad. *Id.*

[89] 22 U.S.C. § 2778; 22 C.F.R. § 120.17. Note that "[d]isclosing (including oral or visual disclosure) or transferring technology to a foreign person, whether in the United States or abroad" counts as an export. 22 C.F.R. § 120.17.

[90] 22 C.F.R. § 125. Requests for a license are required whenever the technical information to be exported exceeds that which is required to support a domestic filing of a patent application when no domestic application has been filed. *Id.* § 125.2(b). Note that the filing of foreign patent applications is covered by the Invention Secrecy Act and foreign filing licenses granted by the Patent Office. *See infra* notes 164-71 and accompanying text; *see also id.* § 125.2.

[91] *See id.*

[92] *Id.* § 120.3(b). Note that the intended use of the technology is not considered relevant to the controls of the Act. *Id.* at § 120.

[93] 22 C.F.R. § 125.1(a).

[94] *Id.* § 120.11.

excluded from the statute if it is common to publish the results.[95] Thus in the biotechnology context, where basic discoveries may have many potential applications, the AECA would not prevent the distribution of the technology.

4. Atomic Energy Act of 1954[96]

The Atomic Energy Act ("AEA") is a good example of a narrowly tailored statute designed to control very specific and threatening technical information. The act is designed to prevent access to and dissemination of information concerning atomic energy and weapons.[97] This concern for the danger of atomic weapons and fuels was carried over into the ISA, where references are constantly made to the Atomic Energy Commissioner and his ability to decide whether the patent would be detrimental to national security.[98] Similar to the ISA, the restrictions of the dissemination of information can apply to both classified and unclassified sources.[99] Unfortunately, when applied to the context of biotechnology, the AEA lends no support to preventing the proliferation of dangerous biotechnology.

IV. USING THE UNITED STATES PATENT SYSTEM TO CONTROL POTENTIALLY DANGEROUS BIOTECHNOLOGY

A. *General Overview of the United States Patent System*

Patents are granted in consideration of a fundamental bargain between the Patent Office, representing the general welfare of the people, and the inventor. Inventors are given a limited monopoly in order to exclude others from making or using their invention for a limited time.[100]

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[95] *Id.* § 120.11(a)(8).

[96] 42 U.S.C. §§ 2011-2297 (1994 & Supp. V 1999).

[97] *Id.* § 2013.

[98] *See* 35 U.S.C. §§ 181-88 (1994 & Supp. V 1999).

[99] *Id.* § 181; 42 U.S.C. §§ 2161-68. The AEA has been criticized for failing to distinguish between classified and unclassified information as private scientists are unaware of whether the information that they are working with would be restricted until the government informs them of such. *See* Funk, *supra* note 77, at 433.

[100] The current term of utility and plant patents is twenty years from the date of filing the application (or of any earlier filed application to which the patent application claims priority). 35 U.S.C. § 154. Design patents, however, only have a term of fourteen years. *Id.* § 173. Given that the term of the utility patent is measured from the date of filing, the

In exchange, the inventor must disclose how to make and use the invention to the public.[101]

Patent applications will only be granted for inventions that are considered patentable subject matter.[102] Originally, living matter such as biotechnology was not considered patentable subject matter.[103] The Supreme Court, however, in *Diamond v. Chakrabarty*,[104] has since taken a very liberal stance as to what constitutes patentable subject matter. This current standard is extremely broad, providing that "anything under the sun modified by man" is patentable.[105] Though plants and seeds enjoy separate consideration for patentability under the Plant Patent Act[106] and

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imposition of a secrecy order would be very relevant to the life of the patent. Patentees can file to have the term for which the secrecy order was in effect added back to their patent's life, as discussed *infra* notes 164-66.

[101] 35 U.S.C. § 112.

[102] The statute provides that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title." *Id.* § 101.

[103] *See* Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948) (holding that a mixture of bacteria with properties that were not thought to be possible in nature was not patentable as it was not an invention, but rather a discovery of a phenomenon of nature). The Supreme Court stated that "[h]e who discovers a hitherto unknown phenomena of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end." *Id.* at 130.

[104] 447 U.S. 303 (1980) (holding that living, engineered microorganisms are patentable subject matter under 35 U.S.C. § 101).

[105] *Id.* at 309. This view has also been embraced by the Court of Appeals for the Federal Circuit. *See In re* Alappat, 33 F.3d 1526 (Fed. Cir. 1994).

> The plain and unambiguous meaning of section 101 is that any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may be patented if it meets the requirements for patentability set forth in Title 35, such as those found in sections 102, 103 and 112. The use of the expansive term "any" in section 101 represents Congress's intent not to place any restrictions on the subject matter for which a patent may be obtained beyond those specifically recited in section 101 and other parts of Title 35.

Id. at 1542.

[106] 35 U.S.C. §§ 161-64. Applicants have a choice when filing a patent for plants or seeds, provided the plant has been asexually reproduced, regarding whether they will seek a utility patent or a plant patent. Though the patent terms are the same, the disclosure requirements are somewhat more relaxed for plant patents than utility patents. *Id.* §§ 161-62. Note that tuber propagated plants are specifically exempted from the Plant Patent Act. *Id.*

the Plant Variety Protection Act,[107] they may still be eligible for the more general utility patent provided the application can satisfy the necessary disclosure requirements.[108] The Board of Patent Appeals and Interferences has also since declared animals statutory subject matter for patents.[109] In essence, the simple fact that the invention concerns biotechnology presents no problem in patenting the invention.[110]

In order to receive a patent, an invention must satisfy three additional requirements. The invention must be useful,[111] novel,[112] and non-obvious to one of ordinary skill in the art at the time the invention was made.[113] Novelty considers whether the invention was known to others before the invention thereof by the inventor.[114] Provided that the inventor has actually created something new, this provision presents no special limitations to the granting of biotechnology patents.

The patent statute requires that patents not only be "new" but that they must also be "useful."[115] Utility, however, is generally not a barrier to patentability. Indeed, the Federal Circuit has stated that "[w]hen a properly claimed invention meets at least one stated objective, utility under [35 U.S.C.] § 101 is clearly shown."[116] As established in *Brenner v. Manson*, the specification must, however, establish that the invention has some specific utility.[117] The Federal Circuit seems to have clarified that

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[107] 7 U.S.C. §§ 2321-2583 (1994).

[108] *See Ex parte* Hibberd, 227 U.S.P.Q.2d (BNA) 443 (Pat. Off. Bd. App. 1985).

[109] *See Ex parte* Allen, 2 U.S.P.Q.2d (BNA) 1425 (Bd. Pat. App. & Int. 1987) (holding that polyploid oysters, wholly created by man, were proper subject matter).

[110] This is not to say that anything and everything can be patented. Mathematical formulas and purely natural phenomena are still excepted from protection. *See, e.g.*, Diamond, 447 U.S. at 309; Parker v. Flook, 437 U.S. 584 (1978); Gottschalk v. Benson, 409 U.S. 63, 67 (1972); Funk Bros. Feed Co. v. Kato Inoculant Co., 333 U.S. 127, 130; O'Reilly v. Morse, 56 U.S. (15 How.) 62, 112-21 (1854); Le Roy v. Tatham, 55 U.S. (14 How.) 156, 175 (1853). The AEA also provides that "[n]o patent shall be granted for any invention or discovery which is useful solely in the utilization of special nuclear material or atomic energy in an atomic weapon." 42 U.S.C. § 2181(a) (1994 & Supp. V 1999).

[111] 35 U.S.C. §101.

[112] *Id.* § 102.

[113] *Id.* § 103.

[114] *Id.* § 102.

[115] *Id.* § 101.

[116] Raytheon v. Roper, 724 F.2d 951, 958 (Fed. Cir. 1983). *See In re* Gottlieb, 328 F.2d 1016, 1019 (CCPA 1964) (stating that "[h]aving found that the antibiotic is useful for some purpose, it becomes unnecessary to decide whether it is in fact useful for the other purposes 'indicated' in the specification as possibly useful").

[117] Brenner v. Manson, 383 U.S. 519 (1966). The Court stated that:

what is required to show specific utility is a low threshold, when it held in *In re Brana* that a compound whose only demonstrated utility was tumor reduction in mice was sufficient utility.[118] In addition, lack of utility is not fatal to the application if it is apparent to a person of ordinary skill that the invention would have a well-established utility.[119] Thus, utility is a fairly low standard that is unlikely to be used to deny a patent application.

The final condition for patentability is that the invention must be non-obvious in light of the prior art at the time of conception of the invention. The basic test for determining non-obviousness was set out in *Graham v. John Deere Co.*,[120] in which the Supreme Court stated that "[u]nder § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved."[121] The Court further stated that "such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented."[122] These secondary considerations can be used to show that the invention was non-obvious at the time the invention was conceived.

The actual filing of a patent application is a rigorous negotiation between the inventor and the patent prosecution section of the Patent Office. The minimum requirements for filing an application consist of a specification of the invention, any drawings that may be necessary to understand the invention, an oath executed by the inventor, and specific

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> The basic *quid pro quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point- where the specific benefit exists in currently available form- there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.

Id. at 534-35. *See In re* Ziegler, 992 F.2d 1197, 1201 (Fed. Cir. 1993) (stating that a disclosure for a composition that is "plasitic-like" was not sufficient to specify a utility for the invention); *In re* Kirk, 376 F.2d 936 (CCPA 1967) (commenting that a new class of steroids that are biologically active is not sufficiently described to be useful).

[118] *In re* Brana, 51 F.3d 1560, 1565 (Fed. Cir. 1995) (commenting that "these tumor models represent a specific disease against which the claimed compounds are alleged to be effective. Accordingly . . . appellants' specification alleges a sufficiently specific use.").

[119] *See In re* Folkers, 344 F.2d 970 (CCPA 1965).

[120] 383 U.S. 1 (1966).

[121] *Id.* at 17.

[122] *Id.* at 17-18.

claims as to what exactly the inventor regards as his invention.[123] The specification is a written description of the invention, and it must also include descriptions of how to make and use the invention as well as the best mode of the invention known to the inventor at the time of filing.[124] The specification must be enabling to one skilled in the art such that they would not have to engage in "undue experimentation" to arrive at the subject matter claimed.[125] The written description requirement is separate from the enablement requirement of how to make and use the invention.[126]

B. *Secrecy Orders and The Invention Secrecy Act of 1951*

1. Definition and Procedure for Issuing a Secrecy Order

The Commissioner of the United States Patent and Trademark Office[127] has the power to withhold the issuance of patents for a limited duration due to national security concerns.[128] The statute contemplates two different types of inventions, those that the government has a property interest in and those that the government has no property interest in, but

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[123] 35 U.S.C. § 111 (1994 & Supp. V 1999). Note that the required oath is not necessary when filing an application to establish a filing date and priority. *Id.*

[124] *Id.* § 112.

[125] *In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988). The court stated that:

> The term "undue experimentation" does not appear in the statute, but it is well established that enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations.

Id.

[126] *See* Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991) (stating that "[t]he purpose of the 'written description' requirement is broader than to merely explain how to 'make and use;' the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention").

[127] The Commissioner of Patents is a position appointed by the Secretary of Commerce. 35 U.S.C. § 3(b)(2). Prior to 1999, the Commissioner of the Patent and Trademark office had the authority to withhold patents for national security reasons. In 1999, the American Inventors Protection Act modified that position, elevating it to the newly formed Undersecretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office. *See* 35 U.S.C. § 3. The Commissioner of Patents oversees the issuance of applications that may be subject to a secrecy order. *See id.* §§ 3, 181.

[128] 35 U.S.C. §§ 181-88.

that may also be detrimental to the national security.[129] When the Commissioner believes that the invention may be detrimental to the national security, he or she will make the application available to the appropriate defense agency for inspection.[130] If it is the opinion of the chief officer of the appropriate defense agency, after review of the patent application, that the invention "would be detrimental to the national security," the chief officer will notify the Commissioner to order the invention kept secret.[131]

When the Commissioner issues a secrecy order on a pending patent application, prosecution of the application will continue as normal.[132]

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[129] Section 181 of the ISA states in relevant part that:

> Whenever publication or disclosure by the publication of an application or by grant of a patent on an invention in which the Government has a property interest might, in the opinion of the head of the interested Government agency, be detrimental to the national security, the Commissioner of Patents upon being so notified shall order that the invention be kept secret and shall withhold the publication of the application or the grant of a patent therefore under the conditions set forth hereinafter.
>
> Whenever the publication or disclosure of an invention by the publication of an application or by the granting of a patent, in which the Government does not have a property interest, might, in the opinion of the Commissioner of Patents, be detrimental to the national security, he shall make the application for patent in which such invention is disclosed available for inspection to the Atomic Energy Commission, the Secretary of Defense, and the chief officer of any other department or agency of the Government designated by the President as a defense agency of the United States.

Id. § 181.

[130] *Id.* Defense agencies under the ISA currently include: the Department of Defense, 35 U.S.C. § 181; the Department of Energy (as successor to the Atomic Energy Commission), 42 U.S.C. § 5908(l) (1994 & Supp. V 1999); the Department of Justice, Exec. Order No. 10,457, 3 C.F.R. 943-44 (1949-53); and most recently the National Aeronautics and Space Administration, 42 U.S.C. § 2457(i) (1994).

[131] 35 U.S.C. § 181.

[132] 37 C.F.R. § 5.3 (2000). Note that as all patent applications are maintained confidentially during their applications pendancy, there are no further concerns of secrecy even though the prosecution continues. 35 U.S.C. § 122 (stating that "applications for patents shall be kept in confidence by the Patent and Trademark Office and no information concerning the same given without authority of the applicant or owner unless necessary to carry out . . . an Act of Congress or in such special circumstances as may be determined by the Director"). As an added measure, all pending applications subject to a security order are also examined by a special patent examining group (Group 3640). U.S. PATENT AND TRADEMARK OFFICE, U.S. DEP'T OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE § 130 (7th ed. rev. 2000) [hereinafter PATENT MANUAL].

Applicants are still responsible for prosecuting or appealing any final rejections[133] the application may receive.[134] However, hearings for any appeals will not be heard unless specially ordered by the Commissioner.[135] National applications that are placed in condition for allowance will be held in a "condition of suspension until the secrecy order is removed."[136] International applications subject to a secrecy order will be processed as a normal application up until the point when they are to be sent to the international authorities, but no information will be forwarded to those authorities.[137] In addition, no interferences[138] will be declared involving applications subject to a secrecy order.[139]

Secrecy orders come in one of three forms, depending on the need to protect the application's disclosure from discovery. The first, the "Secrecy Order and Permit for Foreign Filing in Certain Countries", is tied to the AECA and EAA.[140] It is "intended to permit the widest utilization of the technical data in the patent application while still controlling any publication or disclosure which would result in an unlawful exportation."[141] This type of order allows the application to be filed in certain countries in which the United States has reciprocal security agreements.[142] The second type of order, the "Secrecy Order and Permit for Disclosing Classified Information," is "to be used for those patent applications which contain technical data that is properly classified or classifiable" with no government interest.[143] If the applicant has a current

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[133] Final rejection is a special type of rejection of a patent application an examiner can give to an application that has been examined at least twice. Final rejection limits the applicants ability to amend or appeal the rejection. 37 C.F.R. § 1.113.

[134] *Id.* § 5.3.

[135] *Id.* § 5.3(a).

[136] *Id.* § 5.3(c).

[137] *Id.* § 5.3(d).

[138] An "interference" is a proceeding within the Patent and Trademark Office whereby the priority, or who invented the invention first, is disputed between a pending patent application and another application or patent that has already been issued. *See* 35 U.S.C. § 135 (1994 & Supp. V 1999).

[139] 37 C.F.R. § 5.3.

[140] *See* PATENT MANUAL, *supra* note 132, § 120.

[141] *Id.*

[142] *Id.* "Countries with which the United States has reciprocal security agreements include Australia, Belgium, Canada, Denmark, France, Germany, Greece, Italy, Japan, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Turkey, and the United Kingdom." *Id.* Note that applications under a secrecy order cannot be filed directly with the European Patent Office and must be instead filed with the individual countries. *Id.*

[143] *Id.*

Department of Defense Security Agreement, then "this secrecy order allows disclosure of the technical information as if it were classified."[144] This order is intended "to treat classified technical data presented as a patent application in the same manner as any other classified material."[145] The final type of secrecy order, which is only referred to as "Secrecy Order," is a catchall class that "is used where the other types of Orders do not apply."[146] As the applicant in this type of order does not have a security agreement with the Department of Defense, this order prevents the applicant from disclosing the invention to anyone without prior consent of the Commissioner.[147]

Once a patent application is ordered secret, the Commissioner will notify the applicant of the order.[148] This notice creates an obligation on the part of the applicant not to disclose the invention to others for the duration of the order. Failure to obey a secrecy order results in abandonment of the patent application[149] and, in more extreme cases, can result in a fine and imprisonment.[150]

Secrecy orders are, by nature, limited in duration. They are given for one-year periods that are extendable annually upon a showing by the appropriate agency head requesting the secrecy order that national interest continues to require the security.[151] The Commissioner can terminate these orders prematurely if national security interests no longer exist.[152]

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[144] PATENT MANUAL, *supra* note 132.

[145] *Id.*

[146] *Id.*

[147] *Id.*

[148] 35 U.S.C. § 181.

[149] *Id.* § 182.

[150] *Id.* § 186. The maximum penalty for violation of a secrecy order, upon conviction, is a fine of up to $10,000, up to two years imprisonment, or both. *Id.* This penalty requires knowledge of the secrecy order and willful disclosure or authorization of the disclosure of the invention, which is a higher standard than that required to abandon the invention which can happen through inadvertent disclosure. *See id.* §§ 182, 186. Note that these penalties do not apply to officers or agents of the United States who are acting within the scope of their employment. *Id.* § 187.

[151] 35 U.S.C. § 181. An exception exists for secrecy orders issued during times when the United States is at war. When at war, the order remains in effect for the duration of the hostilities plus an additional year thereafter. *Id.* An additional exception exists for secrecy orders issued during a national emergency declared by the President. Such orders will remain in effect for the duration of the national emergency and an additional six months thereafter. *Id.*

[152] *Id.*

One complaint against secrecy orders is that they are too harsh on inventors.[153] Recently, secrecy orders have been increasingly issued on technologies that can be used for commercial as well as military purposes.[154] The increased use of secrecy has also hampered the transfer of non-threatening technologies from the military sector to the commercial sector.[155] The Pentagon has not turned a deaf ear to these complaints and is working to address the problem.[156] Applicants whose patents have been withheld due to the implication of a secrecy order have a legal right to compensation.[157] The ISA provides that:

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153 *See Morning Edition: Patenting Office Tries to Silence Inventors* (NPR radio broadcast, Sept. 14, 1992). During the broadcast, it was noted that:

> Every year, about 80,000 Americans apply for patents, and for the past few years, several hundred of them have gotten back an ominous-looking letter from the US Patent and Trademark Office. Across the top of the letter in heavy black letters stand the words "secrecy order." This means the Patent Office sent the application over to the Pentagon, where officials decided it should be treated like a military secret even if the inventor had no military use in mind. This may seem like a remnant of the Cold War and it is. The Invention Secrecy Act was passed in 1951 at the height of the McCarthy era. For an inventor, a secrecy order is bad news.

Id.

154 *See* Edmund L. Andrews, *Patents: Cold War Secrecy Still Shrouds Inventions*, N.Y. TIMES, May 23, 1992, at 35. The article mentioned that:

> The biggest growth in secrecy orders has not been those imposed on military secrets, like the blueprints for making nuclear weapons, but rather from "dual use" technologies that can be used for both commercial and military purposes. These can range from certain kinds of computer hardware to advanced ceramic materials, laser systems, semiconductor manufacturing technologies and automated process control systems.

Id.

155 *See* Ralph Vartabedian, *Most Promising U.S. Technology Still Kept Secret*, L.A. TIMES, July 13, 1993, at A1 (stating that "[i]f the military services continue to classify industry's most promising technology, they risk posing a formidable obstacle to . . . [the] effort to help the defense industry convert to commercial enterprises . . .").

156 *See* Teresa Riordan, *Patents*, N.Y. TIMES, Sept. 20, 1993, at D2.

> In response to complaints from industry and scientific groups over a sharp rise in secrecy orders during the 1980's, the Pentagon appears to have begun to slow the number of new secrecy orders issued. During the first half of the 1993 fiscal year, 112 such orders were issued, in contrast to an annual high of 847 orders in 1989, according to figures from the Federation of American Scientists.

Id.

157 35 U.S.C. § 183.

> An applicant, his successors, assigns, or legal representatives, whose patent is withheld as herein provided, shall have the right . . . to apply to the head of any department or agency who caused the order to be issued for compensation for the damage caused by the order of secrecy and/or for the use of the invention by the Government, resulting from his disclosure.[158]

These damages cannot be for an invention whose primary purpose is for military use.[159] There are, however, several ways in which damages can be calculated so it is unclear what measure of compensation an inventor will receive under the ISA.[160]

Applicants whose patents are subject to security orders are not without options. An applicant may first petition for the rescission of the secrecy order.[161] If rescission is not granted, the applicant may then appeal to the Secretary of Commerce.[162] An applicant may also file for permission to modify the secrecy order to use parts of the disclosure for other applications.[163]

Applicants are also not penalized in their patent term by having a secrecy order levied on them. Normally, the term of a patent is twenty years from the date of filing the application.[164] Applications under secrecy orders, however, are allowed to recover any time for which the application is held pending under a secrecy order and may have that time added back to their patent term.[165] The adjustment is measured on a day-to-day basis so that the inventor does not lose any time he would have been entitled to had the patent been issued without a secrecy order.[166]

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158 *Id.*

159 *See* McDonnell Douglas Corp. v. United States, 670 F.2d 156, 163-64 (Ct. Cl. 1982).

160 For an excellent discussion of compensation under the ISA, see Gary L. Hausken, *The Value of a Secret: Compensation for Impositions of Secrecy Orders Under the Invention Secrecy Act*, 119 MIL. L. REV. 201 (1988).

161 37 C.F.R. § 5.4 (2000).

162 35 U.S.C. § 181; *see id.* § 5.4(d).

163 37 C.F.R. § 5.5.

164 35 U.S.C. § 154(a)(2).

165 *Id.* § 154(b). Patent terms can also be extended for the Patent and Trademark Office's failure to take certain actions within specified time frames and the failure of the Patent Office to issue a patent within three years of the actual filing date. *Id.*

166 *Id.*

The only change needed to bring biotechnology patents fully within the scope of secrecy orders is for the President to designate the agencies that monitor and regulate biotechnology research as defense agencies under the ISA. The review of patents for national security at the appropriate agency extends to "any other department or agency of the Government designated by the President as a defense agency of the United States."[167] The extension of status as a defense agency, within the scope of the ISA, is not a far stretch for the imagination when one considers the role the Center for Disease Control plays in combating outbreaks of disease, both natural and man-made. Prevention of epidemic disease outbreaks is just as important to defending the national welfare as more conventional armed services are. In fact, using other agencies may be more appropriate than having the Department of Defense analyze the wide variety of technologies.[168] Given that these other regulatory agencies claim their power in the name of public health and safety, designating them as defense agencies for review of biotechnology patents is completely reasonable given the potential threat that biotechnology can represent to the national welfare.

2. Foreign Filing Licenses

Another part of the ISA that is separate but tied to the secrecy order is the requirement of a license to file for a patent in a foreign country for an invention conceived within the United States.[169] This license is required regardless of whether the invention has any conceivable relation to national security. If a foreign filing license is not obtained and a United States patent issues for the invention, then that patent may be held invalid.[170] A foreign filing license, however, is rarely an obstacle to

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[167] *Id.* § 181.

[168] *See* Riordan, *supra* note 156, at D2 (quoting, in an interview with Donald Singer, chief of the patent division of the Air Force Legal Services, the comment that:

> The military is supposed to review secrecy orders every year for a given patent until it decides to rescind them, but this does not always happen, Mr. Singer said. "It's an enormous administrative burden heaped upon our technical people, who are responsible for doing a lot of other jobs," Mr. Singer said. "No one is hired to do this as their main job—not in the Air Force, anyway.").

Id.

[169] 35 U.S.C. § 184. For a general discussion of patent rights available in foreign countries, see Margaret A. Boulware et al., *An Overview of Intellectual Property Rights Abroad*, 16 HOUS. J. INT'L L. 441 (1994).

[170] *Id.* §§ 184-85.

obtaining a patent and the license is easily acquired. Implicit within the filing of a United States application is the request for a foreign filing license.[171] A license will also be considered to be automatically granted in filing a patent application, provided that six months have passed since filing and that the application is not subject to a secrecy order.[172] In addition, a license can be granted simply by filing a petition asking for such a license, regardless of whether a United States application has been filed or not.[173] Finally, a foreign filing license can even be obtained and then applied retroactively, even after the application issues, through a petition, provided that the foreign filing occurred through error and without deceptive intent.[174]

The foreign filing license is essentially an extension of the secrecy order to patent applications in a foreign country. By declaring any United States patent invalid without a foreign filing license, inventors are discouraged from filing their inventions in foreign countries without first consulting the Patent Office. The United States can also punish the inventor for filing in the foreign country without a license,[175] though this extreme measure may violate Due Process requirements.[176]

3. Advantages of Using Secrecy Orders to Prevent the Disclosure of Potentially Threatening Inventions

The primary advantage of the imposition of the secrecy order is that it allows for the front-end control of dangerous information. All issued patent applications are available to any member of the public for inspection.[177] It has been argued that criminal sanctions should be levied

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[171] 37 C.F.R. § 5.12(a).

[172] 35 U.S.C. § 184; 37 C.F.R. § 5.11(e)(2).

[173] 37 C.F.R. § 5.13.

[174] 35 U.S.C. §184-85. *See* Minnesota Mining & Mfg. Co. v. Norton Co., 366 F.2d 238, 240 (6th Cir. 1966) (holding that a retroactive license is valid for patents that have already been issued). The petition for a retroactive license must include a list of every foreign country and dates in which the information was filed, a verified statement that the subject matter was not under a secrecy order at the time, and an explanation as to why the material was filed abroad in error. 37 C.F.R. § 5.25.

[175] 35 U.S.C. § 186.

[176] *See* Allen M. Shinn, Jr., Note, *The First Amendment and the Export Laws: Free Speech on Scientific and Technical Matters*, 58 GEO. WASH. L. REV. 368, 402-03 (1990).

[177] 37 C.F.R. § 1.11.

against those who would misuse biotechnology.[178] Unfortunately, this would not solve all of the problems associated with biotechnology. Essentially it is too late to control the distribution of the information of the patent once it has been issued as a patent. Secrecy orders, however, restrict access to the applications' disclosure for the duration of the secrecy order.

The imposition of a secrecy order is also a proactive approach to the problems posed by biotechnology. The extra time the government would have due to the order would give the United States a head start to counteract any potential problems. For example, the United States could start work on vaccines before the actual threatening organisms become public knowledge. This idea has been recently acknowledged in a Pentagon study claiming that the United States is ill prepared for a bioterrorism attack, but that one means to counter this deficit is to withhold developed vaccines with patents.[179] Even if others later independently discover the invention under the secrecy order, the time saved through the secrecy order may be enough to make a difference in the outcome.[180]

The use of the secrecy order may also be the only means possible by which the government can attempt to prevent the information from being delivered into the wrong hands. If an applicant can satisfy the Patent Office that the invention is for patentable subject material, and that it is novel, useful, and non-obvious, then there is no reason why that applicant should not receive a patent.[181] With the *Chakrabarty* decision that essentially allows anything modified by man to be patentable, subject

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[178] *See* Richard Kevin Zepfel, Note, *Stopping a "Gruesome Parade of Horribles": Criminal Sanctions to Deter Corporate Misuse of Recombinant DNA Technology*, 59 S. CAL. L. REV. 641, 663-65 (1986).

[179] *See* Pamela Hess, *US Not Ready for Bio-war Attack*, UNITED PRESS INT'L, Sept. 27, 1999.

[180] *See* United States v. Progressive, Inc., 467 F. Supp. 990, 994 (W.D. Wis. 1979) (upholding an injunction against the release of information on how to construct a hydrogen bomb).

> The point has also been made that it is only a question of time before other countries will have the hydrogen bomb. That may be true. However, there are times in the course of human history when time itself may be very important. This time factor becomes critical when considering mass annihilation weaponry—witness the failure of Hitler to get his V-1 and V-2 bombs operational quickly enough to materially affect the outcome of World War II.

Id.

[181] *See* 35 U.S.C. §§ 101-03 (1994 & Supp. V 1999).

matter is no longer a barrier to patentability.[182] Utility is seldom a reason for rejecting patents.[183] Novelty should not be a factor if the inventor is the first to invent the subject matter and does not wait past the statutory time limits to file his patent application.[184] Obviousness rejections can be overcome by arguing secondary considerations that show the invention was in fact non-obvious.[185]

Provided that the application then meets the aforementioned requirements for patentability, there is no reason for the inventor to not receive a patent.[186] Without secrecy orders, any invention satisfying that criteria could be patented regardless of how dangerous the new technology may be to society. Secrecy orders therefore allow the Patent Office to analyze the technology for its potential impact on society and to withhold patents for a limited time to inventions that are direct threats to the national security.

It has been argued that the patent system is not the proper place to analyze technology.[187] However, it is the distinct role of the Patent Office to determine whether inventions are new and useful when prosecuting

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[182] The Court in *Diamond v. Chakrabarty*, 447 U.S. 303, 316 (1980), was aware of the potential dangers of biotechnology and stated that:

> [T]he petitioner, with the support of *amicus*, points to grave risks that may be generated by research endeavors such as respondent's. The briefs present a gruesome parade of horribles. Scientists, among them Nobel laureates, are quoted suggesting that genetic research may pose a serious threat to the human race, or, at the very least, that the dangers are far too substantial to permit such research to proceed apace at this time. We are told that genetic research and related technological developments may spread pollution and disease, that it may result in the loss of genetic diversity, and that its practice may tend to depreciate the value of human life. These arguments are forcefully, even passionately presented; they remind us that, at times, human ingenuity seems unable to control fully the forces it creates—that, with Hamlet, it is sometimes better "to bear those ills we have than fly to others that we know not of."

Id. Despite this the Court still gave an extremely broad standard of patentability that included biotechnology. *Id.*

[183] For a discussion on why utility is a minimal threshold to patentability, see *supra* notes 115-19 and accompanying text.

[184] *See* 35 U.S.C. § 102 (explaining the novelty and statutory bars for patents).

[185] *See Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966).

[186] The patent application still needs an enabling disclosure. *See* 35 U.S.C. § 112.

[187] Robert P. Merges, *Intellectual Property in Higher Life Forms: The Patent System and Controversial Technologies*, 47 MD. L. REV. 1051, 1067-68 (1988).

patent applications.[188] Requests for secrecy orders are also originated by agencies outside of the Patent Office,[189] so that the use of these orders does not detract from the Patent Office's fundamental mission.

V. POTENTIAL PROBLEMS WITH USING THE INVENTION SECRECY ACT TO PREVENT THE DISCLOSURE OF INVENTIONS

A. *First Amendment Concerns*

A secrecy order prevents the applicant or anyone with knowledge of the application from disclosing the invention to others.[190] Such a restraint can be argued to have the effect of a prior restraint on an applicant's right to free speech. There is, however, no obligation upon the part of the United States to grant a patent to any individual.[191] Power to grant a patent is given to the Congress in the Constitution.[192] That power is, of course, tempered by the Bill of Rights.

Once a secrecy order is issued on an application, the inventor is directed not to discuss his invention with anyone under the penalty of law.[193] This requirement is a restraint on the inventor's speech. It is not necessarily accurate to qualify that restraint as a "prior restraint," as the inventor was not forced to file a patent and could have simply disclosed his or her invention to the world, without ever consulting the United States government. But once a secrecy order is given, the inventor is prevented from disclosing his or her invention to anyone else for the duration of the order.[194] In this sense the secrecy order has the effect of what is more traditionally thought of as a prior restraint.[195]

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[188] 35 U.S.C. §§101-02.

[189] *See id.* § 181.

[190] *Id.*

[191] *See id.* § 151 (providing that patent will be issued when "it appears that applicant is entitled to patent under the law" and the payment of issue fees is made).

[192] Article I, Section 8 of the Constitution gives Congress the power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings ad Discoveries." U.S. CONST. art. I, § 8, cl. 8.

[193] 35 U.S.C. § 181 (1994 & Supp. V 1999).

[194] *Id.*

[195] *See* Peter Swan, *A Road Map to Understanding Export Controls: National Security in a Changing Global Environment*, 30 AM. BUS. L.J. 607, 633 (1993) (stating that "[l]icensing controls operate prophylatically; they attempt to prevent certain communications of restricted data before they occur").

Surprisingly, there has been relatively little jurisprudence concerning speech when related to national security interests.[196] The Supreme Court first considered national security exceptions to the First Amendment in *Near v. Minnesota*.[197] Chief Justice Hughes stated that "the protection even as to prior restraint is not absolutely unlimited . . . . No one would question but that a government might prevent actual obstruction to its recruiting service or the publication of the sailing dates of transports or the number and location of troops."[198] While this statement was made in dictum, it was the only pronouncement on the issue for the following forty years.

The "Pentagon Papers" case[199] brought the issue of a national security exception to the First Amendment to the forefront. The United States was seeking an injunction to prevent the publication of a classified study on Vietnam policy.[200] The Court, in a six to three decision, opted not to issue an injunction.[201] In his concurring opinion, joined by Justice Black, Justice Douglas stated that "[s]ecrecy in government is fundamentally anti-democratic, perpetuating bureaucratic errors. Open debate and discussion of public issues are vital to the national health."[202] It is important, however, to keep this statement within the context of the preceding paragraph of the opinion where Justice Douglas explained "[t]he dominant purpose of the First Amendment was to prohibit the widespread practice of governmental suppression of embarrassing information."[203] Thus it is easier to understand why Justice Douglas did not find a need for an injunction in this case when he stated that a "debate of large proportions goes on in the Nation over our posture in Vietnam."[204]

Justice Stewart, with whom Justice White joined in concurrence, however, would have allowed a prior restraint for national security reasons but for the fact that in his opinion the disclosure of the documents would not "surely result in direct, immediate, and irreparable damage to our

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[196] For a general overview of jurisprudence related to the national security exception to the First Amendment, see Martin L.C. Feldman, *Why the First Amendment is not Incompatible with National Security Interests: Maintaining a Constitutional Perspective*, HERITAGE FOUND. REP., January 14, 1997.

[197] 283 U.S. 697 (1931).

[198] *Id.* at 716 (citations omitted).

[199] New York Times Co. v. United States, 403 U.S. 713 (1971).

[200] *Id.*

[201] *Id.* at 714.

[202] *Id.* at 724.

[203] *Id.* at 723-24.

[204] *Id.* at 724.

Nation or its people."[205] Justice Stewart was aware of the need for a national security exception when he stated, "the successful conduct of international diplomacy and the maintenance of an effective national defense require both confidentiality and secrecy."[206]

The relevant standard to allow a prior restraint on information based on national security seems to require "direct, immediate, and irreparable damage".[207] What needs clarifying is just what the damage is. If the damage is using the information to the detriment of the United States, then many peacetime secrecy orders may be found unconstitutional, as the threat is not immediate. However, if the damage is simply that the information is released to the public, to be used by anyone at any time, then the results would be immediate and secrecy orders should be upheld as constitutional. This Note argues that the latter position is correct as once the information has been disclosed to the public through a patent, that information cannot be later removed from the public domain. Hence the disclosure of the information is irreparable, and it would be impossible to prevent any damage resulting from the disclosure of the information.[208] Secrecy orders should not be characterized as impermissible prior restraints. However, it is certainly an unsettled point of law as to exactly how far the national security exception to the First Amendment extends.[209]

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[205] *New York Times*, 403 U.S. at 730.

[206] *Id.* at 728.

[207] *Id.* at 703. *See* Sabing H. Lee, *Protecting the Private Inventor Under the Peacetime Provisions of the Invention Secrecy Act*, 12 BERKELEY TECH L.J. 346, 395 (1997); Shinn, *supra,* note 176, at 386-87. *See also* MORTON H. HALPERIN & DANIEL HOFFMAN, FREEDOM V. NATIONAL SECURITY: SECRECY AND SURVEILLANCE 106-109 (1977) (analyzing the opinions in the Pentagon Papers case).

[208] This line of reasoning was followed in *United States v. Progressive, Inc.*, 467 F. Supp. 990 (1979), which applied the test from the Pentagon Papers case to uphold an injunction against a magazine from publishing how to construct a hydrogen bomb. *Id.*

[209] *See* Bruce E. Fein, *Access to Classified Information: Constitutional and Statutory Dimensions*, 26 WM. & MARY L. REV. 805, 823 (1985). The Court has also applied a national security exception in two other instances. In *Snepp v. United States*, the Court held that a former Central Intelligence Agency ("CIA") employee's employment contract requiring pre-publication review of any information relating to the agency to remove classified information was a necessary prior restraint. 444 U.S. 507 (1980) (per curium). Later, the Court, in holding that the revocation of a passport of an individual that was disclosing information about the CIA, stated that "no governmental interest is more compelling than the security of the Nation." Haig v. Agee, 453 U.S. 280, 307 (1981). In a prior but similar case to *Snepp*, the Fourth Circuit also upheld a pre-employment secrecy agreement. United States v. Marchetti, 466 F.2d 1309 (4th Cir.), *cert. denied* 409 U.S. 1063 (1972).

Equally important in the discussion of First Amendment limitations to the ISA is the fact that the Supreme Court has never addressed whether scientific information even constitutes speech for First Amendment purposes. It has been argued that it should be clear that scientific information should enjoy constitutional protection.[210] Others, however, have looked to the effect of the information. Speech that "contributes to human knowledge and sheds light on the consequences of both alternative national policies and personal choices should be fully protected." [211] It may be, though, that some other scientific speech is more economically oriented, such as instructions on how to improve a product. Thus it should not enjoy full protection as pure speech when it becomes more like lesser-protected commercial speech. It could also be argued that technical information may enjoy some protection under the obscenity standard given in *Miller v. California*[212] that "protects works which, taken as a whole, have serious literary, artistic, political or scientific value."[213] The implication of this standard is that speech of scientific value is more important, and more likely to be protected, than unprotected obscene speech. Still others argue that there are a good number of occasions when the need for secrecy outweighs any First Amendment concerns.[214] Whatever the result may be, it is currently unclear exactly how much protection scientific information enjoys under the First Amendment.

There is also an issue of whether a secrecy order should even be considered a speech issue. An inventor, of course, does not have to file for a patent. If the inventor never files an application, then the government is not given an opportunity to issue a secrecy order. Naturally the inventor then will not be able to have a limited monopoly over the

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[210] *See* HAROLD C. RELYEA, SILENCING SCIENCE: NATIONAL SECURITY CONTROLS AND SCIENTIFIC COMMUNICATION 11 (1994).

[211] Funk, *supra* note 77, at 436-37. *See* Harold P. Green, *Constitutional Implications of Federal Restrictions on Scientific Research and Communication*, 60 UMKC L. REV. 619, 643 (1992) (arguing that the degree of protection scientific information should receive under the First Amendment "depends on a case by case balancing of the respective interests"). *See also* Mark A. Lemley & Eugene Volokh, *Freedom of Speech and Injunctions in Intellectual Property Cases*, 48 DUKE L.J. 147, 241 (arguing that restraints on copyright speech are unconstitutional).

[212] 413 U.S. 15 (1973).

[213] *Id.* at 34. *See also* Steven Goldberg, *The Constitutional Status of American Science*, 1979 U. ILL. L.F. 1, 13 (arguing that scientific information should enjoy protection under the obscenity standard because of the inclusion of "scientific value" in the *Miller* test).

[214] *See* John B. Attanasio, Review Essay, *The Genetic Revolution: What Lawyers Don't Know*, 63 N.Y.U. L. REV. 662, 697 (1988); Benjamin S. DuVal, Jr., *The Occasions of Secrecy*, 47 U. PITT. L. REV. 579, 674 (1986).

invention. But if the inventor's primary concern is that the secrecy order abridges his right to free speech, then he can simply disclose the invention to the public and make his speech. However, if the inventor wants to be able to exploit his invention under the protection of a patent, then he needs to bargain with the Patent Office and he or she runs the risk that his invention may be kept secret.

B. *Other Concerns Involved With Using Secrecy Orders to Restrict the Disclosure of Invention*

The threat of a secrecy order being levied upon an invention may also be a disincentive for inventors. Without the ability to see any rewards or profits for their work, experimentation may become cost ineffective.[215] In the alternative, the threat of a secrecy order may encourage an inventor, where possible, to exploit his invention as a trade secret as opposed to file for a patent and disclose the invention to the public. Trade secrets do have certain distinctive advantages when compared to patents:

> First, it is more expensive to acquire and defend a patent than to keep a new technological development protected by trade secret arrangements. Second, in addition to cost considerations, the law of trade secrets is thought to be more successful in safeguarding proprietary information. Third, because approved patent applications are available for public examination, there is a preference for the security that is afforded by trade secrecy. Finally, there are innovations that are simply not patentable.[216]

This problem of course runs contrary to the basic mission of the patent system, which encourages innovation and public disclosure by granting limited in time monopolies on inventions. Without new inventions reaching the public, the ISA would be in effect stifling the

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[215] *See* Amy E. Carroll, *Not Always the Best Medicine: Biotechnology and the Global Impact of U.S. Patent Law*, 44 AM. U. L. REV. 2433, 2476-77 (1995).

> [T]here are huge costs to consider in biotech research. Specifically in the area of biotechnology-based pharmaceuticals, it takes about a quarter of a billion dollars and four to seven years to bring a product to market. Because of these enormous costs, the U.S. biotech industry views the extra insurance of patents as crucial to protect their investments, both domestically and abroad.

Id.

[216] RELYEA, *supra* note 210, at 21-22.

advancement of technology. The Supreme Court in *Chakrabarty* already addressed this when it was hearing arguments as to whether biotechnology was even patentable subject matter. The Court stated that:

> The grant or denial of patents on micro-organisms is not likely to put an end to genetic research or to its attendant risks. The large amount of research that has already occurred when no researcher had sure knowledge that patent protection would be available suggests that legislative or judicial fiat as to patentability will not deter the scientific mind from probing into the unknown any more than Canute could command the tides.[217]

VI. CONCLUSION

The United States Patent Examining System provides a mechanism to take a proactive stance towards the problems of the proliferation of technological information that could become a threat to the national security of the United States. Biotechnology is a relatively novel and rapidly expanding field of technology that has only recently gained acceptance as patentable subject matter. As a recent development, biotechnology is a not a national security priority at least within the context of issuing patents. Yet biotechnology presents several threats that should not be ignored. Scientists are unsure of what the release of genetically modified organisms would do to the environment, so more study is justified. The application of biotechnology to agriculture could be as baneful as it is beneficial, as modified plants could dominate their ecosystems or become ecological pests themselves.[218] In addition, the ever-present threat of biological warfare is only enhanced as scientists are given the means to create more durable and lethal microbes.

The current statutory and regulatory regime is not equipped to fully deal with the problems that biotechnology presents. Current statutes that control the dissemination of scientific information were written in a time before biotechnology had developed as a science. Most of these statutes cannot even contemplate the domestic concerns of biotechnology. Likewise, domestic regulation is divided among a variety of agencies with differing agendas. In addition, most of this regulation does not address the dissemination of the information generated in scientific research. Thus the

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[217] *Diamond v. Chakrabarty*, 447 U.S. 303, 316, 317 (1980).

[218] *See* LEMBKE, *supra* note 37.

current regulatory scheme cannot prevent the information on how to make and use dangerous biotechnology from falling into the wrong hands.

The ISA provides a reasonable solution to the threats of biotechnology that will still allow the science to develop. The statute allows the Patent Office to restrict patents from issue for a limited duration while their threat to national security is evaluated. While there are some constitutional concerns as to the implication of the secrecy order, this process would allow the technology to be evaluated from the start before it has a chance to become a problem. The information would also be evaluated by the agency that would have appropriate resources to fully analyze the problem. In effect, this would give the United States the first chance to develop counter technologies to these threats, such as vaccines, as may be necessary. At the same time, however, biotechnology patents for non-threatening technologies would continue to issue so that the science could continue to evolve.