

# COMMENTS

## THE ENVIRONMENTAL AND PUBLIC HEALTH IMPACTS OF U.S. PATENT LAW: MAKING THE CASE FOR INCORPORATING A PRECAUTIONARY PRINCIPLE

BY  
SHAWN KOLITCH\*

*Decades often pass before scientists attain—and governments recognize—scientific certainty regarding the possible harmful effects of a newly invented technology or activity. Prior to 1970, governments were generally reluctant to regulate activities until harm was proven to a high degree of certainty, and this led to significant damage to the environment and public health. In response, many nations incorporated some version of the precautionary principle—which asserts that mitigating measures either can or must be taken in the face of scientific uncertainty—into their domestic and international environmental laws and policies. A precautionary philosophy is also used by many nations in other areas of the law, including patent law, where statutes frequently exclude potentially harmful inventions from patentability. However, the United States consistently opposes the precautionary principle, and does not take a precautionary approach in either its environmental laws or its patent laws.*

*This comment examines the environmental and public health consequences of U.S. patent law, and argues that incorporating a form of the precautionary principle would be a practical and effective means of mitigating the harm caused by advancing technology in the absence*

---

\* © Shawn Kolitch, 2006. Associate Editor, *Environmental Law*, 2005–2006; Member, *Environmental Law*, 2004–2005; J.D. expected 2006, Northwestern School of Law of Lewis & Clark College; Ph.D. 1996, University of California, Santa Barbara; M.S. 1990, B.S. 1989 *with honors and distinction*, Columbia University. The author would like to thank Professor Joe Miller for suggesting the topic of this comment, and Professors Joe Miller and Chris Wold for their useful substantive and formal suggestions.

*of such a principle. After examining the methods by which various nations exclude potentially harmful inventions from patentability, the author concludes that explicitly limiting the scope of patentable subject matter in U.S. patent law is an appropriate means for removing the patent incentive to develop and produce technologies that are known, or strongly suspected, to produce harmful impacts on the environment or public health. Furthermore, to ensure an objective scientific basis for excluding inventions from patentability, the U.S. Patent and Trademark Office should apply the new limits to patentable subject matter in consultation with other federal agencies, such as the Environmental Protection Agency, the Department of Health and Human Services, and their subagencies.*

I.	INTRODUCTION .....	223
II.	THE IMPACTS OF PATENTED TECHNOLOGY: THREE CASE STUDIES .....	228
	A. Chlorofluorocarbons (CFCs) .....	229
	B. Dichlorodiphenyltrichloroethane (DDT).....	230
	C. Asbestos and Public Health.....	232
III.	PATENTABLE SUBJECT MATTER IN THE UNITED STATES.....	234
	A. Historical Development of U.S. Patent Law.....	234
	B. Modern U.S. Patent Law .....	235
	1. Formal Requirements.....	236
	2. The Substantive Scope of Patentable Subject Matter .....	236
IV.	THE PRECAUTIONARY PRINCIPLE .....	238
	A. History of the Principle .....	238
	B. Strengths of Precaution .....	240
	1. Distinguishing Strong and Weak Principles.....	240
	2. Hybrid Principles.....	242
	C. Scope of the Principle .....	243
V.	PRECAUTIONARY MEASURES IN FOREIGN PATENT LAWS .....	244
	A. Types of Patentability Exclusions.....	244
	B. The Public Health Exclusion.....	246
	C. The Environmental Harm Exclusion.....	246
VI.	INCORPORATING THE PRECAUTIONARY PRINCIPLE INTO U.S. PATENT LAW .....	248
	A. Proposed Method of Incorporating the Principle .....	248
	B. Practical Considerations: How to Draw the Precautionary Line.....	249
	1. Internal USPTO Evaluation.....	250
	2. Purely External Evaluation.....	251
	3. Internal Evaluation with External Consulting.....	251
	C. Policy Considerations: Where to Draw the Precautionary Line .....	252
	1. Banned Substances and the "Ultraweak" Precautionary Principle.....	253
	2. Other Applications of the "Ultraweak" Principle.....	254
	3. Scientific Uncertainty and True Precaution .....	254
VII.	CONCLUSION .....	255

## I. INTRODUCTION

Scientific consensus regarding the environmental and public health impacts of a technological innovation often arrives years, or even decades, after the innovation itself. One well-documented example of this time delay between an innovation and a reliable scientific assessment of its potential impacts is the case of chlorofluorocarbons (CFCs). The United States Patent and Trademark Office (USPTO) granted the first patents on CFCs for use as refrigerants in the early 1930s,<sup>1</sup> and even as late as the 1950s, CFCs were still considered “miracle chemicals.”<sup>2</sup> However, scientists later hypothesized that chlorine radicals from CFCs destroy atmospheric ozone,<sup>3</sup> which absorbs potentially damaging ultraviolet-B radiation (UV-B). Destruction of atmospheric ozone by CFCs leads to a wide range of harmful impacts,<sup>4</sup> including harm to the skin, eyes, and immune systems of humans and animals,<sup>5</sup> decreased photosynthesis and greater susceptibility to disease by terrestrial plants,<sup>6</sup> and a general reduction in productivity of phytoplankton.<sup>7</sup>

Due to these and other effects, in 1990 the United States signed an international treaty banning CFCs from domestic production beginning in 2000,<sup>8</sup> with very limited exceptions for “essential uses.”<sup>9</sup> Other notable examples of patented innovations later proven harmful to the environment and public health include dichlorodiphenyltrichloroethane (DDT), first patented in the United States as a highly promising insecticide in 1943<sup>10</sup> and eventually banned due to unacceptable risks of negative ecological and public health impacts in 1973,<sup>11</sup> and asbestos, first patented in 1828 as an

---

<sup>1</sup> U.S. Patent No. 1,833,847 (filed Feb. 8, 1930) (issued Nov. 24, 1931); U.S. Patent No. 1,886,339 (filed Dec. 31, 1928) (issued Nov. 1, 1932).

<sup>2</sup> Daniel C. Esty, *Environmental Protection in the Information Age*, 79 N.Y.U. L. REV. 115, 132 (2004).

<sup>3</sup> Mario J. Molina & F. Sherwood Rowland, *Stratospheric Sink for Chlorofluoromethanes: Chlorine Atomc-atalsed [sic] Destruction of Ozone*, 249 NATURE 810 (1974).

<sup>4</sup> See generally UNITED NATIONS ENVIRONMENTAL PROGRAMME, ENVIRONMENTAL EFFECTS OF OZONE DEPLETION: 1998 ASSESSMENT, EXECUTIVE SUMMARY [hereinafter UNEP EXECUTIVE SUMMARY], available at <http://sedac.ciesin.org/ozone/docs/UNEP98/UNEP98p2.html>.

<sup>5</sup> *Id.*

<sup>6</sup> *Id.*

<sup>7</sup> *Id.*

<sup>8</sup> Adjustments and Amendment to the Montreal Protocol on Substances that Deplete the Ozone Layer, June 29, 1990, art. 2A, para. 5, 30 I.L.M. 537, 540 [hereinafter Amendment to the Montreal Protocol].

<sup>9</sup> Essential uses are defined roughly as uses necessary for public health and safety. The only currently allowed essential uses of ODSs (Ozone Depleting Substances) in the United States are in the space program, as a propellant for metered dose inhalers, and when necessary for laboratory research. See U.S. Env'tl. Prot. Agency, Ozone Depletion Rules and Regulations, <http://www.epa.gov/ozone/title6/phaseout/mdi/> (last visited Jan. 22, 2006) (listing the current essential use exemptions and describing the requirements for a use to be essential under the Montreal Protocol).

<sup>10</sup> U.S. Patent No. 2,329,074 (filed Mar. 4, 1941) (issued Sept. 7, 1943).

<sup>11</sup> Press Release, U.S. Env'tl. Prot. Agency, DDT Ban Takes Effect (Dec. 31, 1972), <http://www.epa.gov/history/topics/ddt/01.htm> (last visited Jan. 22, 2006).

insulating material in steam engines<sup>12</sup> and ultimately banned from most products in 1989.<sup>13</sup>

In general, the state of scientific knowledge regarding the potential environmental and public health impacts of an invention progresses from scientific *ignorance*, when any harmful impacts of the invention are completely unknown and unsuspected, to scientific *uncertainty*, when harmful impacts are suggested by some scientific evidence, but the scientific community has not yet reached consensus, and finally to scientific *certainty*, when harmful impacts—if any—are well accepted by the scientific community. For example, when CFCs were invented, the scientific community was ignorant of their harmful impacts and initially knew only of the beneficial uses of CFCs as refrigerants.<sup>14</sup> The era of scientific uncertainty began in 1974, when scientists first theorized that CFC emissions could significantly deplete atmospheric ozone.<sup>15</sup> Finally, scientific certainty dawned in the late 1980s, when scientists accepted as conclusive the link between CFC emissions and ozone depletion.<sup>16</sup>

Perhaps surprisingly, USPTO grants patents without considering the state of scientific knowledge regarding an invention's possible harmful impacts; in fact, the agency is required by federal law to do so,<sup>17</sup> because federal law requires only a showing of patentable subject matter, utility, novelty, and nonobviousness.<sup>18</sup> As a result, USPTO routinely grants patents for inventions that are harmful to the environment and public health, as in the cases of CFCs, DDT, and asbestos. For example, USPTO has granted at least seventeen patents for inventions claiming aerosol uses of CFCs since the United States signed the Montreal Protocol in 1990.<sup>19</sup> In this manner, U.S.

---

<sup>12</sup> Chris Obrion, *Asbestos Through the Ages*, ROANOKE TIMES, Oct. 5, 2003, available at [http://www.roanoke.com/roatimes/special\\_sections/asbestos/asbestostimeline10\\_5.pdf](http://www.roanoke.com/roatimes/special_sections/asbestos/asbestostimeline10_5.pdf).

<sup>13</sup> U.S. Evtl. Prot. Agency, Asbestos Ban and Phase Out, <http://www.epa.gov/asbestos/pubs/ban.html> (last visited Jan. 22, 2006).

<sup>14</sup> Indeed, a connection between CFC emissions and atmospheric ozone depletion would have been impossible even in principle in the 1930s since there were no prior CFC emissions and therefore no data to suggest that CFCs emitted near the surface of Earth would persist into the stratosphere.

<sup>15</sup> See generally Molina & Rowland, *supra* note 3.

<sup>16</sup> See, e.g., J. G. Anderson, et al., *Ozone Destruction by Chlorine Radicals Within the Antarctic Vortex: The Spatial and Temporal Evolution of ClO-O3 Anticorrelation Based on in Situ ER-2 Data*, 94 J. GEOPHYS. RES. 11, 465-79 (1989) (finding a conclusive link between chlorine molecules dissociated from CFCs and stratospheric ozone depletion).

<sup>17</sup> Consolidated Patent Laws, 35 U.S.C. §§ 1-376 (2000). Patentable subject matter is broadly defined and does not generally exclude inventions on the basis of their possible future impacts on public health or the environment. See *infra* Part III for a more detailed discussion of our current system of patent laws, including currently excluded subject matter.

<sup>18</sup> 35 U.S.C. §§ 101-103 (2000). In addition, a patent application must meet various formal and procedural requirements. *Id.* § 112.

<sup>19</sup> These patents are all directed to using CFCs as "blowing agents" to produce various types of aerated materials. In order of their date of issue, the patents are U.S. Patent No. 4,960,804 (filed Mar. 30, 1990) (issued Oct. 2, 1990); U.S. Patent No. 4,992,222 (filed Dec. 29, 1988) (issued Feb. 12, 1991); U.S. Patent No. 4,994,217 (filed Dec. 29, 1988) (issued Feb. 19, 1991); U.S. Patent No. 5,001,164 (filed Aug. 19, 1988) (issued Mar. 19, 1991); U.S. Patent No. 5,030,664 (filed Dec. 24, 1990) (issued July 9, 1991); U.S. Patent No. 5,071,881 (filed May 22, 1990) (issued Dec. 10, 1991); U.S. Patent No. 5,086,083 (filed July 2, 1991) (issued Feb. 4, 1992); U.S. Patent No. 5,089,033 (filed Jan. 30, 1991) (issued Feb. 18, 1991); U.S. Patent No. 5,102,923 (filed Jan. 14,

patent law arguably encourages—and certainly fails to discourage—the development of harmful technologies.

Of course, USPTO cannot deny a patent on the basis of an invention's harmful impacts during an era of scientific ignorance of those impacts. In some cases, laws requiring testing and approval of potentially harmful substances may suffice to delay or prevent production and widespread use of the substances until they are proven safe.<sup>20</sup> In other cases of scientific ignorance, where the subject matter of an invention falls beyond the scope of required testing, measuring the invention's environmental and public health impacts may only be possible after the invention is patented and comes into widespread use.<sup>21</sup>

USPTO, however, also issues patents even during eras of both scientific uncertainty and certainty regarding harmful impacts of the proposed invention. This occurs, for example, when a patent application describes an improvement to a previously patented invention,<sup>22</sup> the impacts of which have come under suspicion as harmful in the time since the original patent was issued, or when an invention's harmful impacts are *a priori* apparent (such as a known pollutant or carcinogen put to a novel use). During times of either scientific uncertainty or certainty with respect to an invention's potentially harmful impacts, one can reasonably ask whether granting a patent without regard to those impacts is sound public policy, or whether USPTO should apply a heightened patentability standard.

USPTO encourages research, development, and production of an invention by offering the possibility of a patent for that invention, because a patent essentially provides a temporary monopoly to the inventor, with a term that begins when the patent issues and expires twenty years from the date of application for the patent.<sup>23</sup> More precisely, a patent provides a right

1993) (issued Apr. 7, 1992); U.S. Patent No. 5,140,052 (filed Feb. 3, 1992) (issued Apr. 18, 1992); U.S. Patent No. 5,162,384 (filed Sept. 13, 1991) (issued Nov. 10, 1992); U.S. Patent No. 5,199,962 (filed Feb. 14, 1992) (issued Apr. 6, 1993); U.S. Patent No. 5,250,582 (filed July 23, 1990) (issued Oct. 5, 1993); U.S. Patent No. 5,286,759 (filed Mar. 8, 1991) (issued Feb. 15, 1994); U.S. Patent No. 5,426,126 (filed Dec. 30, 1992) (issued June 20, 1995); U.S. Patent No. 5,605,936 (filed Mar. 28, 1996) (issued Feb. 25, 1997); and U.S. Patent No. 5,693,686 (filed Feb. 10, 1994) (issued Dec. 2, 1997).

<sup>20</sup> For example, the U.S. Food and Drug Administration (FDA) requires an elaborate approval process for all drugs marketed to the public. See U.S. Food and Drug Administration Center for Drug Evaluation and Research, *Drug Approval Application Process*, <http://www.fda.gov/cder/regulatory/applications/Default.htm> (last visited Jan. 22, 2006) (detailing the approval process).

<sup>21</sup> A basic principle of United States patent law is that a patent will not be granted unless the related application is filed within a year of any public disclosure or offer for sale of the invention. Therefore, patenting often precedes or closely follows public use. 35 U.S.C. § 102(b) (2000).

<sup>22</sup> Federal law allows patents for “any new and useful improvement” of a preexisting technology. *Id.* § 101.

<sup>23</sup> This temporary monopoly is subject to several exceptions. First, if the application refers to one or more earlier filed applications, the term begins to run from the earliest filing date of all of the applications to which the current application refers. *Id.* § 154(a)(2) (2002). Second, the term of a patent resulting from an application filed before June 8, 1995 runs for the longer of 17 years from the date of issue of the patent, or 20 years from the date of its application. See ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, *PATENT LAW AND POLICY: CASES AND*

to exclude others from manufacturing, selling, offering for sale, or importing products that contain all the elements of the patented invention.<sup>24</sup> Thus, an inventor or a patent holder is partially motivated to develop patentable technologies by the possibility of a federally granted temporary right to exclude.

In providing such an incentive for the development and production of inventions without regard to their possible harmful impacts, Congress is tacitly relying on the market and on other areas of law, particularly environmental and public health law, to mitigate or prevent any potential resulting harm. However, due to the general insistence of the United States on a showing of actual harm before regulating an allegedly harmful activity,<sup>25</sup> these forces have been ineffective in many cases. This is particularly true during times of scientific uncertainty, when scientists suspect harmful impacts of an invention based only on limited evidence. However, delays in regulatory action often allow production and use of an invention even after scientists reach a state of certainty regarding its harmful effects. During such times of scientific uncertainty and certainty, providing a patent incentive to further develop and produce the invention seems questionable as a matter of public policy.

The precautionary principle's evolution in environmental law is partially a result of the typical lag time between the development of a technological innovation and scientific certainty regarding the consequences of the innovation's production and use. Although the precautionary principle is still evolving and has no universally agreed-upon definition,<sup>26</sup> this principle may be viewed essentially as one of preventing environmental harm in cases where the scientific community has an incomplete understanding of the consequences of a putative environmental threat.

In its "weak" form, the precautionary principle merely permits mitigating actions in the absence of scientific certainty about the environmentally harmful effects of an activity. For example, the Rio Declaration on Environment and Development<sup>27</sup> states that "[w]here there

---

MATERIALS 59 (3rd ed. 2002) (describing this exception). Finally, the term of a patent may be extended due to delays in the examination process attributable to the United States Patent and Trademark Office (USPTO). 35 U.S.C. § 154(b) (2000).

<sup>24</sup> See 35 U.S.C. § 271 (2000), *amended by* Pub. L. No. 108-73, tit. XI(A) § 1101(d), 117 Stat. 2457 (2003) (defining patent infringement).

<sup>25</sup> See J. Wiener & M. Rogers, *Comparing Precaution in the United States and Europe*, 5 J. RISK RESEARCH 317, 317-18 (2002), *available at* [http://www.law.duke.edu/fac/wiener/PP\\_EU\\_US\\_paperJRR2002final.pdf](http://www.law.duke.edu/fac/wiener/PP_EU_US_paperJRR2002final.pdf) (summarizing the U.S. position on the precautionary principle). On the other hand, some local governments within the United States advocate the precautionary principle. See Dept. of the Env't, City and County of San Francisco, *The Precautionary Principle and the City and County of San Francisco* (Mar. 2003), *available at* [http://www.breastcancerfund.org/atf/cf/{DE68F7B2-5F6A-4B57-9794-AFE5D27A3CFF}/PP\\_white\\_paper.pdf](http://www.breastcancerfund.org/atf/cf/{DE68F7B2-5F6A-4B57-9794-AFE5D27A3CFF}/PP_white_paper.pdf) (detailing the reasons San Francisco adopted the precautionary principle).

<sup>26</sup> UNITED NATIONS DEVELOPMENT PROGRAMME, HUMAN DEVELOPMENT REPORT 2001: MAKING NEW TECHNOLOGIES WORK FOR HUMAN DEVELOPMENT 70 (2001), *available at* <http://hdr.undp.org/reports/global/2001/en/> [hereinafter UN HUMAN DEVELOPMENT REPORT] (describing various formulations of the precautionary principle).

<sup>27</sup> United Nations Conference on Environment and Development: Rio Declaration on Environment and Development, June 14, 1992, 31 I.L.M. 874 [hereinafter the Rio Declaration].

are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.”<sup>28</sup> On the other hand, the “strong” precautionary principle requires such measures. For example, the Third International Conference for Protection of the North Sea<sup>29</sup> formulated a commonly cited example of the strong precautionary principle which requires “participants . . . to take action to avoid potentially damaging impacts of substances that are persistent, toxic and liable to bioaccumulate even when there is no scientific evidence to prove a causal link between emissions and effects.”<sup>30</sup>

Despite differences in strength, essentially all versions of the precautionary principle share an important feature—although the principle will not necessarily stop an activity that may have environmentally harmful impacts, it provides that scientific uncertainty should not be used to postpone measures to prevent, mitigate, or reduce the adverse environmental impacts of the activity. In other words, although the potentially harmful activity typically will move forward, the principle provides that certain actions may—or, in the case of strong versions of the principle, must—be undertaken to prevent or mitigate its adverse effects.

If Congress were to incorporate the precautionary principle into U.S. patent law, this would reduce the adverse environmental and public health effects of potentially harmful inventions by removing the patent incentive for their development and production. This “precautionary patentability requirement” would resemble the weak precautionary principle because even if an invention were excluded from patentability on the basis of its potentially harmful impacts, the new requirement would not preclude production of the invention. Rather, the proposed new requirement would simply remove the patent incentive for inventions whose commercial production and use would likely cause harmful environmental or public health effects by using scientific evidence available at the time of the patent application to exclude such inventions from patentable subject matter. However, the new requirement would resemble the strong precautionary principle in that USPTO would be required—rather than simply allowed—to deny a patent if scientific evidence either strongly suggests or proves that use of the invention would have certain harmful effects.

Part II of this comment examines several prominent cases in which widespread use of patented inventions has led to harmful impacts on the environment and public health, and argues that those impacts were not only allowed, but encouraged by the current system of patent laws in this country. Part III gives a brief history of U.S. patent law, focusing on its evolution towards a broader and broader scope of patentable subject matter, and away from evaluation of the impacts of inventions on public welfare. Part IV describes in more detail the origins of the precautionary principle,

---

<sup>28</sup> *Id.* at 879.

<sup>29</sup> *Final Declaration of the Third International Conference on Protection of the North Sea*, Mar. 7-8, 1990, 1 YB INT'L ENVTL. L. 658, 662-73 (1990) [hereinafter the Third North Sea Conference], available at <http://www.dep.no/md/html/conf/declaration/hague.html>.

<sup>30</sup> *Id.* at 661.

and examines the range of embodiments in which the principle is incorporated into domestic and international laws. Part V examines how the laws of various other nations address the patentability of inventions having potentially harmful environmental and public health impacts, and argues that a majority of nations already have effectively incorporated a form of the precautionary principle into their patent laws by selectively excluding such inventions from patentability. Part VI provides specific suggestions for incorporating precautionary exclusions into U.S. patent law, and explains the likely consequences. Finally, Part VII concludes that introduction of a form of the precautionary principle into U.S. patent law would be an appropriate mechanism to mitigate or reduce the harmful environmental and public health impacts of new technologies.

## II. THE IMPACTS OF PATENTED TECHNOLOGY: THREE CASE STUDIES

In practice, many technologies evolve through eras of scientific ignorance, uncertainty, and certainty regarding their potential impacts on the environment and public health. At the same time, new technologies progress through successive generations of improvements and modifications leading to an array of patents issued at different times. This section examines three prominent cases in which USPTO granted patents for inventions related to specific technologies at various times during the evolution of scientific knowledge concerning the impacts of the technology. These are the cases of chlorofluorocarbons (CFCs), dichlorodiphenyltrichloroethane (DDT), and asbestos. In each case, the scientific community ultimately—and universally—came to accept that the technology causes serious harm to the environment and public health. Yet in each case, USPTO granted patents related to the technology not only during the era of scientific ignorance, but also at times of scientific uncertainty and certainty regarding the harm caused by the technology. The three cases discussed here are far from isolated instances. Similar cases include, for example, various other persistent organic pollutants such as polychlorinated biphenyls (PCBs),<sup>31</sup> carcinogenic food and beverage additives such as some FD&C dyes,<sup>32</sup> and mechanical inventions such as the two-stroke internal combustion engine.<sup>33</sup>

---

<sup>31</sup> PCBs were first synthesized in the late nineteenth century. *See, e.g.*, Env'tl. Literacy Council, PCBs, <http://www.envroliteracy.org/article.php/1176.html> (last visited Jan. 22, 2006) (describing the history of PCBs). PCBs were ultimately banned by Congress in 1976 due to their toxic effects. Toxic Substances Control Act, 15 U.S.C. § 2605(e) (1976).

<sup>32</sup> *See, e.g.*, U.S. Food and Drug Admin., *Color Additives Fact Sheet*, <http://www.cfsan.fda.gov/~dms/cos-221.html> (last visited Jan. 22, 2006) (describing the history of various banned food dyes).

<sup>33</sup> Two-stroke engines in snowmobiles and other off-road vehicles are a subject of much current controversy. Although they produce “as much harmful pollution in seven hours as a passenger car driven for 100,000 miles,” these engines are not yet banned domestically on a large scale. *EPA Issues Weak Rule on Snowmobile Emissions After Earful from Graham*, 3 OMB Watcher 19 (2002), available at <http://www.ombwatch.org/article/articleview/1092/1/151>.

*A. Chlorofluorocarbons (CFCs)*

The case of CFCs dramatically illustrates how the patentability of a technology overlaps various states of knowledge with respect to the technology's environmental impacts, and in particular how our patent laws keep the patent incentive in place long after harmful impacts are suspected. Thomas Midgley, Jr. first synthesized CFCs in 1928,<sup>34</sup> and they were introduced in the United States in the early 1930s as an ostensibly safer alternative to sulfur dioxide and ammonia-based refrigerants.<sup>35</sup> USPTO granted the first United States patents on the use of CFCs as refrigerants within a few years of their invention,<sup>36</sup> and in 1941 Midgley received chemistry's highest honor, the Priestley Prize, for his work.<sup>37</sup> The subsequent use of CFCs not only as refrigerants, but also as aerosol propellants, cleaning solvents, and blowing agents<sup>38</sup> led to depletion of stratospheric ozone in the earth's atmosphere, and a plethora of serious environmental and public health consequences.<sup>39</sup> However, scientists did not hypothesize a link between the use of CFCs and stratospheric ozone depletion until 1974,<sup>40</sup> and the scientific community did not accept this link as conclusive until approximately 1987,<sup>41</sup> long after the original CFC patents had expired. Thus, USPTO granted the original CFC patents, and these patents ran to their full terms, during a time of scientific ignorance regarding the harmful effects of CFCs.

Although the seminal CFC patents expired during the era of scientific ignorance with regard to the impacts of CFCs, USPTO continued to grant patents for CFC-related inventions during the subsequent era of scientific uncertainty. This period extended from 1974 through approximately 1987 as scientists gradually accumulated evidence supporting the hypothesis that CFCs were depleting the earth's atmospheric ozone.<sup>42</sup> These years were characterized both by controversy between environmentalists and representatives of the CFC industry (with environmentalists asserting a link between CFCs and atmospheric ozone depletion, and the CFC industry

---

<sup>34</sup> THEO COLBORN ET AL., *OUR STOLEN FUTURE: ARE WE THREATENING OUR FERTILITY, INTELLIGENCE, AND SURVIVAL? A SCIENTIFIC DETECTIVE STORY* 243 (1996).

<sup>35</sup> Glenn B. Raiczuk, *Future Development, Montreal Protocol on Substances That Deplete the Ozone Layer: Conference Calling for Accelerated Phase-Out of Ozone-Depleting Chemicals Is Planned for 1992*, 5 TEMP. INT'L & COMP. L.J. 363, 365-66 (1992).

<sup>36</sup> U.S. Patent No. 1,833,847 (filed Feb. 8, 1930) (issued Nov. 24, 1931); U.S. Patent No. 1,886,339 (filed Dec. 31, 1928) (issued Nov. 1, 1932).

<sup>37</sup> COLBORN ET AL., *supra* note 34, at 243.

<sup>38</sup> See UNITED NATIONS ENVIRONMENT PROGRAMME, *MONTREAL PROTOCOL ON SUBSTANCES THAT DEplete THE OZONE LAYER: 1991 ASSESSMENT REPORT OF THE TECHNOLOGY AND ECONOMIC ASSESSMENT PANEL, CHAPTER TWO: CONTROLLED SUBSTANCES* (1991), available at <http://www.ciesin.org/docs/011-494/011-494.html> (describing the various uses of CFCs).

<sup>39</sup> See UNEP EXECUTIVE SUMMARY, *supra* note 4 (summarizing the effects of ozone depletion on human and animal health, terrestrial ecosystems, aquatic ecosystems, biogeochemical cycles, air quality, and materials).

<sup>40</sup> Molina & Rowland, *supra* note 3.

<sup>41</sup> See Anderson, *supra* note 16 (finding a conclusive link between chlorine molecules dissociated from CFCs and stratospheric ozone depletion).

<sup>42</sup> RICHARD E. BENEDICK, *OZONE DIPLOMACY* 11-22 (2d ed. 1998).

consistently denying any such link),<sup>43</sup> and by USPTO granting several new patents for CFC-related products.<sup>44</sup> In other words, despite increasing evidence that CFCs were linked to atmospheric ozone depletion, USPTO continued to grant patents for inventions using aerosol forms of CFCs, as required by U.S. patent law.<sup>45</sup>

Most surprisingly, USPTO granted CFC patents even in the post-1987 era of scientific certainty regarding the impacts of CFCs. After scientists reached consensus as to the effects of CFCs on the ozone layer in the mid-1980s,<sup>46</sup> twenty-three primary CFC-producing nations, including the United States, signed the Montreal Protocol on Substances that Deplete the Ozone Layer<sup>47</sup> in an effort to reduce CFC concentrations in the atmosphere. However, even after the United States signed the Montreal Protocol and its 1990 amendment requiring the phase out of CFC production by the year 2000<sup>48</sup> (thus clearly recognizing scientific certainty about the destructive effects of CFCs on the ozone layer), USPTO granted at least seventeen patents specifying aerosol uses of CFCs.<sup>49</sup> Only in the years since 1997 has USPTO apparently stopped issuing patents for inventions likely to lead to atmospheric release of CFCs.<sup>50</sup> This change, however, did not result from restrictions on CFC patentability, but rather because there was no remaining market incentive to procure a U.S. patent for an invention whose domestic production had been essentially completely banned. In other words, USPTO did not take any action to stop granting CFC patents; inventors simply stopped applying when the market incentive disappeared.

### *B. Dichlorodiphenyltrichloroethane (DDT)*

The case of DDT further illustrates how USPTO grants patents on an environmentally toxic substance even after scientists reach consensus regarding the harmful effects of the substance. DDT is an organic chemical compound that was first synthesized in 1874.<sup>51</sup> It was introduced as a highly

---

<sup>43</sup> *Id.* at 12.

<sup>44</sup> *See, e.g.*, U.S. Patent No. 4,174,295 (filed Aug. 9, 1977) (issued Nov. 13, 1979) (claiming an aerosol propellant including 40–95% CFCs by weight); U.S. Patent No. 4,407,982 (filed Feb. 3, 1982) (issued Oct. 4, 1983) (claiming a method of producing polyurethane foam including use of a CFC blowing agent); U.S. Patent No. 4,508,631 (filed Aug. 2, 1983) (issued Apr. 2, 1985) (claiming a dehydrating refrigeration fluid including a CFC refrigerant); U.S. Patent No. 4,518,557 (filed May 18, 1981) (issued May 21, 1985) (claiming a method of producing a polymer plastic using a CFC blowing agent).

<sup>45</sup> 35 U.S.C. § 102 (2002).

<sup>46</sup> *See* BENEDICK, *supra* note 42, at 14–15 (documenting the extensive multi-national cooperative effort that identified the harmful effects of CFCs on the ozone layer).

<sup>47</sup> Montreal Protocol on Substances That Deplete the Ozone Layer, *opened for signature* Sept. 16, 1987, S. Treaty Doc. No. 100-10, 26 I.L.M. 1550 (1987) (entered into force Jan. 1, 1989).

<sup>48</sup> *See* Amendment to the Montreal Protocol, *supra* note 8, at 539 (reducing produced substances to zero).

<sup>49</sup> *See supra* note 19 (listing the 17 patents).

<sup>50</sup> This conclusion is based on the author's personal search of publicly available USPTO records.

<sup>51</sup> DDT, A REVIEW OF SCIENTIFIC AND ECONOMIC ASPECTS OF THE DECISION TO BAN ITS USE AS A PESTICIDE (1975), *available at* <http://www.epa.gov/history/topics/ddt/02.htm> (report by EPA to

promising insecticide—indeed it was heralded as a “miraculous pesticide”—in 1938.<sup>52</sup> USPTO granted the first U.S. DDT patents in 1943<sup>53</sup> during a period of scientific ignorance regarding its toxic effects. DDT subsequently was successfully used to combat epidemics of insect-borne illnesses such as typhus and malaria. For instance, “an incipient epidemic of typhus in Naples, Italy was thwarted by spraying all the civilians and the occupying allied troops with DDT.”<sup>54</sup> Partly as a result of the widely recognized role of DDT in preventing such epidemics, Paul Muller, the Swiss chemist who first synthesized the substance, received the Nobel Prize for medicine in 1948.<sup>55</sup>

However, despite the beneficial uses of DDT as an airborne insecticide, questions about its deleterious effects quickly gave rise to an era of scientific uncertainty. Specifically, scientists began voicing reservations about DDT “almost as soon as it first went into use”<sup>56</sup> due to the knowledge that it was persistent in soil for a period of years, and could be magnified in the food chain.<sup>57</sup> The possible environmental and public health problems associated with DDT became widely known to the public in 1962 with the publication of the popular book *Silent Spring*,<sup>58</sup> which detailed numerous harmful properties of DDT, including its effects on bird reproduction,<sup>59</sup> its toxicity to fish,<sup>60</sup> and its effects as a carcinogen and producer of blood disorders in humans.<sup>61</sup>

More recently, scientists have classified DDT as a member of the larger group of “persistent organic pollutants”<sup>62</sup> (POPs), which have a number of known adverse environmental and human health effects. These include effects on various species of birds, such as sterility, altered nesting patterns, population declines, and severe birth deformities;<sup>63</sup> reproductive failures, genital abnormalities, and resulting population declines in mink, whales, alligators, and other wildlife species;<sup>64</sup> and genital abnormalities and decreased fertility among humans.<sup>65</sup>

The end of the era of scientific ignorance regarding the harmful effects of DDT—and even scientific uncertainty eventually giving rise to scientific

---

U.S. House of Representatives).

<sup>52</sup> COLBORN ET AL., *supra* note 34, at 68.

<sup>53</sup> U.S. Patent No. 2,329,074 (filed Mar. 4, 1941) (issued Sept. 7, 1943).

<sup>54</sup> United Nations Environment Programme, History of POPs Discovery, Use and Ban, <http://pops.gpa.unep.org/04histo.htm> (last visited Jan. 22, 2006).

<sup>55</sup> COLBORN ET AL., *supra* note 34, at 69.

<sup>56</sup> United Nations Environment Programme, History of POPs Discovery, Use and Ban, *supra* note 54.

<sup>57</sup> *Id.*

<sup>58</sup> RACHEL CARSON, *SILENT SPRING* (1962).

<sup>59</sup> *Id.* at 108–09 (documenting dramatic drop in bird population due to DDT).

<sup>60</sup> *Id.* at 143–44 (citing example of toxic flow killing fish for vast expanses of river).

<sup>61</sup> *Id.* at 225–28 (showing rise in human leukemia associated with various toxic substances).

<sup>62</sup> See Elizabeth B. Baldwin, *Reclaiming Our Future: International Efforts to Eliminate the Threat of Persistent Organic Pollutants*, 20 HASTINGS INT’L & COMP. L. REV. 855, 856 (1997) (describing compounds classified as POPs and their global effects).

<sup>63</sup> COLBORN ET AL., *supra* note 34, at 2 (observing sudden and drastic changes in mating behaviors of bald eagles).

<sup>64</sup> *Id.* at 3, 6, 12, 14, 144–47.

<sup>65</sup> *Id.* at 172–79, 232–34.

certainty—had no effect on the patentability of DDT. In the late 1960s, studies commissioned by the United States Department of Agriculture (USDA) confirmed that DDT not only had numerous harmful impacts, but also persisted residually in the environment.<sup>66</sup> As a result, USDA cancelled the registration of many uses of DDT in 1969, effectively outlawing those uses of the chemical.<sup>67</sup> The United States Environmental Protection Agency (EPA) banned the use of DDT domestically in 1973 due to its negative ecological and public health impacts,<sup>68</sup> subject to a small number of public health exceptions.<sup>69</sup> However, USPTO regularly granted patents for inventions related to insecticidal use of DDT during each of the eras of scientific ignorance, uncertainty, and certainty regarding the harmful effects of the chemical.<sup>70</sup> Moreover, USPTO would be legally compelled to grant such a patent today if an inventor met all of the statutory requirements of our current patent laws.<sup>71</sup>

### C. Asbestos and Public Health

The patenting of asbestos-related inventions provides a compelling example of a substance for which the state of knowledge regarding its effects on public health—as opposed to the environment—has had no impact on its patentability under U.S. law. The term “asbestos” refers to any of six naturally occurring minerals: chrysotile, amosite, crocidolite, tremolite, anthophyllite, and actinolite.<sup>72</sup> Processed asbestos fibers are very strong and have excellent insulating properties, and for these reasons, asbestos has been used for centuries in many products including floor tiles, plaster, wallboard, pipe insulation, and roof shingles, among many others.<sup>73</sup>

---

<sup>66</sup> NORTH AMERICAN COMMISSION FOR ENVIRONMENTAL COOPERATION, HISTORY OF DDT IN NORTH AMERICA TO 1997, at 2 [hereinafter HISTORY OF DDT], available at [http://www.cec.org/files/pdf/POLLUTANTS/HistoryDDTe\\_EN.PDF](http://www.cec.org/files/pdf/POLLUTANTS/HistoryDDTe_EN.PDF).

<sup>67</sup> *Id.*

<sup>68</sup> Press Release, U.S. Env'tl. Prot. Agency, *supra* note 11.

<sup>69</sup> These exceptions include “[p]ublic health, quarantine, and a few minor crop uses . . . as well as export of the material.” *Id.* Export of DDT is permitted because DDT is still considered the best way to prevent the spread of malaria in some developing nations, despite its adverse effects. HISTORY OF DDT, *supra* note 66, at 2, 7–8.

<sup>70</sup> See, e.g., U.S. Patent No. 2,329,074 (filed Mar. 4, 1941) (issued Sept. 7, 1943) (the original DDT patent); U.S. Patent No. 3,400,093 (filed Mar. 11, 1966) (issued Sept. 3, 1968) (claiming an insecticide solution comprising DDT); U.S. Patent No. 4,751,082 (filed Aug. 20, 1986) (issued June 14, 1988) (claiming an insecticide comprising a combination of DDT and a fungus). Note that in contrast to the case of CFCs, the export market for DDT has provided a production incentive extending beyond the final ban on domestic use of the chemical.

<sup>71</sup> Although DDT is not currently manufactured in the United States, its manufacture and export are in fact not prohibited by law, presenting a possible market incentive to further develop products related to its pesticidal use in other nations. See HISTORY OF DDT, *supra* note 66, at 2 (noting that Congress has not yet acted to prohibit domestic production of DDT).

<sup>72</sup> See WIS. DEPT OF NATURAL RES., ASBESTOS: HISTORY AND USES, <http://www.dnr.state.wi.us/org/aw/air/reg/asbestos/asbes3.htm> (last visited Jan. 21, 2006) (defining “asbestos” and relating some of its useful properties).

<sup>73</sup> See U.S. Env'tl. Prot. Agency, Where Can Asbestos Be Found?, <http://www.epa.gov/asbestos/pubs/asbuses.pdf> (last visited Jan. 22, 2006) (listing several dozen categories of products in which asbestos is commonly found).

Due to its fire-resistant nature, asbestos has been used perhaps most commonly in building materials, fireproof clothing, automobile brake linings, and the like. Unfortunately, however, asbestos is carcinogenic, and human exposure to its dust—which is particularly likely for workers involved in cutting or otherwise resizing it—can lead to a host of health hazards including lung cancer, mesothelioma, and other forms of cancer.<sup>74</sup>

Asbestos has a long and well-documented history of producing human illness among those who are exposed to the substance. For example, factory inspectors first noticed the health hazards of breathing asbestos particles at least as early as 1898,<sup>75</sup> and others may have recorded their observations of the harmful health effects of asbestos as early as the time of Christ.<sup>76</sup> This knowledge grew through medical research and other studies, until asbestosis—a scarring of the lungs that can lead to breathing problems and heart failure, and which is the most common asbestos-related affliction—“was by 1935 widely recognized as a mortal threat affecting a large fraction of those who had regularly worked with the material.”<sup>77</sup> In 1952, an international panel of lung cancer experts, chaired by an American doctor affiliated with the U.S. National Cancer Institute, convened in Leuven, Belgium, to discuss recent worldwide increases in the rate of lung cancer.<sup>78</sup> In 1953, the panel published a report that unequivocally acknowledged that asbestos was carcinogenic.<sup>79</sup> On July 12, 1989, EPA formally banned most products containing asbestos.<sup>80</sup> Although the EPA ban was partially reversed by the Fifth Circuit Court of Appeals,<sup>81</sup> the reversal was for legal rather than scientific reasons,<sup>82</sup> and many asbestos-containing products remain banned domestically on the basis of their harmful effects on human health.

Despite the evolving state of scientific understanding about the harmful effects of asbestos on human health, USPTO has granted patents for asbestos-containing products since the early nineteenth century,<sup>83</sup> including many in the years since the 1989 EPA ban.<sup>84</sup> In fact, the U.S. Department of Health and Human Services (DHHS) estimates that “patents have been

<sup>74</sup> BARRY I. CASTLEMAN, ASBESTOS: MEDICAL AND LEGAL ASPECTS 90–100 (1984).

<sup>75</sup> See THE PRECAUTIONARY PRINCIPLE IN THE 20TH CENTURY: LATE LESSONS FROM EARLY WARNINGS I (Poul Harremoës et al. eds., 2002) (noting that although a factory inspector in the United Kingdom observed the harmful effects of white asbestos dust on factory workers in 1898, the U.K. government only banned the substance one hundred years later, resulting in hundreds of thousands of foreseeable deaths).

<sup>76</sup> CASTLEMAN, *supra* note 74, at 1.

<sup>77</sup> *Id.* at 31.

<sup>78</sup> *Id.* at 68.

<sup>79</sup> *Id.*

<sup>80</sup> U.S. Envtl. Prot. Agency, Asbestos Ban and Phase Out, *supra* note 13.

<sup>81</sup> Corrosion Proof Fittings v. U.S. Envtl. Prot. Agency, 947 F.2d 1201, 1230 (5th Cir. 1991).

<sup>82</sup> See *id.* at 1229 (describing EPA’s failure to consider Congressionally-mandated alternatives to an outright ban as the basis for the Fifth Circuit’s decision partially reversing the ban).

<sup>83</sup> See Obron, *supra* note 12 (describing the first U.S. patent for an asbestos-containing product, issued in 1828).

<sup>84</sup> See, e.g., U.S. Patent No. 6,642,164 (filed Nov. 21, 2001) (issued Nov. 4, 2003) (claiming a frost-resistant insulating building material having asbestos as a possible component); U.S. Patent No. 4,546,024 (filed June 24, 1982) (issued Oct. 8, 1985) (claiming load-bearing horizontal tiles that may be constructed from asbestos).

issued for more than 5,000 different asbestos-containing products.”<sup>85</sup> In other words, although the era of scientific certainty with respect to the harmful public health impacts of many asbestos-containing products began with the 1953 Leuven report (arguably even sooner), and despite EPA’s attempts to ban most such products, USPTO has continued to grant U.S. patents for asbestos-containing inventions essentially up to the present day. Thus, the case of asbestos illustrates—in a manner similar to the cases of CFCs and DDT—an apparent disconnect between scientific evidence indicating potentially harmful effects of a substance, domestic and international attempts to ban such substances, and the scope of patentable subject matter in this country.

### III. PATENTABLE SUBJECT MATTER IN THE UNITED STATES

#### *A. Historical Development of U.S. Patent Law*

The concept of a patent—essentially providing a temporary right to exclude others from manufacturing, selling, or importing a proprietary invention—was apparently first set forth in writing in the fourth century B.C. by Aristotle, who attributed the idea to Hippodamus.<sup>86</sup> However, Renaissance-era Venice provides the first known regulated system of granting patents. The Venetian Senate’s 1474 Act<sup>87</sup> includes

most of the essential features of a modern patent statute. It defines its coverage (“devices”); provides for registration with a specific administrative agency; requires inventions to be “new and useful,” “reduced to perfection,” and “not previously made in this Commonwealth”; specifies a fixed term of ten years; and sets forth a procedure to determine infringement, as well as a remedy.<sup>88</sup>

Notably for purposes of this comment, the 1474 Act did not provide any statutory exclusions to patentability due to policy considerations such as an invention’s potential harm to public health, national security, or the environment. Many nations—although not the United States—have adopted such exclusions in their modern patent statutes.<sup>89</sup>

American patent law probably has its statutory roots in the 1474 Act, which likely spread through European trade routes to reach England by the sixteenth century.<sup>90</sup> The new concept ultimately resulted in the English Statute of Monopolies, passed by Parliament in 1623 to grant patents for the “sole working or making of any manner of new manufacture” to “the true

---

<sup>85</sup> Genesee County, N.Y., *Asbestos Exposure*, <http://www.co.genesee.ny.us/frameset.html?/dpt/publichealth/chasbestos090403.html&1> (last visited Jan. 22, 2006); see also Nat’l Cancer Inst., *Asbestos Exposure: Questions and Answers*, <http://www.cancer.gov/cancertopics/factsheet/Risk/asbestos> (last visited Jan. 22, 2006) (describing asbestos-containing products manufactured both historically and currently).

<sup>86</sup> MERGES & DUFFY, *supra* note 23, at 1.

<sup>87</sup> *Id.* at 3.

<sup>88</sup> *Id.* at 4.

<sup>89</sup> See *infra* Part V.

<sup>90</sup> MERGES & DUFFY, *supra* note 23, at 4.

and first inventor.”<sup>91</sup> In the United States, the notion of patent protection found its way into the Constitution, which authorizes Congress to “promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.”<sup>92</sup> The first Congress used this power to create both the United States patent and copyright systems, passing seminal versions of the United States Patent Act<sup>93</sup> and the United States Copyright Act in 1790.<sup>94</sup>

The Patent Act of 1790 included the patentability requirement that any application for a patent be examined and that “the Secretary of State, the Secretary for the department of war, and the Attorney General, or any two of them . . . shall deem the invention or discovery *sufficiently useful and important*.”<sup>95</sup> This process of granting patents based on examination, rather than mere registration, “was not received with favor by either inventors or those required to implement it.”<sup>96</sup> When Congress repealed the Patent Act of 1790 and replaced it with the Patent Act of 1793, it dropped the examination requirement from the Act<sup>97</sup> and reverted to “a patent system based not on examination but on registration, a system that was closely akin to its British counterpart.”<sup>98</sup> In 1836, however, Congress passed the third United States Patent Act and reinstated both a system of examination—although now conducted by professional Examiners—and the “sufficiently useful and important” requirement.<sup>99</sup> Although Congress has altered the requirements for obtaining a patent several times since 1836, the basic system of patent examination by professional Examiners—whose job it is to check that these requirements are met—remains intact.

### *B. Modern U.S. Patent Law*

United States patent law operates by granting to inventors the temporary right to exclude others within the United States from making, selling, or offering for sale the patented invention, and from importing it into the United States.<sup>100</sup> A party who violates these prohibitions is said to have infringed the patent and is subject to civil penalties including injunctive relief, damages, and attorney fees.<sup>101</sup> Currently, this right to exclude generally extends from the date of issuance of the patent to a date twenty

---

<sup>91</sup> English Statute of Monopolies of 1623, 21 Jac. 1, c. 3, *reprinted in* DONALD S. CHISUM, CHISUM ON PATENTS app. 8-3 (perm. ed., 2005). *See also* J.H. BAKER, AN INTRODUCTION TO ENGLISH LEGAL HISTORY 378–81 (2d ed. 1979) (describing the history of English patent law).

<sup>92</sup> U.S. CONST. art. I, § 8, cl. 8.

<sup>93</sup> Patent Act of 1790, ch. 8, 1 Stat. 109 (1790).

<sup>94</sup> Copyright Act of 1790, ch. 15, 1 Stat. 124 (1790).

<sup>95</sup> Patent Act of 1790 § 1, *reprinted in* EDWARD C. WALTERSCHEID, TO PROMOTE THE PROGRESS OF USEFUL ARTS: AMERICAN PATENT LAW AND ADMINISTRATION, 1798–1836, at 463–68 (1998) (emphasis added).

<sup>96</sup> WALTERSCHEID, *supra* note 95, at 145.

<sup>97</sup> Patent Act of 1793, ch. 11, 1 Stat. 318 (1793) *reprinted in* WALTERSCHEID, *supra* note 95, at 479–84.

<sup>98</sup> WALTERSCHEID, *supra* note 95, at 145.

<sup>99</sup> Patent Act of 1836 § 7, *reprinted in* WALTERSCHEID, *supra* note 95, at 500–01.

<sup>100</sup> 35 U.S.C. § 271 (2000).

<sup>101</sup> *Id.* §§ 281–285.

years from the date of filing the patent application, with—for present purposes—some relatively minor exceptions.<sup>102</sup> An inventor must pass several formal and substantive hurdles to obtain a patent, and every patent application is evaluated by one or more professional patent Examiners employed by USPTO to check that these requirements are properly met.<sup>103</sup>

### 1. *Formal Requirements*

The formal requirements for a patent include submission of a detailed specification (often referred to as a disclosure) of the invention containing:

[A] written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor for carrying out his invention.<sup>104</sup>

Thus, every granted patent must describe the patented invention in enough detail that others in the same field of endeavor could recreate the invention and thus have the opportunity to refine and improve it. This is one of the ways in which U.S. patent law seeks to ensure technological progress in exchange for granting the right to exclude others from using, producing, selling, or importing an invention. Furthermore, a patent application must include at least one patentable “claim” defining the subject matter of the invention and supported by the language of the written disclosure.<sup>105</sup> Finally, USPTO imposes numerous formal and stylistic requirements upon patent applications that are not of particular concern here.<sup>106</sup>

### 2. *The Substantive Scope of Patentable Subject Matter*

In addition to the aforementioned formal issues, the patent code imposes four substantive requirements to obtain a patent: utility, novelty, nonobviousness, and—most importantly here—a requirement that the invention fall within the confines of patentable subject matter as defined both by statute and the common law.<sup>107</sup> Patentable subject matter is broadly defined by statute: “Whoever 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.”<sup>108</sup> Of course, once Congress has

---

<sup>102</sup> *Id.* § 154 (a)(2). For an explanation of the exceptions to the standard patent term, see *supra* note 23 and accompanying text.

<sup>103</sup> *Id.* § 131.

<sup>104</sup> *Id.* § 112.

<sup>105</sup> *Id.*

<sup>106</sup> See, e.g., *id.* §§ 113, 115, 119 (requiring at least one drawing—if necessary for understanding, an oath of originality by the inventor, and a statement claiming priority to any earlier filed applications).

<sup>107</sup> *Id.* §§ 101–103.

<sup>108</sup> *Id.* § 101.

spoken, it is the “province and duty of the judicial department to say what the law is,”<sup>109</sup> so that the interpretation of this standard has been developed at common law. As a result, patentable subject matter specifically excludes laws of nature, physical phenomena, abstract ideas, and naturally occurring substances that have not been purified or otherwise refined by the inventor.<sup>110</sup> Thus, for example, a physicist may not patent a newly discovered theory, nor may a geologist patent a newly discovered mineral.<sup>111</sup> Furthermore, for reasons of national security, Congress has acted to exclude from patentability “any invention or discovery which is useful solely in the utilization of special nuclear material or atomic energy in an atomic weapon.”<sup>112</sup>

Aside from the specific and limited exclusions to patentable subject matter described above, the courts have given only limited attention to the more general question of excluding an invention because of its possible negative impacts upon society, under what is sometimes called the doctrine of “beneficial utility.”<sup>113</sup> This doctrine dates back to 1817, when the court in *Lowell v. Lewis*<sup>114</sup> summarized the 19th century view of beneficial utility in stating that “the law requires . . . the invention should not be frivolous or injurious to the well-being, good policy, or sound morals of society.”<sup>115</sup> More recently, however, in an opinion upholding patentability of an invention which had the effect of misleading consumers as to the source of the purchased product,<sup>116</sup> the Federal Circuit noted that “the principle that inventions are invalid if they are principally designed to serve immoral or illegal purposes has not been applied broadly in recent years.”<sup>117</sup> *Whistler Corp. v. Autotronics* demonstrates this laissez-faire treatment of inventions designed to facilitate breaking the law.<sup>118</sup> In that case, the court enforced a patent for radar detectors designed to help motorists avoid speeding tickets and stated that the court “cannot and should not substitute its own views in place of those of . . . the several legislatures, or the Congress.”<sup>119</sup> In other words, the courts have, at least in recent decades, declined to carve out a

---

<sup>109</sup> *Marbury v. Madison*, 5 U.S. (1 Cranch) 137, 177 (1803).

<sup>110</sup> See, e.g., *O'Reilly v. Morse*, 56 U.S. 62, 119–20 (1853) (holding unpatentable the abstract idea of using electromagnetism to produce written characters at a distance); *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95, 103 (S.D.N.Y. 1911) (finding a purified form of naturally occurring adrenaline salt patentable but suggesting that it would be unpatentable if the inactive organic substances in the naturally occurring salt had not been removed from the patented product).

<sup>111</sup> The distinction between an abstract idea and an invented process is not clearly defined, and has been shifting towards allowing greater patentability in recent years. For example, computer programs and business methods are currently both patentable if they produce a “useful, concrete, and tangible result.” *State St. Bank & Trust Co. v. Signature Fin. Group, Inc.*, 149 F.3d 1368, 1373 (Fed. Cir. 1998).

<sup>112</sup> 42 U.S.C. § 2181(a) (2000).

<sup>113</sup> See generally MERGES & DUFFY, *supra* note 23, at 216–28 (defining and describing the history and current status of the doctrine).

<sup>114</sup> 15 F. Cas. 1018 (C.C.D. Mass. 1817) (No. 8568).

<sup>115</sup> *Id.* at 1019.

<sup>116</sup> *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1367 (Fed. Cir. 1999).

<sup>117</sup> *Id.* at 1366–67.

<sup>118</sup> 14 U.S.P.Q.2d 1885 (N.D. Tex. 1988).

<sup>119</sup> *Id.* at 1886.

moral or legal exclusion to the broad standard of patentable subject matter laid out in 35 U.S.C. section 101, instead leaving this task to Congress.

In fact, the courts have progressively broadened the definition of patentable subject matter in the United States, culminating with the Supreme Court's statement in 1980—based on the Committee Reports accompanying the 1952 Patent Act<sup>120</sup>—that “anything under the sun that is made by man” should be patentable.<sup>121</sup> In light of this statement and the holding of *Whistler*, no precautionary statutory or common law exclusions related to legality, public health, or the environment are currently incorporated into the bounds of patentable subject matter in this country.<sup>122</sup> Thus, USPTO routinely grants patents for inventions that have unforeseen (and in many instances, suspected or even known) harmful impacts on public health and the environment, and in fact is required by law to do so.<sup>123</sup>

#### IV. THE PRECAUTIONARY PRINCIPLE

##### *A. History of the Principle*

If perfect scientific understanding is a prerequisite for implementing legal measures to deter environmentally harmful impacts of new technologies or activities, then preventative measures often will arrive well after the harmful impacts have begun to occur. This fact gave rise to the precautionary principle in environmental law, which rejects the notion that only unequivocal scientific proof of environmental harm is sufficient to set limits on public and corporate behavior that may affect the environment.<sup>124</sup> Instead, the precautionary principle generally emphasizes the following factors:

- (1) the vulnerability of the environment;
- (2) the limitations of science to accurately predict threats to the environment, and the measures required to prevent such threats;

---

<sup>120</sup> 1952 Patent Act, Pub. L. No. 82-593, 66 Stat. 792 (1952); *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

<sup>121</sup> *Chakrabarty*, 447 U.S. at 309.

<sup>122</sup> However, Congress has recently passed a single morality-based statutory exclusion to prevent patenting of human clones: “None of the funds appropriated or otherwise made available under this Act may be used to issue patents on claims directed to or encompassing a human organism.” Consolidated Appropriations Act, Pub. L. No. 108-199, § 634, 118 Stat. 3, 101 (2004). Furthermore, as previously noted, Congress has barred certain nuclear materials from patentability for national security reasons. 42 U.S.C. § 2181(a) (2000); *see supra* text accompanying note 112.

<sup>123</sup> 35 U.S.C. § 102 states that “A person *shall* be entitled to a patent unless—” before stating the novelty requirement. 35 U.S.C. § 102 (2000) (emphasis added).

<sup>124</sup> William C.G. Burns & Mark Simmonds, Precautionary Principle Guidelines: Progress Report 3 (Oct. 23, 2004), *available at* [http://www.institute.redlands.edu/p3/ACCOBAMSPP\[1\].doc](http://www.institute.redlands.edu/p3/ACCOBAMSPP[1].doc).

- (3) the availability of alternatives (both methods of production and products) which permit the termination or minimization of inputs into the environment; and
- (4) the need for long-term, holistic economic considerations, accounting for, among other things, environmental degradation and the costs of waste treatment.<sup>125</sup>

In other words, the precautionary principle deemphasizes traditional, purely economic considerations in favor of environmental concerns by 1) recognizing that scientific uncertainty about the possible impacts of an activity may not justify ignoring those impacts when setting government policy, and 2) including the potential long-term expenses of environmental degradation when determining the cost of mitigating measures.

Although policymakers have recently started using the term “precautionary principle” in the public arena, the precautionary concept has ancient roots. For example, the Hippocratic Oath, generally attributed to the Greek physician Hippocrates *circa* 400 B.C.E.,<sup>126</sup> includes the dictum to “abstain from whatever is deleterious and mischievous.”<sup>127</sup> Legal systems in other nations have incorporated the legal precautionary principle since at least the late 1960s, when Sweden introduced the principle into its Environmental Protection Act of 1969.<sup>128</sup> Since an international agreement first explicitly incorporated the precautionary principle in 1987,<sup>129</sup> almost all environmental protection and preservation treaties and policy documents, as well as various federal environmental laws and state regulations, have incorporated the precautionary principle in one form or another.<sup>130</sup> However, the United States government generally opposes the principle, and waits for evidence of actual harm before regulating an activity.<sup>131</sup> The

---

<sup>125</sup> Ellen Hey, *The Precautionary Concept in Environmental Policy and Law: Institutionalizing Caution*, 4 GEO. INT'L ENVTL. L. REV. 303, 308 (1992).

<sup>126</sup> See, e.g., Hippocrates of Chios, <http://www-groups.dcs.st-and.ac.uk/~history/Mathematicians/Hippocrates.html> (last visited Jan. 22, 2006) (giving a brief biography of Hippocrates and defining his life as extending from about 470 B.C.E. to 410 B.C.E.).

<sup>127</sup> The Oath by Hippocrates, Internet Classics Archive, <http://classics.mit.edu/Hippocrates/hippooath.html> (last visited Jan. 22, 2006).

<sup>128</sup> Ylva Arvidsson, *The Precautionary Principle: Experiences from Implementation into Swedish Law*, INT'L INST. FOR INDUS. ENVTL. ECON. 9 (2001), available at <http://www.institute.redlands.edu/p3/Ylva.pdf>. The use of the principle in the Swedish environmental law has evolved and now, according to the Swedish government, “[t]he precautionary approach is the basis for all provisions in the Code.” Government Offices of Sweden, Swedish Environmental Legislation, <http://www.sweden.gov.se/sb/d/3704/a/21606> (last visited Jan. 22, 2006). The German Clean Air Act of 1974 provides another early example of explicit incorporation of the precautionary principle into national legislation. See THE PRECAUTIONARY PRINCIPLE IN THE 20TH CENTURY, *supra* note 75, at 4 (2002) (describing incorporation of the principle into the German Act).

<sup>129</sup> See Second International Conference on the Protection of the North Sea: Ministerial Declaration Calling for Reduction of Pollution, Nov. 25, 1987, 27 I.L.M. 835, 835 (calling for pollution reduction by acts including “precautionary actions”).

<sup>130</sup> W.C.G. Burns, The Precautionary Principle Project (P3), Project Overview, <http://www.institute.redlands.edu/p3/> (last visited Jan. 22, 2006) [hereinafter *P3 Project Overview*].

<sup>131</sup> See *supra* note 25 and accompanying text.

precautionary principle is typically applied in situations involving “false negatives,” where a technology or an activity was originally regarded as harmless, but where later evidence suggests environmentally harmful effects that might justify government action.<sup>132</sup> In other words, the principle is typically applied during a state of scientific uncertainty with regard to the possibly harmful effects on a targeted activity.

### *B. Strengths of Precaution*

Some version of the precautionary principle “has been included in virtually every recent treaty and policy document related to the protection and preservation of the environment,”<sup>133</sup> but the application of the principle varies significantly among its different embodiments.<sup>134</sup> These embodiments span a continuum, the extremes of which generally have been termed “weak” and “strong” precautionary principles.<sup>135</sup>

#### *1. Distinguishing Strong and Weak Principles*

Although all versions of the principle—both strong and weak—target scenarios involving some degree of scientific uncertainty, they differ from one another in various other respects, such as 1) whether the principle merely allows mitigating action or requires it,<sup>136</sup> 2) whether the principle places the burden of proving environmental harm on the party alleging the harm or places the burden of proving lack of harm on the proponent of the allegedly harmful activity,<sup>137</sup> 3) to what degree of likelihood the party bearing the burden must prove its position,<sup>138</sup> 4) to what degree public input

---

<sup>132</sup> See generally THE PRECAUTIONARY PRINCIPLE IN THE 20TH CENTURY, *supra* note 75 (providing fourteen case studies of “false negatives” where the precautionary principle was applied).

<sup>133</sup> David Freestone & Ellen Hey, *Origins and Development of the Precautionary Principle*, in THE PRECAUTIONARY PRINCIPLE & INTERNATIONAL LAW 3 (David Freestone & Ellen Hey eds., 1996); see also William C.G. Burns, The Precautionary Principle Project (P3), Texts Incorporating the Precautionary Principle, <http://www.institute.redlands.edu/p3/text.htm> (last visited Jan. 22, 2006) (listing treaties, non-legally binding international instruments, and multilateral agreements incorporating the precautionary principle).

<sup>134</sup> See THE PRECAUTIONARY PRINCIPLE IN THE 20TH CENTURY, *supra* note 75, tbl. 1.2, at 6 (providing seven different embodiments of the precautionary principle in recently enacted international treaties and agreements).

<sup>135</sup> Julian Morris, Science, Technology, and Innovation Viewpoints: Defining the Precautionary Principle, <http://www.cid.harvard.edu/cidbiotech/comments/comments79.htm> (last visited Jan. 22, 2006).

<sup>136</sup> Compare the version of the precautionary principle expressed by the Rio Declaration, *supra* note 28 and accompanying text, with the version expressed by the Third North Sea Conference, *supra* note 30 and accompanying text.

<sup>137</sup> Burns & Simmonds, *supra* note 124, at 4–6.

<sup>138</sup> See Rosie Coone, Africa Resources Trust, The Precautionary Principle in Wildlife Conservation, <http://www.traffic.org/briefings/precautionary.html> (last visited Jan. 22, 2006) (noting “[i]t is currently unclear what standard of proof is necessary for the proponent of an activity to discharge the evidentiary burden and demonstrate that a proposed course of action does not involve unacceptable risk.”).

will be a factor in determining if an activity will go forward,<sup>139</sup> 5) to what extent the costs of mitigating measures will be considered,<sup>140</sup> and 6) whether the principle allocates the cost of mitigating measures to government (and thus to society at large), to the activity's proponent, or to a combination of the two.<sup>141</sup>

However, the primary distinction between existing embodiments of the precautionary principle—and the one most often used to distinguish strong from weak versions—is whether precautionary measures are required or merely permitted in the absence of scientific certainty. For instance, a typical embodiment of the strong principle is provided in the Treaty on the European Union, which provides that

[c]ommunity policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Community. It shall be based on the precautionary principle and on the principles that preventive action *should* be taken, that environmental damage *should* as a priority be rectified at [the] source and that the polluter *should* pay. Environmental protection requirements *must* be integrated into the definition and implementation of other Community policies.<sup>142</sup>

This statement of the strong principle requires mitigating action by a polluter—with costs to be borne by the polluter—and also requires that precautionary measures be integrated into other European Community (EC) policy areas.<sup>143</sup>

---

<sup>139</sup> See Joyeeta Gupta, *Globalization: The Precautionary Principle and Public Participation, with Special Reference to the UN Framework Convention on Climate Change*, in THE PRECAUTIONARY PRINCIPLE AND INTERNATIONAL LAW 238–46 (David Freestone & Ellen Hey eds., 1996) (proposing various models of public participation in implementing the precautionary principle with respect to problems of climate changes produced by human activities).

<sup>140</sup> See David Fleming, *The Economics of Taking Care: An Evaluation of the Precautionary Principle*, in THE PRECAUTIONARY PRINCIPLE AND INTERNATIONAL LAW 147–67 (David Freestone & Ellen Hey eds., 1996) (describing the economic implications of various forms of the precautionary principle).

<sup>141</sup> See Konrad von Moltke, *The Relationship Between Policy, Science, Technology, Economics and Law in the Implementation of the Precautionary Principle*, in THE PRECAUTIONARY PRINCIPLE AND INTERNATIONAL LAW 106–07 (David Freestone & Ellen Hey eds., 1996) (describing various applications of the precautionary principle that incorporate government subsidies when mitigating actions are unaffordable to an activity's proponent). The determination of who should bear the cost of mitigating measures often involves some degree of risk assessment, as stated in a classic opinion by Judge Learned Hand with regard to moored ships: "the owner's duty . . . to provide against resulting injuries is a function of three variables: (1) the probability that she will break away; (2) the gravity of the resulting injury, if she does; (3) the burden of adequate precautions." *United States v. Carroll Towing Co.*, 159 F.2d 169, 173 (2d Cir. 1947).

<sup>142</sup> Treaty on the European Union, as amended by the Maastricht Treaty, Feb. 7, 1992, Art. 130r, § 2, 31 I.L.M. 247, 285 (emphasis added).

<sup>143</sup> Significantly, precautionary measures already may be integrated into patent laws governing the EC as part of the European Patent Convention, which provides that

European patents shall not be granted in respect of: (a) inventions the publication or exploitation of which would be contrary to "ordre public" or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States . . . .

On the other hand, a typical statement of the weak principle merely prevents lack of scientific certainty from postponing mitigating measures (but does not actually require the measures), as indicated by the embodiment of the principle articulated in the United Nations Convention on Biological Diversity: “Noting also that where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize such a threat.”<sup>144</sup>

## 2. Hybrid Principles

Some agreements incorporate versions of the precautionary principle in which certain actions are compulsory and others are optional, i.e., versions that are weak in some respects and strong in others. For example, the Ministerial Declaration on Sustainable Development in the ECE Region provides that

[i]n order to achieve sustainable development, policies must be based on the precautionary principle. Environmental measures must anticipate, prevent and attack the causes of environmental degradation. Where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation.<sup>145</sup>

This declaration is strong in that it mandates certain anticipatory environmental measures in advance of harm (arguably an inherently uncertain endeavor), but weak in its explicit treatment of scientific uncertainty. Similarly, the Draft Agreement on Straddling and Highly Migratory Fish Stocks (Draft Agreement)<sup>146</sup> also embodies both weak and strong precautionary elements. It provides the weak principle that “States shall be more cautious when information is poor. The absence of adequate scientific information shall not be used as a reason for postponing or failing to take conservation and management measures.”<sup>147</sup> However, the Draft Agreement later asserts that “States *shall* determine precautionary reference points, and the actions to be taken if they are exceeded. When precautionary reference points are approached, measures *shall* be taken to ensure that

---

European Patent Convention, Oct. 5, 1973, art. 53, *available at* <http://www.european-patent-office.org/legal/epc/e/ar53.html#A53>. However, no known court decisions have addressed whether the term “ordre public” encompasses environmental harm. *See id.* note 29 and links contained therein (describing decisions of the EC Enlarged Board of Appeal related to art. 53).

<sup>144</sup> U.N. Conference on Environment and Development, Rio de Janeiro, June 5, 1992, *Preamble*, 31 I.L.M. 818, 822.

<sup>145</sup> Ministerial Declaration on Sustainable Development in the ECE Region, May 16, 1990, para. 7, <http://www.institute.redlands.edu/p3/sl9.htm> (last visited Jan. 22, 2006).

<sup>146</sup> U.N. Conference on Straddling Fish Stocks and Highly Migratory Fish Stocks, *Draft Agreement for the Implementation of the Provisions of the UN Convention on the Law of the Sea of 10 December 1982 Relating to the Conservation and Management of Straddling Fish Stocks and Highly Migratory Fish Stocks*, New York, Aug. 23, 1994, art. 6, para. 2, *available at* <http://daccessdds.un.org/doc/UNDOC/GEN/N94/338/70/IMG/N9433870.pdf?OpenElement>.

<sup>147</sup> *Id.*

they will not be exceeded.”<sup>148</sup> This mandatory creation of precautionary reference points is an embodiment of the strong principle.

### C. Scope of the Principle

The precautionary principle extends in both the international and domestic arenas beyond purely environmental legislation. For example, the official definition of the precautionary (Vorsorge) principle in German law states:

The principle of precaution commands that the damages done to the natural world (which surrounds us all) should be avoided in advance and in accordance with the opportunity and possibility. Vorsorge further means the early detection of dangers to health and environment by comprehensive, synchronized (harmonized) research, *in particular about cause and effect relationships* . . . . Precaution means to develop, *in all sectors of the economy*, technological processes that significantly reduce environmental burdens . . . .<sup>149</sup>

Thus, German law embraces the application of its precautionary principle to all economic activities affecting the environment, and suggests that activities with potentially harmful impacts should be blocked in advance.

Since granting patents encourages development and production of inventions, one method of avoiding the environmental damage that the Vorsorge principle seems to contemplate is to remove the patent incentive for potentially harmful inventions.<sup>150</sup> Similarly, in the international arena, the precautionary principle extends into human rights law.<sup>151</sup> For instance, the European Court of Human Rights has admitted complaints in which “the applicants were not required to demonstrate that they had already become victims of a violation of a provision of the European Convention on Human Rights,”<sup>152</sup> but rather merely “allege to be running a risk of becoming a victim of the application of an existing piece of legislation or an existing

---

<sup>148</sup> *Id.* at art. 6, para. 3(d) (emphasis added).

<sup>149</sup> James Cameron & Juli Abouchar, *The Status of the Precautionary Principle in International Law*, in *THE PRECAUTIONARY PRINCIPLE & INTERNATIONAL LAW* 38 (David Freestone & Ellen Hey eds., 1996) (emphasis added).

<sup>150</sup> In a possible reflection of this broad application of the precautionary principle, German patent law states: “Patents shall not be granted in respect of . . . inventions the publication or exploitation of which would be contrary to public policy . . . .” Patentgesetz of Germany, pt. I, § 2-1 (1995), available at [http://www.wipo.int/clea/docs\\_new/pdf/en/de/de017en.pdf](http://www.wipo.int/clea/docs_new/pdf/en/de/de017en.pdf). In light of the Vorsorge principle, the German definition of “public policy” likely is extended to environmental considerations in the patent context. See Cameron & Abouchar, *supra* note 149, at 38 (outlining the German Vorsorge principle).

<sup>151</sup> See generally Menno T. Kamminga, *The Precautionary Approach in International Human Rights Law: How It Can Benefit the Environment*, in *THE PRECAUTIONARY PRINCIPLE & INTERNATIONAL LAW* 171–86 (David Freestone & Ellen Hey eds., 1996) (examining the application of human rights law to environmental protection in situations of uncertainty).

<sup>152</sup> *Id.* at 181.

policy.”<sup>153</sup> In other words, the court in those cases suspended traditional “ripeness” considerations and took a precautionary approach.

Despite widespread incorporation of the precautionary principle into environmental laws—and more recently into some other areas of law as noted above—products and practices later found with scientific certainty to have significant harmful impacts on the environment and public health often still come into general use. This usually occurs either because the harmful practices develop so quickly that they are not yet subject to environmental laws at the time of their introduction, because the precautionary principle is not yet applied in the relevant jurisdiction or area of law, or because the precautionary principle is asserted too weakly to prevent the harmful activity. In the United States, the reason is straightforward: Our federal laws do not yet embrace the precautionary principle.<sup>154</sup> However, in light of the myriad embodiments of the principle, and its application in a variety of intranational and international settings, the time may be approaching to introduce some form of the principle into U.S. law.

## V. PRECAUTIONARY MEASURES IN FOREIGN PATENT LAWS

### *A. Types of Patentability Exclusions*

As previously noted, U.S. patent law substantively requires only a showing of patentable subject matter, utility, novelty, and nonobviousness to obtain a patent; our patent code includes no precautionary provisions. However, many other nations do incorporate precautionary measures in their patent laws to varying degrees. For example, Brazilian patent law provides a number of statutory exclusions from patentability, essentially limiting the definition of patentable subject matter to exclude various categories of inventions for policy reasons. These exclusions apply regardless of whether the invention otherwise meets the basic requirements of novelty and utility in the Brazilian patent code.

Specifically, in Brazilian law, the following are not patentable:

- I. anything contrary to morals, standards of respectability and public security, order and health;
- II. substances, materials, mixtures, elements or products of any kind, as well as the modification of their physical-chemical properties and the respective processes for obtainment or modification, when resulting from the transformation of the atomic nucleus; and

---

<sup>153</sup> *Id.* at 180.

<sup>154</sup> *See supra* note 25 and accompanying text (summarizing the U.S. position on the precautionary principle).

- III. all or part of living beings, except transgenic microorganisms that satisfy the three requirements of patentability—novelty, inventive step and industrial application—provided for in Article 8 and which are not mere discoveries.<sup>155</sup>

The Brazilian exclusions to patentable subject matter are typical of precautionary exclusions in the patent laws of many nations.<sup>156</sup> In general, nations have adopted precautionary exclusions to patentable subject matter based on five criteria: morality, public policy (or public order), legality, public health, and environmental harm.<sup>157</sup> More specifically, of 142 nations having independent patent laws with clearly delineated patentability standards, 104 have a morality exclusion, 83 have a public policy or public order exclusion, 38 have a legality exclusion (barring patents on inventions the use of which would conflict with other national laws),<sup>158</sup> 21 have a public health exclusion, and 11 have an environmental harm exclusion.<sup>159</sup> Indeed, only 27 of the 142 nations, including the United States, do not exclude inventions from patentability based on any of these five factors.<sup>160</sup>

Each of the five exclusionary factors noted above—morality, public policy, legality, public health, and environmental harm—arguably can form the basis for denying a patent for an invention that is potentially harmful to the environment or public health. For example, an invention having the potential to harm the environment also may be deemed immoral and against public policy, may have public health ramifications, or may be illegal based on environmental or public health laws. However, because the exclusions based on public health and environmental harm are most clearly suited for this purpose, the next two sections will focus on how various nations have incorporated statutory public health and environmental harm exclusions into their patent laws.

---

<sup>155</sup> Brazil Industrial Property Law No. 9,279, tit. I, ch. II, § III, art. 18 (1996), available at [http://www.wipo.int/clea/docs\\_new/pdf/en/br/br003en.pdf](http://www.wipo.int/clea/docs_new/pdf/en/br/br003en.pdf).

<sup>156</sup> See generally PATENTS THROUGHOUT THE WORLD (West 2004) (summarizing the patent laws of over 150 nations and cooperative treaties).

<sup>157</sup> Other arguably precautionary statutory exclusions exist, such as the “security” exclusion of the Brazilian code, which patent laws of other nations commonly phrase as an exclusion for national security. *Id.* Here, however, I am primarily concerned with exclusions that might provide a statutory bar to the patentability of an environmentally harmful invention.

<sup>158</sup> In addition, nine nations specifically disclaim a legal exclusion. For example, the patent laws of the United Kingdom provide that a patent shall not be granted “for an invention the publication or exploitation of which would be generally expected to encourage offensive, immoral or anti-social behaviour,” but that “behaviour shall not be regarded as offensive, immoral or anti-social only because it is prohibited by any law in force in the United Kingdom.” Patents Act 1977 of Great Britain, ch. 37, pt. I, §§ 1(3)(a), 1(4) (1977), available at [http://www.wipo.int/clea/docs\\_new/pdf/en/gb/gb001en.pdf](http://www.wipo.int/clea/docs_new/pdf/en/gb/gb001en.pdf).

<sup>159</sup> The author compiled these statistics through an independent study of PATENTS THROUGHOUT THE WORLD, *supra* note 156. See *infra* notes 161 and 166 for complete lists of nations having a statutory public health or environmental harm exception.

<sup>160</sup> As determined by the author. PATENTS THROUGHOUT THE WORLD, *supra* note 156.

### B. The Public Health Exclusion

At least twenty-one nations currently include a statutory public health exclusion to patentable subject matter in their patent laws.<sup>161</sup> A typical example of such an exclusion is provided by the patent code of India, which includes a provision rendering unpatentable “an invention the primary or intended use of which would be contrary to law or morality or injurious to public health.”<sup>162</sup> Similarly, the patent laws of Panama provide that a patent will be denied for “inventions contrary to national laws, health, public policy, morality, proper practice or State security.”<sup>163</sup> India, Panama, and the other nations that similarly limit patentable subject matter on the basis of public health commonly use this exclusion to prevent patenting of pharmaceutical drugs, to control overpricing of those drugs.

For example, India has excluded pharmaceutical drug products from patentability for the past thirty-five years, while allowing patenting of processes for the manufacture of those drugs.<sup>164</sup> This has decreased barriers to entry in the Indian pharmaceutical industry, leading to increased competition and lower prices. As a result, India has a vibrant generic pharmaceutical industry that offers some pharmaceutical drugs, such as anti-AIDS drugs, at a fraction of the price of non-Indian pharmaceutical companies, and India is the world’s leading supplier of generic drugs.<sup>165</sup> Thus, although the public health exclusion provides the possibility of denying a patent directed to a substance harmful to public health, this does not appear to be its primary purpose in existing patent laws. Rather, nations have primarily adopted this exclusion to prevent profiteering, particularly in their domestic pharmaceutical industries.

### C. The Environmental Harm Exclusion

Eleven nations specifically include an environmental harm exclusion to patentability in their patent laws,<sup>166</sup> and the statutory language and procedures used by several of these nations is worth examining in some

---

<sup>161</sup> The nations whose patent laws are known to include a statutory public health exclusion are Costa Rica, Ghana, India, Iran, Japan, Kenya, South Korea, Mongolia, Mozambique, Nepal, Nicaragua, Panama, Peru, Portugal, Saudi Arabia, Somalia, Taiwan, Thailand, Trinidad and Tobago, Uruguay, and Vietnam. *Id.*

<sup>162</sup> India Patents Act of 1970, ch. II, § 3(b) (1970), available at [http://www.wipo.int/clea/docs\\_new/pdf/en/in/in004en.pdf](http://www.wipo.int/clea/docs_new/pdf/en/in/in004en.pdf).

<sup>163</sup> Panama Law No. 35 Enacting Provisions on Industrial Property, ch. II, § 14.9 (1996), available at [http://www.wipo.int/clea/docs\\_new/pdf/en/pa/pa002en.pdf](http://www.wipo.int/clea/docs_new/pdf/en/pa/pa002en.pdf).

<sup>164</sup> See Health Global Access Project, Fact Sheet: Changes to India’s Patents Act and Access to Affordable Generic Medicines After January 1, 2005, available at [http://www.healthgap.org/press\\_releases/04/121404\\_HGAP\\_FS\\_INDIA\\_patent.pdf](http://www.healthgap.org/press_releases/04/121404_HGAP_FS_INDIA_patent.pdf) (describing India’s history of denying product patents for medicines).

<sup>165</sup> *Id.* However, India must comply with the World Trade Organization’s Agreement on Trade-Related Intellectual Property Rights, Annex 1C-Results of the Uruguay Round, 33 I.L.M. 1125 (1994) [hereinafter TRIPS], starting in 2005, and to do so must reinstate patentability of pharmaceutical drugs. See *id.* (discussing the effects of TRIPS on the India Patents Act).

<sup>166</sup> The eleven nations are Bolivia, Colombia, Ecuador, Jordan, Kenya, Mongolia, Peru, Saudi Arabia, Trinidad and Tobago, Uruguay, and Venezuela. See *supra* note 159.

detail. For example, the patent laws of Kenya provide that “[t]he following shall not be patentable— . . . (b) inventions contrary to public order, morality, public health and safety, principles of humanity and environmental conservation.”<sup>167</sup> Perhaps recognizing that patent examiners may not always have sufficient expertise to competently evaluate patentability under this standard, the statute states that for purposes of examination, the Managing Director of the patent office “may submit the application together with the relevant documents to an examiner *or other competent authority* for examination as to the patentability of the claimed invention.”<sup>168</sup> In other words, the Managing Director of the Kenyan patent office may send an application to an outside scientific or technical evaluator, presumably a government or private agency within Kenya, to check its compliance with the environmental and public health patentability standards of the statute. According to the statutory language, the role of the outside evaluator apparently extends beyond mere consultation, to actual examination of the application.

Similarly, Trinidad and Tobago allows for the possibility that its patent Examiners may not be qualified to determine the potential impacts of a proposed invention. Its patent statute provides that

[a] patent shall not be granted for an invention the commercial exploitation of which would be contrary to public order or morality, or which is prejudicial to human, animal or plant life or health, or to the environment, provided that such refusal is not based solely on the ground that the commercial exploitation is prohibited by a law in force in Trinidad and Tobago.<sup>169</sup>

However, in addition to authorizing appointment of designated Examiners,<sup>170</sup> the statute also provides that “for the purposes of examination . . . the Controller may transmit the application to a duly authorized authority with which an arrangement to that effect has been made.”<sup>171</sup>

An example of a similar but even more far-reaching approach is provided by the patent laws of the Andean Community of Nations, which includes Bolivia, Colombia, Ecuador, Peru, and Venezuela. The Andean Community patent statute provides that

[t]he following inventions shall not be patentable: . . . b) inventions, when the prevention of the commercial exploitation within the respective Member Country of the commercial exploitation is necessary to protect human or animal life or health or to avoid serious prejudice to plant life and the

---

<sup>167</sup> Kenya Industrial Property Act No. 3 (2001), pt. III, § 26, *available at* [http://www.wipo.int/clea/docs\\_new/pdf/en/ke/ke001en.pdf](http://www.wipo.int/clea/docs_new/pdf/en/ke/ke001en.pdf).

<sup>168</sup> *Id.* At pt. V, § 44(4) (emphasis added).

<sup>169</sup> Trinidad and Tobago Patents Act, pt. IV, § 12 (1996), *available at* [http://www.wipo.int/clea/docs\\_new/pdf/en/tt/tt036en.pdf](http://www.wipo.int/clea/docs_new/pdf/en/tt/tt036en.pdf). This statute has the interesting feature of disclaiming illegality as a basis for showing harm to public health, plant life or the environment, perhaps recognizing that although laws and administrative provisions may change over time and according to political currents, a truly objective measure of the harm caused by an invention—such as scientific consensus—will not.

<sup>170</sup> *Id.* pt. III, § 5.

<sup>171</sup> *Id.* pt. VI, § 24(2).

environment, provided that such exclusion is not made merely because the exploitation is prohibited or regulated by a legal or administrative provision . . . .<sup>172</sup>

In the case of the Andean Community, such measures are said to be weighed by “[t]he competent national office”<sup>173</sup>—presumably the national patent examination office—which renders a decision on the patentability of the invention. However, in reaching its decision, this office “may request reports from experts or from scientific or technological bodies that are considered suitable, to get their opinions on the patentability of the invention. *It may also, as it deems fit, request reports from other intellectual property offices.*”<sup>174</sup>

Thus, as in the cases of Kenya and Trinidad and Tobago, the patent examination offices in each of the Andean Community nations may send an application to one or more outside evaluators to check its compliance with the patentability standards of the statute, including whether the invention at issue is prejudicial to public health or the environment. In addition, however, these nations, recognizing that inventors often seek patents in a plurality of countries, and that the patent offices of other nations therefore already may have evaluated an invention’s impacts under similar standards, also are empowered to seek patentability reports from the patent offices of those other nations.<sup>175</sup>

## VI. INCORPORATING THE PRECAUTIONARY PRINCIPLE INTO U.S. PATENT LAW

### *A. Proposed Method of Incorporating the Principle*

In principle, either the courts or Congress could act to incorporate the precautionary principle into U.S. patent law. However, as previously noted, modern courts have largely ignored, if not overturned, the common law doctrine of beneficial utility,<sup>176</sup> which required that an invention should not be “injurious to the well-being, good policy, or sound morals of society.”<sup>177</sup> Therefore, Congress must incorporate the precautionary principle into U.S.

---

<sup>172</sup> Andean Community Decision 486: Common Intellectual Property Regime, tit. II, art. 20 (2000), available at <http://www.sice.oas.org/Trade/Junac/Decisiones/dec486e.asp>.

<sup>173</sup> *Id.* at tit. III, art. 46.

<sup>174</sup> *Id.* (emphasis added).

<sup>175</sup> The patent statute of Uruguay provides a second example of the Andean Community’s international approach. It states that “[t]he following shall not be patentable: . . . (b) inventions contrary to public order, morality, public health, the population’s food supply, safety or the environment.” Uruguay Law No. 17.164, Regulating Rights and Obligations Relating to Patents, Utility Models and Industrial Designs, tit. II, ch. 1, § 14 (1999), available at [http://www.wipo.int/clea/docs\\_new/pdf/en/uy/uy002en.pdf](http://www.wipo.int/clea/docs_new/pdf/en/uy/uy002en.pdf). To judge patentability under this standard, the statute specifies that “it shall be permissible . . . (b) to seek the advice of bodies which carry out scientific and technological activities; (c) to utilize patent documents, search and examination reports or similar documents prepared by other patent offices.” *Id.* ch. III, § 32.

<sup>176</sup> See *supra* note 113 and accompanying text (describing the rise and fall of the doctrine at common law).

<sup>177</sup> *Lowell v. Lewis*, 15 F. Cas. 1018, 1019 (C.C. Mass. 1817).

patent law, either by passing a new statute or by amending an existing one. Although such an action would run against the Supreme Court's recent trend of expanding patentable subject matter, the Court in *Chakrabarty* stated, in response to the argument that the Court should "weigh . . . potential hazards in considering whether respondent's invention is patentable subject matter,"<sup>178</sup> that "the balancing of competing values and interests . . . is the business of elected representatives. . . . [T]he contentions now pressed on us should be addressed to the Congress and the Executive, and not to the courts."<sup>179</sup> This statement apparently gives Congress the Court's blessing to limit patentable subject matter. Of course, Congress has constitutional authority to pass patent laws in any case.<sup>180</sup>

Specifically, Congress should narrow the scope of patentable subject matter to exclude inventions deemed harmful to the environment or public health by amending 35 U.S.C. § 101. This section currently reads: "Whoever 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 therefor, subject to the conditions and requirements of this title."<sup>181</sup> I propose that Congress add to section 101 the phrase: "However, a patent will not be granted for an invention the use of which is deemed sufficiently detrimental to the environment or public health." As with any statutory revision affecting an administrative agency, the proposed language would likely be fleshed out by federal regulations, and the final interpretation of both the statute and the regulations ultimately would be left to the courts.

#### *B. Practical Considerations: How to Draw the Precautionary Line*

Under the amended section 101, USPTO would have the authority to exclude an invention "deemed sufficiently detrimental to the environment or public health." Aside from the policy question—addressed in the next section—of where the line for "sufficiently detrimental" should be drawn, the proposed amendment also raises the important question of how, as a practical matter, USPTO could apply the new exclusions. In principle, three possible approaches to evaluating the patentability of a potentially harmful invention are: 1) purely internal patent examination by USPTO, 2) purely external examination by outside experts, such as scientific panels or other government agencies, and 3) internal evaluation in consultation with outside experts, including the patent offices of other nations.

The patent laws of other nations may be instructive in this regard. Based on similar statutory exclusions in the patent laws of numerous other nations—and as embodied in the laws of Kenya, Trinidad and Tobago, and

---

<sup>178</sup> *Diamond v. Chakrabarty*, 447 U.S. 303, 316–17 (1980).

<sup>179</sup> *Id.* at 317.

<sup>180</sup> U.S. CONST. art. I, § 8, cl. 8.

<sup>181</sup> 35 U.S.C. § 101 (2000).

the Andean Community of nations<sup>182</sup>—internal evaluation in consultation with outside experts seems to be the most common approach.

In the U.S. system, each approach would have certain inherent advantages and disadvantages, based on the internal structure of USPTO, and on other practical and political considerations. However, internal USPTO examination in consultation with outside experts would likely be the most efficient and objective approach.

### *1. Internal USPTO Evaluation*

USPTO employs professional patent Examiners who evaluate each patent application to see that it meets all of the statutory requirements for patentability. As discussed above, these requirements include various formal issues related to the style and content of a patent application, as well as the substantive requirements of patentable subject matter, utility, novelty, and nonobviousness. Under the current system, Examiners are assigned to a Technology Center (TC),<sup>183</sup> and then to a numerically referenced Art Unit within that TC.<sup>184</sup> These assignments are made according to the background of each Examiner, presumably because an Examiner will more efficiently and knowledgeably evaluate inventions within the area of his or her technical expertise.

In light of this structure—and the overall absence of impact evaluation within it—currently no USPTO Examiners are specifically qualified to evaluate the potential environmental or public health impacts of inventions. Therefore, if USPTO were to internally evaluate inventions to render an opinion on their potential harm to the environment or public health, this would likely require one or more new Examiner “Impact Units” dedicated for that purpose. In turn, establishing such new units would require hiring and training new Examiners with specialized environmental and public health knowledge, at significant expense to the public. On the other hand, a system of internal USPTO evaluation might have the advantage that it would be relatively efficient, since applications would stay within USPTO for the duration of their examination, allowing Examiners of the new “Impact Units” to communicate conveniently with Examiners of the application’s originally assigned Art Unit.

---

<sup>182</sup> See *infra* Part V(C) (describing the approaches to evaluating the potential environmental harm of proposed inventions used by these nations).

<sup>183</sup> There are currently seven USPTO Technology Centers (TCs): 1) Biotechnology and Organic Chemistry; 2) Chemical and Materials Engineering; 3) Computer Architecture, Software, and Information Security; 4) Communications; 5) Semiconductors, Electrical and Optical Systems and Components; 6) Transportation, Electronic Commerce, Construction, Agriculture, National Security and License and Review; and 7) Mechanical Engineering, Manufacturing, and Products, Designs. USPTO, Patent Technology Centers, <http://www.uspto.gov/web/info/pat-tech.htm> (last visited Jan. 22, 2006).

<sup>184</sup> See, e.g., USPTO Biotechnology and Organic Chemistry, <http://www.uspto.gov/web/info/1600.htm> (last visited Jan. 22, 2006) (listing Art Units within the Biotechnology and Organic Chemistry TC).

## *2. Purely External Evaluation*

A second possible approach to evaluating the potentially harmful impacts of an invention is to allow existing USPTO Examiners to initially screen applications, flag those applications for inventions an Examiner suspects might have harmful impacts, and then send the flagged applications to an external consultant for final evaluation. Likely consultants include government agencies such as EPA, DHHS, and their various subagencies.<sup>185</sup> This approach has the advantage that it probably would not require significant new USPTO or external agency infrastructure, and would therefore be relatively inexpensive. On the other hand, existing USPTO Examiners may not be qualified to render an initial decision on the possible harmful impacts of an invention. This could lead to inconsistencies in the initial screening process, defeating the goal of the greatest possible precaution based on objective scientific evidence.

Furthermore, sending applications to external agencies may be less efficient than keeping the applications within USPTO, perhaps even unacceptably slowing the patent process. Finally, allowing outside agencies to render a final patentability decision would require new statutory authority, and arguably would introduce subjective political forces into the examination process to a greater than necessary degree.

## *3. Internal Evaluation with External Consulting*

A third approach is some combination of the previous two, as exemplified by the patent laws of the Andean Community of nations. In this scenario, USPTO would create a reliable system to screen applications for potential harmful impacts on the environment or public health. The next step would be an optional consultation with external agencies regarding the connection between the invention and its suspected impacts. USPTO could then render a final decision on patentability. Keeping the final decision on patentability in the hands of USPTO would overcome the objections of increased politicization and lack of statutory authority to deny a patent, while still allowing Examiners to obtain outside scientific expertise related to an invention's possible impacts.

To overcome the objection that existing Examiners are not trained to perform the initial screening, USPTO could, for example, cooperate with other federal agencies to maintain lists of substances that are suspected or known to be hazardous to the environment or public health, and could screen new patent applications by referencing these lists of known hazards. For example, EPA, FDA, and other agencies could, at a minimum, provide lists of banned and phased out substances, the presence of which in a patent claim would trigger external review of the application. Of course, those agencies could also provide lists of substances merely suspected to be

---

<sup>185</sup> For example, the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), or the National Center for Environmental Health (NCEH) (all subagencies of DHHS).

harmful to the environment or public health; the extent of such lists is more a policy matter than a practical one.

Since under this approach, USPTO would issue rejections just as it does in the existing examination system, the inventor still would be allowed to respond to the rejection at least once—in accordance with due process requirements—before USPTO could issue a final denial of patent rights.<sup>186</sup> If a rejection were based on environmental concerns, the inventor could respond, for example, by introducing evidence that the proposed invention would not cause the harm suggested by USPTO, or by suitably modifying the claimed invention.

In short, this approach would preserve the entire structure of the existing USPTO examination system, and simply add the possibility of an Examiner requesting a patentability opinion from an external agency. In fact, the U.S. government already does this type of interagency consultation in other contexts. For example, under the Endangered Species Act, an agency undertaking a federal action must consult with the Fish and Wildlife Service to ensure that the federal action does not jeopardize the continued existence of any endangered or threatened species that might be affected by the action.<sup>187</sup> Similarly, under the Clean Water Act, the Corps of Engineers must seek the opinion of EPA concerning the impacts of proposed dredging operations.<sup>188</sup>

### *C. Policy Considerations: Where to Draw the Precautionary Line*

Under the proposal of the previous section, USPTO would determine if an invention lies within the exclusionary scope of amended 35 U.S.C. § 101 through initial list-based screening, followed by selective external consulting with other government agencies. However, the vital policy question remains: exactly what would be the exclusionary scope of the amended statute? In other words, *how* detrimental is “sufficiently detrimental” to exclude an invention from patentability? In amending section 101, Congress would undoubtedly express its views about how the amended statute should be applied, and in doing so, would necessarily balance environmental and public health interests with the economic interests of potential inventors and other would-be patent owners.<sup>189</sup> The courts would subsequently consider the same balance, along with the plain language of the statute and the expressed legislative intent of Congress, when interpreting the statute. This section discusses where Congress and the courts might reasonably draw the line between precautionary exclusion from patentability, and offering an economic patent incentive for new and potentially harmful innovations.

---

<sup>186</sup> Consolidated Patent Act, 35 U.S.C. § 132 (2000).

<sup>187</sup> Endangered Species Act of 1973, 16 U.S.C. § 1536 (2000).

<sup>188</sup> Federal Water Pollution Control Act, 33 U.S.C. § 1252 (2000).

<sup>189</sup> A patent owner is not necessarily the inventor named on the patent. For example, an employee of a corporation may (and typically does) assign to her employer all patent rights related to work done in the scope of her employment.

### 1. Banned Substances and the “Ultraweak” Precautionary Principle

From a public policy standpoint, USPTO should, at a minimum, use the proposed new limits on patentable subject matter to exclude from patentability all inventions claiming substances that face an imminent domestic ban on production (or a phase out of domestic production) at the time of the patent examination.<sup>190</sup> This application of amended section 101 would close the loophole between unequivocal government recognition that a substance is harmful—as indicated by regulatory action leading towards a ban on production of the substance—and the ban taking final effect. In the case of CFCs, for example, using amended section 101 in this manner would have excluded the seventeen or more patents USPTO issued for aerosol uses of CFCs after the United States signed the Amendment to Montreal Protocol in 1990.<sup>191</sup> Strictly speaking, this use of amended section 101 is not even a weak embodiment of the precautionary principle, since no scientific uncertainty attends its application. Rather, this “ultraweak” embodiment of the principle would allow USPTO to remove the patent incentive for inventions known *with scientific certainty* to be harmful, in advance of already enacted government regulation taking final effect. Removing the patent incentive in such cases is inherently reasonable, since an imminent ban or phase out of production of a substance is a clear indication that the U.S. government has deemed the substance harmful enough to prevent its manufacture, and strongly suggests that use of the invention is also “sufficiently detrimental” to exclude it from patentability.

Applying similar logic, USPTO also should use amended section 101 to exclude from patentability all inventions claiming substances facing an imminent ban or phase out on domestic *use* (as opposed to production) at the time of the patent examination. Under this approach, for example, USPTO would not have issued DDT-related patents in the period between the 1969 USDA actions outlawing most DDT uses and the final 1973 EPA ban on DDT use. Typically, a ban on domestic use without a commensurate ban on domestic production indicates that a substance still may be used in other nations, as in the case of DDT. Arguably, therefore, USPTO should preserve the patent incentive in such cases, to induce potential inventors to “improve” these fields of invention for the foreign market. However, as the goal of patent law is to “promote progress of science and the useful arts,”<sup>192</sup> inducing research in alternative technologies by removing the patent incentive for clearly harmful substances would better serve this goal. Furthermore, excluding from subsequent patentability a substance whose domestic use

---

<sup>190</sup> The same exclusion would apply to substances whose production is already banned. However, this situation is unlikely to arise in practice, because if an inventor cannot produce the invention domestically, there would be little reason to pursue a U.S. patent. In the strange scenario where domestic production was banned but domestic use was *not* banned, an inventor planning to produce the invention in another country conceivably might pursue a U.S. patent to prevent other foreign manufacturers from selling similar products in this country. In that unlikely event, the exclusion should apply.

<sup>191</sup> See *supra* note 19 (listing the 17 patents).

<sup>192</sup> U.S. CONST. art. I, § 8, cl. 8.

was banned would in no way affect either domestic production or foreign use of previously patented inventions related to the substance.

### *2. Other Applications of the “Ultraweak” Principle*

In addition to using imminent regulatory bans on production and use as indicators that a substance is “sufficiently detrimental” to be excluded from patentability, USPTO should use other indications of scientific certainty—which are often the precursors of bans—to exclude harmful substances from patentability under amended section 101. An example of such an alternative in the context of asbestos is the Leuven panel report of 1953,<sup>193</sup> which was a clear indication of scientific certainty regarding the carcinogenic effects of asbestos, but which preceded the EPA asbestos ban by some 46 years. Under amended section 101, USPTO—possibly in conjunction with external consultants—could have used the Leuven report to exclude hundreds, if not thousands, of asbestos-related inventions from patentability in the period between 1953 and 1989, perhaps significantly decreasing development of these inventions in favor of safer alternatives.

Similarly, other reports by scientific panels, scientific review articles, conference proceedings, and the like could be used to close the gap between the arrival of scientific certainty regarding the harmful impacts of a technology and the removal of the patent incentive to develop that technology. This use of amended section 101 would represent another “ultraweak” application of the precautionary principle, since USPTO would only be taking actions to exclude harmful inventions from patentability during the era of scientific certainty with respect to the invention’s impacts.

### *3. Scientific Uncertainty and True Precaution*

Finally, and perhaps most controversially, USPTO could use amended section 101 in a truly precautionary manner to exclude from patentability inventions merely suspected of causing harm to the environment or public health. USPTO could assess potential harm, for example, in conjunction with the same government agencies it consults with regarding banned substances and substances otherwise known with scientific certainty to have “sufficiently detrimental” environmental or public health effects. These agencies might include, for example, EPA, DHHS, FDA, CDC, and NCEH, among others. In addition, USPTO could assess risks in conjunction with the EPA subagency, National Center for Environmental Assessment, whose stated mission is to “conduct[] risk assessments, carr[y] out research to improve the state-of-the-science of risk assessment, and provide[] guidance and support to risk assessors.”<sup>194</sup> Although the precise standards for such risk assessments would have to be defined with regard to patentability, the

---

<sup>193</sup> See *supra* notes 78–79 and accompanying text (describing the Leuven study and the resulting 1953 report).

<sup>194</sup> National Center for Environmental Assessment, Mission Statement, <http://cfpub.epa.gov/ncea/cfm/aboutncea.cfm?ActType=AboutNCEA> (last visited Jan. 22, 2006).

obstacles to arriving at a well-defined standard of patentability for suspected inventions seem—at least in principle—to be surmountable.

## VII. CONCLUSION

Incorporating a precautionary measure into the patent laws of the United States would have ample international precedent. Various forms of the precautionary principle are commonly used to guide the formation of international environmental laws, treaties, and other agreements, as well as the domestic environmental policies of many nations. Furthermore, other areas of law currently incorporate some form of the precautionary principle, although sometimes without invoking it by name. Over one hundred nations, as well as several international intellectual property organizations, include statutory exclusions to patentable subject matter that are precautionary in nature, in the sense that they seek to mitigate harm to the public welfare in advance of the scientific certainty that often only arrives with the harm itself. The exclusions are usually based on considerations of morality, general public policy, legality, public health, and environmental harm. The United States is one of a relatively small minority of nations that does not incorporate any of these five exclusions into its patent laws.

Furthermore, the mitigating—rather than preventative—nature of the precautionary principle suggests a certain compatibility between the precautionary principle and patent laws, because failure to obtain a patent does not prevent an inventor from producing or selling a product.<sup>195</sup> Rather, the requirements for obtaining a patent place a burden on the inventor to show that the invention is worthy of a temporary right to exclude, due to its patentable subject matter, utility, novelty, and nonobviousness, and this burden can be characterized as mitigating the potential harm that might result if patents were granted for inventions not meeting those standards. The current definition of patentable subject matter in the United States focuses almost entirely on the potential economic harm that would result if inventors were given a right to exclude others from inventions deemed to fall outside the scope of that definition. However, many other nations also consider the environment and public health when defining patentable subject matter.

The essential purpose of patent laws is to accelerate “the progress of science and useful arts.”<sup>196</sup> To this end, U.S. law offers potential inventors the incentive of a temporary right to exclude others from making, using, selling, or importing any invention deemed worthy of a patent. However, some products and processes have significant harmful environmental and public health impacts when put into use, and the trend in U.S. law of continually broadening the scope of patentable subject matter provides inventors with an equal incentive to develop both harmful and beneficial

---

<sup>195</sup> Rather, once a patent has been granted on an invention, it prevents other parties from legally manufacturing or selling the invention without permission from the patent owner. In this sense, a patent confers a negative right, rather than an affirmative one. *See supra* notes 100–01 and accompanying text (discussing patent infringement).

<sup>196</sup> U.S. CONST. art. I, § 8, cl. 8.

inventions. This incentive should be removed during times of scientific certainty regarding the harmful impacts of an invention, as indicated by imminent bans on production and use of a substance claimed in the invention or by other evidence of clear scientific consensus as to the harmful effects of the substance.

Furthermore, the patent incentive also should be removed in some instances as a precautionary measure during times of scientific uncertainty regarding the impacts of an invention, if scientific evidence suggests a strong possibility of potential harm, and a risk assessment indicates that this possibility outweighs the putative economic benefits of providing a patent incentive to develop the technology. To provide statutory authority for removing the patent incentive in these cases, Congress should narrow the scope of patentable subject matter by amending section 101 of the patent code to exclude from patentability all inventions "deemed sufficiently harmful to the environment or public health."