

THE PROPER SCOPE OF PATENTABILITY IN INTERNATIONAL LAW

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INTRODUCTION

The primary goal of patent law is to promote technological progress.¹ To this end, a patent generally provides an inventor with the incentive of a temporary monopoly on the right to make, use, and sell a patented invention,² in return for full public disclosure of the invention.³ However, both the incentive to invent and the reward for inventing may have unintended and undesirable consequences because the harm caused by some inventions, or in some cases simply by the grant of the monopoly, may outweigh the benefits of the disclosure. On one hand, society may not wish to provide an incentive to invent in areas where the potentially harmful effects of an invention outweigh its putative benefits. On the other hand, even for an entirely beneficial invention, providing a patent may limit public access to the invention by allowing monopolistic pricing during the term of the patent. In such cases, the patent incentive is arguably misplaced.

Rather than ignoring the unintended—but nonetheless, harmful—effects of granting a patent, and focusing solely on maximizing the economic benefit to the inventor, patent law should counteract those effects by selectively limiting both the incentive to invent and the reward for inventing. This Article examines the undesirable consequences that may result from the patent incentive currently provided under U.S. and international law, and proposes a method by which those impacts can be limited by selectively narrowing the legal scope of patentability.

In this country, the United States Patent and Trademark Office (USPTO) is required by federal law to grant patents without considering either an invention's possible harmful impacts or the effects on public health of monopoly pricing resulting from a patent.⁴ Instead, U.S. law requires only a showing of utility, novelty, and

1. In the United States, this goal is explicitly announced in the Constitution, which authorizes Congress “[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.” U.S. CONST. art. I, § 8, cl. 8.

2. 35 U.S.C. § 271 (2000) (defining infringement of a U.S. patent).

3. *Id.* § 112 (describing the requirements of patent disclosure).

4. *See id.* §§ 101–103, 131, 151. 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. This Article will consider in more detail the current U.S. patent system, including currently excluded subject matter. *See* discussion *infra* Part II.

nonobviousness,⁵ with patentable subject matter broadly defined to include “anything under the sun that is made by man.”⁶ This policy has two important consequences. First, the USPTO routinely grants patents for inventions that are harmful to the environment and public health.⁷ Second, by indiscriminately granting patents on beneficial inventions, U.S. law allows monopoly pricing of many such inventions without regard to the impact of such pricing. This may, for example, contribute to the high costs of pharmaceuticals and of health care generally in this country.⁸ Although such costs may be appropriate in the United States—and in other highly industrialized and relatively wealthy nations⁹—monopoly power can severely limit access to pharmaceutical drugs and other beneficial inventions in developing nations. The problem is exacerbated by the fact that many developing nations lack the effective antitrust regulations of the United States.

5. 35 U.S.C. §§ 101–103. In addition, a patent application must meet various formal and procedural requirements. *Id.* § 112.

6. S. REP. NO. 82-1979, at 5 (1952), *as reprinted in* 1952 U.S.C.C.A.N. 2394, 2399; H.R. REP. NO. 82-1923, at 6 (1952); *e.g.*, *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

7. For example, the USPTO has granted at least seventeen patents for inventions claiming aerosol uses of chlorofluorocarbons (CFCs) since the United States signed the Montreal Protocol banning production of CFCs in 1990. These patents are all directed to using CFCs as blowing agents to produce various types of aerated materials: U.S. Patent No. 5,605,936 (filed Mar. 28, 1996) (issued Feb. 25, 1997); U.S. Patent No. 5,693,686 (filed Feb. 10, 1994) (issued Dec. 2, 1997); U.S. Patent No. 5,426,126 (filed Dec. 30, 1992) (issued June 20, 1995); U.S. Patent No. 5,199,962 (filed Feb. 14, 1992) (issued Apr. 6, 1993); U.S. Patent No. 5,140,052 (filed Feb. 3, 1992) (issued Apr. 18, 1992); U.S. Patent No. 5,162,384 (filed Sep. 13, 1991) (issued Nov. 10, 1992); U.S. Patent No. 5,089,033 (filed July 2, 1991) (issued Feb. 4, 1992); U.S. Patent No. 5,286,759 (filed Mar. 8, 1991) (issued Feb. 15, 1994); U.S. Patent No. 5,086,083 (filed Jan. 30, 1991) (issued Feb. 18, 1991); U.S. Patent No. 5,102,923 (filed Jan. 14, 1991) (issued Apr. 7, 1992); U.S. Patent No. 5,030,664 (filed Dec. 4, 1990) (issued July 9, 1991); U.S. Patent No. 5,250,582 (filed July 23, 1990) (issued Oct. 5, 1993); U.S. Patent No. 5,071,881 (filed May 22, 1990) (issued Dec. 10, 1991); U.S. Patent No. 4,960,804 (filed Mar. 30, 1990) (issued Oct. 2, 1990); U.S. Patent No. 5,001,164 (filed Aug. 19, 1988) (issued Mar. 19, 1991); U.S. Patent No. 4,994,217 (filed Dec. 29, 1988) (issued Feb. 19, 1991); and U.S. Patent No. 4,992,222 (filed Dec. 29, 1988) (issued Feb. 12, 1991).

8. For example, one recent study found that in the year 2000, the average cost of pharmaceuticals in the United States was the highest among a group of eight industrialized nations, and it was up to 3.5 times greater than the cost of the same drugs in the other countries studied, which included Canada, the United Kingdom, Sweden, France, Spain, Australia, and New Zealand. PRODUCTIVITY COMM’N, INTERNATIONAL PHARMACEUTICAL PRICE DIFFERENCES: RESEARCH REPORT (2001), *available at* <http://www.pc.gov.au/study/pbsprices/finalreport/pbsprices.pdf>.

9. The United States currently ranks seventh in the world in gross domestic product, at \$41,600 per capita. CIA, *The World Factbook, Rank Order*, <https://www.cia.gov/cia/publications/factbook/rankorder/2004rank.html> (last visited Dec. 22, 2006) [hereinafter CIA World Factbook].

Denying a patent based on the potentially harmful impacts of an invention is complicated by the fact that scientific consensus regarding the environmental and public health impacts of a new technology often arrives years, or even decades, after the technology itself. In the interim, the state of knowledge regarding the potential impacts of an invention generally 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, the USPTO granted the first patents on chlorofluorocarbons (CFCs) for use as refrigerants in the early 1930s,¹⁰ and CFCs were still considered “miracle chemicals” as late as the 1950s.¹¹ However, scientists later hypothesized that chlorine radicals from CFCs destroy atmospheric ozone,¹² resulting in a wide range of harmful impacts.¹³ In the late 1980s, scientists accepted as conclusive the link between CFC emissions and ozone depletion,¹⁴ and in 1990, the United States signed an international treaty banning CFCs from production starting in 2000.¹⁵ There are many other notable examples of

10. 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).

11. Daniel C. Esty, *Environmental Protection in the Information Age*, 79 N.Y.U. L. REV. 115, 132 (2004).

12. Mario J. Molina & F.S. Rowland, *Stratospheric Sink for Chlorofluoromethanes: Chlorine Atom-catalysed [sic] Destruction of Ozone*, 249 NATURE 810 (1974).

13. These include, for example, harm to the skin, eyes, and immune systems of humans and animals. UNITED NATIONS ENV'T PROGRAMME, MONTREAL PROTOCOL ON SUBSTANCES THAT DEplete THE OZONE LAYER: 2002 ASSESSMENT REPORT OF THE TECHNOLOGY AND ECONOMIC ASSESSMENT PANEL (2003), available at http://ozone.unep.org/teap/Reports/TEAP_Reports/TEAP2002.pdf; UNITED NATIONS ENV'T PROGRAMME, MONTREAL PROTOCOL ON SUBSTANCES THAT DEplete THE OZONE LAYER: 1998 ASSESSMENT REPORT OF THE TECHNOLOGY AND ECONOMIC ASSESSMENT PANEL (1998) [hereinafter UNEP ASSESSMENT REPORT 1998], available at http://ozone.unep.org/teap/Reports/TEAP_Reports/TEAPAS98.pdf.

14. 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. GEOPHYSICAL RES. 11,465, 11,465–79 (1989) (finding a conclusive link between chlorine molecules dissociated from CFCs and stratospheric ozone depletion).

15. Montreal Protocol Parties: Adjustments and Amendments to the Montreal Protocol on Substances that Deplete the Ozone Layer, June 29, 1990, 30 I.L.M. 537, 539 [hereinafter Amendment to the Montreal Protocol]. There are limited exceptions to the ban for “essential uses,” defined roughly as uses necessary for public health and safety. The only currently allowed essential uses of CFCs 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.

patented innovations that have later proven harmful, two of which—dichlorodiphenyltrichloroethane (DDT) and asbestos—will be discussed in more detail below.¹⁶

Analyzing the effects of patentability on the pricing of beneficial inventions is also complicated, but by economic rather than scientific considerations. Although granting a patent for an invention results in less competition and higher prices in the marketplace, removing the patent incentive entirely gives rise to the possibility that a product will never reach the market at all. For some of the most beneficial products, such as pharmaceuticals, research and development involves large sunk costs, lengthy development times, and great financial risk. As a result, the lure of monopoly pricing may be the deciding factor that induces a company to develop the product in the first place. Therefore, any proposal to limit patent rights must maintain a financial incentive sufficient to justify the risk and expense of developing beneficial new products. In other words, the law should strike a balance between providing inventors with a sufficient incentive to invent, and maximizing the number of people who can afford to purchase the resulting products. A key to striking this balance may lie in the large disparity in wealth among various nations. For example, in 2004, per capita gross domestic product (GDP) ranged from a low of \$400 in East Timor to a high of \$69,900 in Bermuda,¹⁷ a difference of more than two orders of magnitude. As this huge discrepancy indicates, regardless of the presence or absence of a patent incentive, the citizens of different nations are not equally able either to develop high-cost inventions or to pay monopoly prices for those inventions.

EPA, Essential Use Exemptions and Metered Dose Inhalers (MDIs), <http://www.epa.gov/ozone/title6/phaseout/mdi/> (last visited Nov. 4, 2006) (listing the current essential use exemptions and describing the requirements for a use to be essential under the Montreal Protocol).

16. DDT was first patented in the United States as a highly promising insecticide in 1943. U.S. Patent No. 2,329,074 (filed Mar. 4, 1941) (issued Sept. 7, 1943). It was eventually banned in 1973 due to its negative ecological and public health impacts. Press Release, U.S. Env't. Prot. Agency, DDT Ban Takes Effect (Dec. 31, 1972) [hereinafter DDT Ban Press Release], available at <http://www.epa.gov/history/topics/ddt/01.htm>. Asbestos was first patented in 1828 as an insulating material in steam engines and ultimately banned from most products as a carcinogen in 1989. See Chris Obrion, *Asbestos Through the Ages*, THE ROANOKE TIMES, Oct. 5, 2003, at A1, available at http://whitepages.roanoke.com/roantimes/special_sections/asbestos/asbestostimeline10_5.pdf (outlining the history and evolution of patents); U.S. EPA, Asbestos Ban and Phase Out, <http://www.epa.gov/asbestos/pubs/ban.html> (last visited Nov. 4, 2006) [hereinafter EPA Asbestos Ban] (explaining the EPA final rule to ban asbestos-containing products). See *infra* Part I.

17. CIA World Factbook, *supra* note 9.

This Article examines the environmental and public health consequences of patent laws around the world and argues that the patent incentive should be selectively removed to mitigate the harmful effects of granting patents without regard to the invention-specific impacts of doing so. After examining the scope of patentable subject matter provided by the domestic laws of the United States, the laws of other nations, and several international treaties, I conclude that patentable subject matter should be universally limited to exclude from patentability inventions that are known or strongly suspected to cause certain sufficiently harmful impacts, and it should be selectively limited to exclude from patentability certain classes of beneficial inventions in developing nations.

Part I examines the phenomenon of the undesirable patent, exploring, in particular, several past instances in which the widespread use of a patent has led to significant environmental and public health consequences. In the context of such cases, I will explore the extent to which patent laws not only permitted, but facilitated, the development of harmful technologies. Part II examines various national laws and international treaties that address the scope of patentability. This includes a brief examination of the evolution of U.S. patent law toward an increasingly broader scope of patentable subject matter without adequate evaluation of the public welfare impacts of patents. I then focus, in particular, on the attempts by other nations to institute precautionary measures to mitigate harms caused by unlimited patent incentives. Part III offers an assessment of the current inadequacies of existing patent laws, ultimately concluding that placing selective limits on the scope of patentable subject matter, which will exclude protection for some inventions, is warranted as a necessary means to counteract the possible undesirable effects of unrestrained patent incentives. Part III also presents some specific suggestions regarding the proper scope of patentability, including an examination of what should be excluded in accordance with necessary public policy considerations.

I. THE ENVIRONMENTAL AND PUBLIC HEALTH CONSEQUENCES OF PATENTED TECHNOLOGY

As technology evolves, opportunities for improvement are identified and instituted, but the passage of time may also bring with it new information and insight into the unintended consequences of that technology. Our understanding of the implications of various patented technologies for the environment and public health progresses through eras of scientific ignorance, uncertainty, and then finally to some degree

of certainty regarding the potential consequences. Throughout this time, successive generations of improvements and modifications typically result in the issuance of an increasing array of patents.

An examination of past practice of the USPTO in granting patents for inventions at various times during the evolution of scientific knowledge concerning the impacts of the underlying technology is instructive in better understanding this phenomenon. In three notable cases involving CFCs, DDT, and asbestos, patents were issued for substances that the scientific community ultimately—and universally—later came to recognize and accept caused serious harm to the environment and public health. Yet in each of these instances, the USPTO granted related patents not only during the era of scientific ignorance, but also at times of scientific uncertainty and certainty regarding the harm caused by the substances.

One of the most dramatic illustrations of how U.S. law keeps the patent incentive in place, regardless of whether harmful impacts of a technology are suspected or known with scientific certainty, is the case with respect to CFCs. CFCs are a class of synthetic chemicals and were introduced in the United States in the early 1930s as an ostensibly safer alternative to refrigerants such as sulfur dioxide and the ammonia-based refrigerants that were then commonly used.¹⁸ Shortly thereafter, the USPTO began granting U.S. patents related to CFCs.¹⁹ Unfortunately, scientists later determined that the widespread use of CFCs as refrigerants, aerosol propellants, cleaning solvents, and blowing agents²⁰ had led to depletion of stratospheric ozone in the earth's atmosphere, resulting in a variety of serious environmental and public health consequences due to increased transmission of ultraviolet radiation to the earth's surface.²¹ However, the link between stratospheric ozone depletion and CFCs in the atmosphere was not hypothesized until

18. THEO COLBORN ET AL., *OUR STOLEN FUTURE: ARE WE THREATENING OUR FERTILITY, INTELLIGENCE, AND SURVIVAL? A SCIENTIFIC DETECTIVE STORY* 243 (1996); Glenn B. Raiczky, *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).

19. U.S. Patent No. 1,833,847 (filed Feb. 8, 1930) (issued Nov. 24, 1931); U.S. Patent No. 1,886,339 (filed Dec. 30, 1928) (issued Nov. 1, 1932).

20. See UNITED NATIONS ENV'T PROGRAMME, *MONTREAL PROTOCOL ON SUBSTANCES THAT DEplete THE OZONE LAYER: 1991 ASSESSMENT REPORT OF THE TECHNOLOGY AND ECONOMIC ASSESSMENT PANEL* § 2.1 (1991), available at <http://www.ciesin.org/docs/011-494/011-494.html> (describing the various uses of CFCs).

21. See generally, e.g., UNEP ASSESSMENT REPORT 1998, *supra* note 13.

1974,²² and the scientific community only accepted this link as conclusively proven in 1987,²³ at which time the patent incentive for development of CFC-related inventions had already been in place for over fifty years.

Although the original CFC patents were granted—and expired—during an era of scientific ignorance with regard to the harmful effects of CFCs on the ozone layer, the USPTO continued granting CFC-related patents throughout the subsequent eras of scientific uncertainty and certainty regarding the destructive effects of the compounds. For example, during the era of scientific uncertainty between 1974 and 1987, the USPTO granted several new patents for CFC-related aerosol products,²⁴ irrespective of the debate then being waged between environmentalists—who asserted a link between CFCs and atmospheric ozone depletion—and the CFC industry, which consistently denied any such link.²⁵ Even in the post-1987 era of relative scientific certainty regarding the negative impacts of CFCs, the USPTO continued granting new patents for CFC-related products and methods. Disturbingly, the USPTO continued this practice even after twenty-three primary CFC-producing nations, including the United States, signed the Montreal Protocol²⁶ in an effort to reduce CFC concentrations in the atmosphere. Despite such a clear indication of a national policy to avoid further production and dissemination of CFCs, and even after the United States signed the Protocol's 1990 amendment requiring a phase out of CFC production by the year 2000,²⁷ the USPTO granted at least seventeen patents specifying aerosol uses of CFCs.²⁸

A second example illustrating the USPTO practice of granting patents on environmentally toxic substances is DDT. DDT is an organic chemical compound that was introduced commercially in 1938 as a

22. Molina & Rowland, *supra* note 12.

23. See Anderson et al., *supra* note 14 (finding a conclusive link between chlorine molecules dissociated from CFCs and stratospheric ozone depletion).

24. See, e.g., 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. 4,407,982 (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. 4,518,557 (filed May 18, 1981) (issued May 21, 1985) (claiming a method of producing a polymer plastic using a CFC blowing agent); 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).

25. Anderson et al., *supra* note 14, at 12.

26. Montreal Protocol on Substances that Deplete the Ozone Layer, Sept. 16, 1987, S. Treaty Doc. No. 100-10 (1987), 1522 U.N.T.S. 3 [hereinafter Montreal Protocol].

27. See Amendment to the Montreal Protocol, *supra* note 15.

28. See *supra* note 7.

highly promising insecticide with the potential to curtail insect-borne diseases.²⁹ Since its introduction, DDT has been successfully used in many countries to combat epidemics of such serious illnesses as typhus and malaria.³⁰ However, questions about the harmful environmental effects of DDT quickly arose, and scientists began voicing reservations about DDT “almost as soon as it first went into use”³¹ because it was found to persist in soil “for several years and could become magnified in a food chain.”³² Scientists now classify DDT as a “persistent organic pollutant”³³ (POP), and it is well-accepted that DDT in the environment leads to a number of adverse human health effects, including genital abnormalities and decreased fertility.³⁴

However, as required by current U.S. law, the USPTO continued to grant DDT-related patents when the era of scientific ignorance regarding DDT ended and even after scientific uncertainty gave rise to an era of scientific certainty about DDT’s harmful effects. As in the case of CFCs, the patent incentive for DDT remained in place even when other U.S. government action clearly indicated the existence of a national policy to eliminate virtually all domestic use of the chemical. Specifically, studies commissioned by the U.S. Department of Agriculture (USDA) in the late 1960s confirmed that DDT had numerous harmful consequences and persisted residually in the environment,³⁵ and as a result, the USDA cancelled the registration of many uses of DDT in 1969, effectively outlawing harmful uses of the chemical.³⁶ The U.S. Environmental Protection Agency (EPA) followed suit in 1973 by banning the domestic use of DDT due to its negative ecological and public health impacts,³⁷ subject to a small number of public health exceptions.³⁸ However, despite these actions by other U.S.

29. COLBORN ET AL., *supra* note 18, at 68.

30. History of POPs Discovery, Use and Ban, <http://www.cneac.com/article/list.asp?id=25> (last visited Nov. 5, 2006).

31. *Id.*

32. *Id.*

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

34. *Id.* at 857.

35. N. AM. COMM’N FOR ENVTL. COOPERATION, HISTORY OF DDT IN NORTH AMERICA TO 1997, http://www.cec.org/files/pdf/POLLUTANTS/HistoryDDTe_EN.PDF (last visited Nov. 5, 2006) [hereinafter HISTORY OF DDT].

36. *Id.*

37. DDT Ban Press Release, *supra* note 16.

38. 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

government agencies, the USPTO continued to grant patents for inventions related to insecticidal use of DDT.³⁹ Under U.S. patent law, the USPTO would be legally compelled to grant such a patent even now, if an inventor met all of the statutory requirements for patentability.⁴⁰

A third and especially compelling example is that of asbestos-related inventions, which illustrates how the state of knowledge regarding the effects of a substance on public health has no impact on the patentability of the substance under U.S. law. Processed asbestos fibers are very strong and have excellent insulating properties, and as a result asbestos has been used for centuries in many products. These products include, for example, floor tiles, plaster, wallboard, pipe insulation, and roof shingles, among many others.⁴¹ However, asbestos is carcinogenic—particularly when inhaled—and human exposure to its dust can lead to a host of maladies, including cancers such as lung cancer and mesothelioma, among others.⁴²

Health hazards related to asbestos have been known since at least 1898, when factory inspectors noticed the harmful consequences of breathing asbestos particles.⁴³ More generally, asbestos has a long and well-documented history of producing human illness among those exposed to the substance. Asbestosis, a scarring of the lungs that can

still considered the best way to prevent the spread of malaria in some developing nations, despite its adverse effects. *Id.*

39. See, e.g., 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); 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. 2,329,074 (filed Mar. 4, 1941) (issued Sept. 7, 1943) (the original DDT patent). 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.

40. 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 35, at 2 (noting that Congress has not yet acted to prohibit domestic production of DDT).

41. See Where Can Asbestos Be Found?, <http://www.epa.gov/asbestos/pubs/asbuses.pdf> (last visited Nov. 5, 2006) (listing several dozen categories of products in which asbestos is commonly found).

42. BARRY I. CASTLEMAN, ASBESTOS: MEDICAL AND LEGAL ASPECTS 90–100 (1984).

43. See EUROPEAN ENVTL. AGENCY, LATE LESSONS FROM EARLY WARNINGS: THE PRECAUTIONARY PRINCIPLE IN THE 20TH CENTURY 1 (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 government of the United Kingdom did not ban the substance until one hundred years later, resulting in hundreds of thousands of arguably foreseeable deaths).

lead to breathing problems and heart failure, “was by 1935 widely recognized as a mortal threat affecting a large fraction of those who had regularly worked with the material.”⁴⁴ An international panel of lung cancer experts, chaired by an American doctor affiliated with the U.S. National Cancer Institute, convened in 1952 to discuss recent worldwide increases in the rate of lung cancer.⁴⁵ The following year, the panel published a report—the so-called “Louvain report” of 1953—unequivocally acknowledging that asbestos was carcinogenic.⁴⁶ Action by the U.S. government eventually followed in 1989, when the EPA formally banned the production and sale of most products containing asbestos.⁴⁷ Although this ban was later partially reversed by the U.S. Court of Appeals for the Fifth Circuit,⁴⁸ the reversal was for legal rather than scientific reasons,⁴⁹ and many asbestos-containing products remain banned domestically as a result of the 1989 EPA action.

Nevertheless, the USPTO has been continuously granting patents for asbestos-containing products since the early nineteenth century.⁵⁰ Because patentability in this country is completely decoupled from actions by other U.S. government agencies relating to public health, the patent incentive for asbestos-related inventions remains in place despite even the formal ban on asbestos by the EPA, and the USPTO has granted many patents on asbestos-containing products since then.⁵¹ Put differently, despite a longstanding era of scientific certainty with respect to the harmful public health impacts of asbestos, the USPTO has continued to grant U.S. patents for asbestos-containing inventions essentially up to the present day.

Furthermore, the cases of CFCs, DDT, and asbestos are by no means isolated. Other notable instances of patented technologies that

44. CASTLEMAN, *supra* note 42, at 31.

45. *Id.* at 68.

46. *Id.*

47. EPA Asbestos Ban, *supra* note 16.

48. *Corrosion Proof Fittings v. Envtl. Prot. Agency*, 947 F.2d 1201, 1230 (5th Cir. 1991).

49. *See id.* at 1229 (describing the 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).

50. *See* Obron, *supra* note 16 (describing the first U.S. patent for an asbestos-containing product, issued in 1828).

51. *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 Dec. 5, 1983) (issued Oct. 8, 1985) (claiming load-bearing horizontal tiles that may be constructed from asbestos).

have given rise to harmful consequences include patents for various other chemical pollutants such as polychlorinated biphenyls (PCBs),⁵² carcinogenic food and beverage additives such as some food, drug, and cosmetic (FD&C) dyes,⁵³ and mechanical inventions such as the two-stroke internal combustion engine.⁵⁴ The proliferation of such patents—in some cases even concurrent with attempts by other government agencies to ban the substances—evidences the inadequacies of our current laws. At present, there is simply no connection between scientific evidence indicating that a substance has harmful effects, domestic and international attempts to ban the substance, and the patent incentive.

II. THE SCOPE OF PATENTABILITY

A patent essentially provides to the patentee a temporary right to exclude others from manufacturing, selling, using, or importing a proprietary invention. This concept was apparently first set forth in writing in the fourth century B.C. by Aristotle (who attributed the idea to Hippodamus),⁵⁵ but Renaissance-era Venice provides the first known regulated system of granting patents. In fact, according to one commentator, the Venetian Senate's 1474 Act⁵⁶ 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

52. PCBs were first synthesized in the late nineteenth century. *See, e.g.*, Environmental Literacy Council, Persistent Organic Pollutants, <http://www.enviroliteracy.org/article.php/1176.html> (last visited Nov. 4, 2006) (describing the history of PCBs). PCBs were ultimately banned by Congress in 1976 due to their toxic effects. Toxic Substances Control Act, Pub. L. No. 94-469, 90 Stat. 2003 (codified as amended at 15 U.S.C. § 2605(e) (2000)).

53. *See, e.g.*, FDA, Ctr. for Food Safety and Applied Nutrition, Color Additives Fact Sheet, <http://www.cfsan.fda.gov/~dms/cos-221.html> (last visited Nov. 22, 2006) (describing the history of various banned food dyes).

54. 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. Press Release, Env'tl. Def., Env'tl. Def. Blasts Snowmobile Pollution Standards (Sept. 13, 2002), available at <http://www.environmentaldefense.org/pressrelease.cfm?ContentID=2300>.

55. ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, *PATENT LAW AND POLICY: CASES AND MATERIALS* 1 (3d ed. 2002).

56. *Id.* at 3.

sets forth a procedure to determine infringement, as well as a remedy.⁵⁷

Notably, however, 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. While this remains the case under current U.S. law, many other nations have chosen to incorporate such exclusions into their contemporary patent statutes.⁵⁸ The current scope of patentability under the laws of the United States and foreign nations are briefly considered in this section.

A. A Brief Examination of Patentable Subject Matter in the United States

U.S. patent law grants to inventors the temporary right to exclude others within this country from making, using, selling, or importing the patented invention, as defined by the "claims" of the patent.⁵⁹ Violating any of these prohibitions is called infringing the patent, and a party who does so may be subject to civil penalties including an injunction, damages, and attorney fees.⁶⁰ With some relatively minor exceptions, the right to exclude currently extends from the date the USPTO issues the patent, to a date twenty years from the filing date of the patent application.⁶¹ To obtain a patent, an inventor must satisfy a number of formal and substantive requirements. These are intended to ensure the novelty and authenticity of the invention, as well as to require sufficient public disclosure in return for the right to exclude. To check that these requirements are properly met, every patent application is evaluated by one or more professional Patent Examiners employed by the USPTO.⁶²

57. *Id.* at 4.

58. *See infra* Part II.B.

59. 35 U.S.C. § 271 (2000).

60. *Id.* §§ 281–285.

61. *Id.* § 154(a)(2). The exceptions are 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.* Second, the term of a patent resulting from an application filed before June 8, 1995, runs for the longer of either seventeen years from the date of issue of the patent or twenty years from the date of its application. *See MERGES & DUFFY, supra* note 55, at 59 (describing this exception). Finally, the term of a patent may be extended due to delays in the examination process attributable to the USPTO. 35 U.S.C. § 154(b).

62. 35 U.S.C. § 131.

1. Formal Requirements

To ensure adequate public disclosure of an invention in return for the temporary right to exclude others from its practice, a patent application must include a specification of the invention, to be published upon the grant of a patent, which contains the following:

[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 of carrying out his invention.⁶³

In addition to the development incentive offered by the possibility of a temporary monopoly, public disclosure via the patent specification is the primary mechanism by which patent law seeks to promote technological progress. By requiring enough disclosure to allow others in the same field to copy, refine, and improve the patented invention, the written specification requirement is designed to ensure that inventors can build upon the prior ideas of others, presumably leading to more rapid progress in that field. The patented invention itself must be precisely described in an application by at least one patentable “claim,” which must be supported by the language of the written disclosure, and which legally defines the subject matter of the invention.⁶⁴ Finally, the USPTO also imposes a large number of additional formal and stylistic requirements upon patent applications.⁶⁵ These are largely designed with clarity of the public record and agency efficiency in mind, and are not of particular concern here.

2. The Substantive Scope of Patentable Subject Matter

U.S. patent law also imposes four substantive requirements to obtain a patent. These include sufficient utility, novelty, and nonobviousness of the invention, and also a requirement that the invention fall within the confines of patentable subject matter. Patentable subject matter is defined in the United States both by statute and by the common law.⁶⁶ The Patent Act states broadly that “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of

63. *Id.* § 112.

64. *Id.*

65. *See, e.g., id.* §§ 113, 115, 119 (requiring a drawing when necessary, an oath of originality by the inventor, and a statement claiming priority to any earlier filed applications).

66. *Id.* §§ 101–103.

matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”⁶⁷ However, once Congress has spoken, it is the “province and duty of the judicial department to say what the law is,”⁶⁸ and the limits of patentable subject matter have been further developed at common law. As a result, certain categories of inventions have been specifically excluded from patentable subject matter in the United States, including physical phenomena, abstract ideas, and naturally occurring substances that have not been purified or otherwise refined by the inventor.⁶⁹ Thus, for example, a physicist may not patent a newly discovered theory, and a geologist may not patent a newly discovered mineral.⁷⁰ In addition, for obvious national security reasons, separate federal legislation excludes from patentability “any invention or discovery which is useful solely in the utilization of special nuclear material or atomic energy in an atomic weapon.”⁷¹

Although the exclusions described above limit patentable subject matter in various narrowly defined ways, the courts have given only limited attention to the more general question of whether to exclude an invention from patentability merely because of its possible negative impacts upon society. This exclusionary doctrine of so-called “beneficial utility”⁷² dates back at least to 1817, when the court in *Lowell v. Lewis*⁷³ summarized the nineteenth-century view of the doctrine 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.”⁷⁴ However, beneficial utility no longer plays a significant role

67. *Id.* § 101.

68. *Marbury v. Madison*, 5 U.S. (1 Cranch) 137, 177 (1803).

69. *See, e.g., O’Reilly v. Morse*, 56 U.S. (15 How.) 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).

70. The distinction between an abstract idea and an invented process is not entirely clearly defined, and it 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) (citation omitted).

71. 42 U.S.C. § 2181(a) (2000).

72. *See generally* MERGES & DUFFY, *supra* note 55, at 216–28 (defining and describing the history and current status of the doctrine).

73. *Lowell v. Lewis*, 15 F. Cas. 1018 (C.C.D. Mass. 1817) (No. 8568).

74. *Id.* at 1019.

in defining the boundaries of patentable subject matter in this country. For instance, in an opinion upholding the patentability of an invention that had the effect of misleading consumers as to the source of the purchased product,⁷⁵ 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.”⁷⁶ As a result, even inventions specifically designed to facilitate breaking the law may be deemed patentable. For example, in *Whistler Corp. v. Autotronics, Inc.*,⁷⁷ the court enforced a patent directed toward radar detectors designed to help motorists avoid speeding tickets. In stating that the court “cannot and should not substitute its own views in place of those of . . . the several legislatures, or the Congress,”⁷⁸ the *Whistler* court declined to carve out a legality-based exclusion to the broad statutory standard of patentable subject matter laid out in the U.S. Patent Act, instead indicating that this carving out should fall to Congress.

In fact, the trend in recent decades has been for courts in the United States to define the bounds of patentable subject matter ever more broadly. Other than the requirements of utility, novelty, and nonobviousness, Congress has carved out only two relatively minor statutory exceptions from patentable subject matter: inventions the sole use of which is to build a nuclear weapon,⁷⁹ and human clones.⁸⁰ Thus, the bounds of patentable subject matter in this country currently incorporate no statutory or common law exclusions related to legality, public health, or the environment,⁸¹ and in fact the current U.S. practice is that “anything under the sun that is made by man” should be patentable.⁸² As a result, the USPTO routinely grants patents for inventions that have harmful impacts on public health and the

75. *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1367 (Fed. Cir. 1999).

76. *Id.* at 1366–67.

77. *Whistler Corp. v. Autotronics, Inc.*, 14 U.S.P.Q.2d 1885 (N.D. Tex. 1988).

78. *Id.* at 1886.

79. 42 U.S.C. § 2181(a) (2000); *see supra* text accompanying note 71.

80. 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. *See supra* note 71 and accompanying text.

81. *See supra* note 80.

82. S. REP. NO. 82-1979, at 5 (1952), *as reprinted in* 1952 U.S.C.C.A.N. 2394, 2399; H.R. REP. NO. 82-1923, at 6 (1952).

environment, and is required by law to do so.⁸³ This is true regardless of whether the harmful impacts of the invention are merely suspected or are known with scientific certainty, and it remains true even if the actions of other U.S. government agencies indicate a national policy to eliminate the subject matter of the invention from public use. Figure 1 below illustrates the broad scope of patentability under current U.S. law.

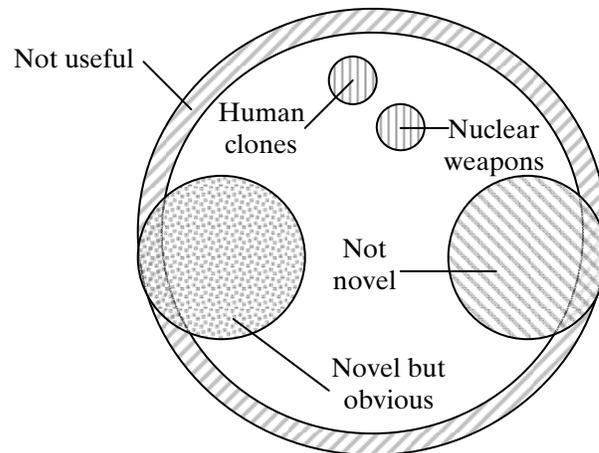


Figure 1

The scope of patentability in the United States as of 2004, with areas excluded from patentability indicated by shading. In addition to the requirements of utility, novelty, and nonobviousness, Congress has carved out only two relatively minor statutory exceptions from patentable subject matter: inventions the sole use of which is to build a nuclear weapon and human clones.

B. Patentable Subject Matter in Foreign Laws and International Treaties

1. Exclusions for Harmful Inventions

In contrast to the broad scope of patentable subject matter in the United States, the laws of many other nations incorporate provisions designed to remove the patent incentive for sufficiently harmful

83. Before outlining any exceptions and requirements, including the novelty requirement, § 102 states that “[a] person shall be entitled to a patent.” 35 U.S.C. § 102 (2000) (emphasis added).

inventions. For example, Brazilian patent law provides a number of statutory exclusions from patentability, which limit the scope 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 utility, novelty, and nonobviousness in the Brazilian patent code. The Brazilian exclusions include not only nuclear technology and human clones⁸⁴ as in the United States, but also “anything contrary to morals, standards of respectability and public security, order and health.”⁸⁵

The Brazilian exclusions to patentable subject matter are typical of precautionary exclusions in the patent laws of many nations.⁸⁶ In general, nations have adopted similar exclusions to patentable subject matter based on at least five criteria: morality, public policy (or public order), legality, public health, and environmental harm. More specifically,⁸⁷ of at least 142 nations having independent patent laws with clearly delineated patentability standards, as of 2004, approximately 104 had a morality exclusion, 83 had a public policy or public order exclusion, 38 had a legality exclusion (barring patents on inventions the use of which would conflict with other national laws),⁸⁸ 21 had a public health exclusion,⁸⁹ and 11 had an environmental harm exclusion.⁹⁰ Only 27 of the 142 nations, including the United States, did not exclude inventions from patentability based on any of these five factors.⁹¹ Figure 2 illustrates the scope of patentability with sufficiently harmful inventions excluded.

84. Decreto No. 9.279, de 14 de maio de 1996, D.O.U. de 14.05.1996. (Brazil).

85. *Id.*

86. *See generally* PATENTS THROUGHOUT THE WORLD (Alan J. Jacobs ed., 4th ed. 2006) (summarizing the patent laws of over 150 nations and cooperative treaties).

87. The author has compiled the statistics cited in the text through an independent study of *Patents Throughout the World*. *Id.*

88. 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, c. 37, §§ 1(3)–(4) (Eng.).

89. 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. *See supra* note 87.

90. The eleven nations are Bolivia, Colombia, Ecuador, Jordan, Kenya, Mongolia, Peru, Saudi Arabia, Trinidad and Tobago, Uruguay, and Venezuela. *See supra* note 87.

91. *See supra* note 87.

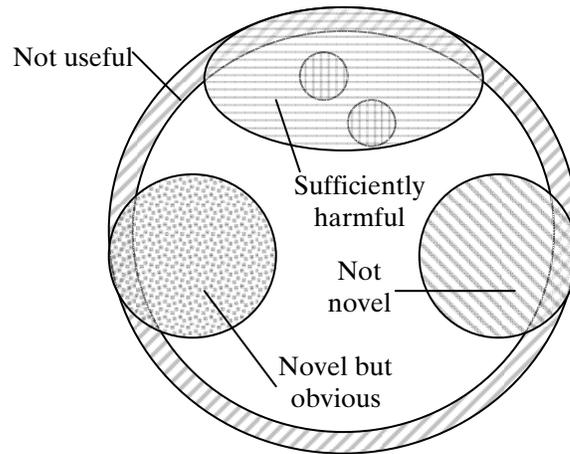


Figure 2

The scope of patentability with sufficiently harmful inventions excluded, as provided, for example, by the patent law of Brazil. Many other national laws and some international treaties exclude from patentability inventions deemed harmful to morality, public policy, legality, public health, and/or the environment.

2. Exclusions for Beneficial Inventions

At first glance, providing patent protection for inventions that have purely beneficial impacts appears entirely appropriate, and this is true with respect to incentivizing development of such inventions. However, when monopoly pricing is combined with the tremendous disparity in wealth that exists between the people of various nations today, the result may be that only the wealthiest citizens gain access to beneficial products, some of which may be vital to maintain the public health. To combat this possibility, many nations have historically excluded various beneficial inventions from patentability, although the number of such nations has been steadily decreasing under pressure from the United States and other industrialized countries.⁹² For example, prior to 2005, the patent law of India excluded the following from patentability:

92. For example, a United Nations survey in the 1970s showed that “about 90 developing countries and a few developed countries including France, Germany, Italy, Japan, Switzerland and Sweden had enacted national laws on patents which excluded pharmaceutical products from patent production.” K. Balasubramaniam, Advisor & Coordinator, Health Action Int’l Asia-Pacific, Patent Policies and Pharmaceutical Prices,

- (g) a method or process of testing applicable during the process of manufacture for rendering the machine, apparatus or other equipment more efficient or for the improvement or restoration of the existing machine, apparatus or other equipment or for the improvement or control of manufacture;
- (h) a method of agriculture or horticulture; [and]
- (i) any process for the medicinal, surgical, curative, prophylactic or other treatment of human beings or any process for a similar treatment of animals or plants to render them free of disease or to increase their economic value or that of their products.⁹³

Indian law further provided that for inventions “claiming substances intended for use, or capable of being used, as food or as medicine or drug . . . no patent shall be granted in respect of claims for the substances themselves.”⁹⁴ In other words, prior to 2005, Indian law excluded from patentability efficiency testing methods, agricultural methods and products, and medical methods and products, including pharmaceutical drugs. However, although a substantial number of developing nations have attempted to mitigate monopoly pricing of beneficial products through their domestic patent laws, regional and international treaties such as the North American Free Trade Agreement (NAFTA)⁹⁵ and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs Agreement)⁹⁶ have forced those nations to undo these mitigating patentability exclusions and to provide patent protection equivalent to that of the most developed nations.⁹⁷ Figure 3 illustrates the scope of patentability with both sufficiently harmful and various beneficial inventions excluded.

Lecture delivered to Post Graduate Diploma in Health Development, Faculty of Medicine at the University of Colombo (Oct. 16, 2004), <http://www.haiap.org/unipaper.htm>. As of 1988, there were approximately fifty such nations. Julio Nogués, *Patents and Pharmaceutical Drugs: Understanding the Pressures on Developing Countries* 4 (Int’l Econ. Dept., The World Bank, Working Paper No. 502, 1990), available at http://www-wds.worldbank.org/servlet/WDSContentServer/WDSP/IB/1990/09/01/000009265_3960929170142/Rendered/PDF/multi0page.pdf.

93. Patents Act, No. 39 of 1970, Acts of Parliament, 1970.

94. *Id.*

95. North American Free Trade Agreement, U.S.-Can.-Mex., Dec. 17, 1992, 32 I.L.M. 605 (1993) [hereinafter NAFTA].

96. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments—Results of the Uruguay Round, 33 I.L.M. 1125, 1197 [hereinafter TRIPs Agreement].

97. For example, to comply with the TRIPs Agreement, India amended its Patent Act in 2005 to remove section 5, which had excluded pharmaceuticals from patentability. Patents (Amendment) Act, 2005, No. 15, Acts of Parliament, 2005.

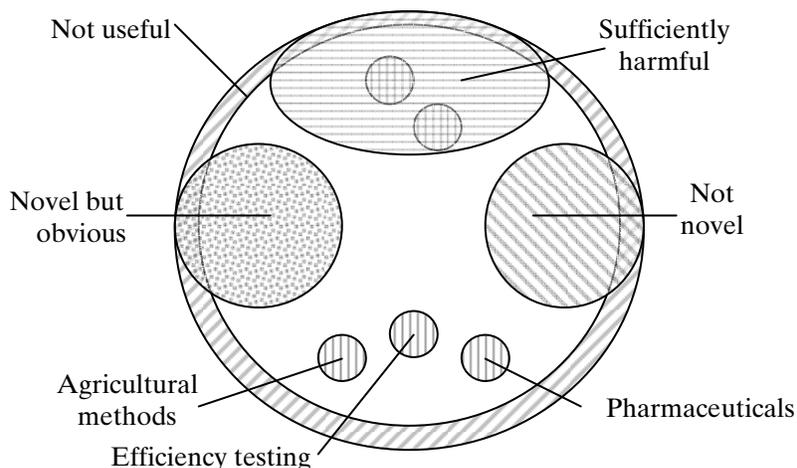


Figure 3

The scope of patentability with all sufficiently harmful and some beneficial inventions excluded, as exemplified by the patent law of India prior to 2005. In addition to excluding harmful inventions from patentability, Indian law also excluded certain beneficial inventions to preclude monopoly pricing for those inventions. The excluded categories included testing methods for improving manufacturing efficiency, agricultural methods and products, and perhaps most significantly, pharmaceutical drugs.

3. Exclusions in International Treaties

As noted above, a number of international treaties also govern patentability. Rather than serving as distinct sources of law, these treaties generally require signatory nations to conform their national laws to the treaty provisions or face economic sanctions. For example, the European Patent Convention,⁹⁸ which governs the patent laws of thirty-one member states,⁹⁹ provides that patents shall not be granted for “inventions the publication or exploitation of which would be contrary

98. Convention on the Grant of European Patents, Oct. 5, 1973, 1065 U.N.T.S. 199 [hereinafter European Patent Convention].

99. A list of the thirty-one member states of the European Patent Organization (EPO) is available on the EPO Web site. See EPO Member States, <http://www.european-patent-office.org/epo/members.htm> (last visited Nov. 14, 2006).

to ‘ordre public’ or morality.”¹⁰⁰ Even more broadly, the Eurasian Patent Convention,¹⁰¹ ratified by ten Eurasian nations,¹⁰² provides that Eurasian patents shall not be granted for . . . inventions, the commercial use of which it is essential to prevent, for the purposes of protecting public order or morality, including the protection of the life and health of people and animals or the protection of plants, or in order to prevent serious damage being caused to the environment.¹⁰³

Significantly, the exclusions provided by the European and Eurasian conventions are mandatory, rather than optional. In other words, the thirty-one states party to the European Patent Convention *must* incorporate a morality exclusion into their national patent laws, and the ten states party to the Eurasian Patent Convention *must* incorporate exclusions based on public morality, public health, and environmental harm.¹⁰⁴

In contrast, a second set of treaties allow for optional patentability exclusions for harmful inventions. For example, NAFTA provides that [a] Party *may* exclude from patentability inventions if preventing in its territory the commercial exploitation of the inventions is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to nature or the environment, provided that the exclusion is not based solely on the ground that the Party prohibits commercial exploitation in its territory of the subject matter of the patent.¹⁰⁵

Similarly, the TRIPs Agreement provides that

[m]embers *may* exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to

100. European Patent Convention, *supra* note 98, art. 53.

101. Eurasian Patent Convention, Sept. 9, 1994, Industrial Property Laws & Treaties, text 2-013, *available at* http://www.wipo.int/clea/docs_new/pdf/en/ea/ea001en.pdf.

102. These nations are the Republic of Azerbaijan, the Republic of Armenia, the Republic of Belarus, Georgia, the Republic of Kazakhstan, the Kyrgyz Republic, the Republic of Moldova, the Russian Federation, the Republic of Tajikistan, and Ukraine. Eurasian Patent Organization (EAPO), States Party to the Convention, <http://www.eapo.org/eng/information/about.html> (last visited Nov. 14, 2006).

103. Patent Regulations Under the Eurasian Patent Convention, ch. II, R. 3(4), Dec. 1, 1995, Industrial Property Laws & Treaties, text 2-014, *available at* <http://www.eapo.org/eng/documents/doc/ea002en.pdf>.

104. *See supra* notes 98–103.

105. NAFTA, *supra* note 95, art. 1709 (first emphasis added).

avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by domestic law.¹⁰⁶

However, since the patentability exclusions provided in NAFTA and the TRIPs Agreement are merely optional, neither treaty should be viewed as providing meaningful limits to the scope of patentability. Instead, these optional exclusions simply render NAFTA and the TRIPs Agreement compatible with the laws of nations already requiring exclusions for harmful inventions, such as the signatories to the European and Eurasian conventions.

In fact, NAFTA and the TRIPs Agreement have the overall effect of significantly broadening patentability scope worldwide by forcing member nations to provide patents for all inventions other than those subject to the optional exclusions noted above. For example, the TRIPs Agreement provides that aside from the optional exclusions, “patents shall be available for *any* inventions, whether products or processes, in *all* fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.”¹⁰⁷ This apparently includes, *inter alia*, efficiency testing methods, agricultural methods, and pharmaceuticals, i.e., all of the exclusions carved out by Indian law. That the TRIPs Agreement requires patentability of these and other beneficial inventions is highly significant to the world economy. As an agreement promulgated by the World Trade Organization (WTO), the TRIPs Agreement applies to all WTO member nations,¹⁰⁸ of which there are currently 149, with another thirty-two “observer” nations committed to eventual membership.¹⁰⁹ Thus, the TRIPs Agreement—and to a lesser extent NAFTA¹¹⁰—essentially precludes all patentability

106. TRIPs Agreement, *supra* note 96, art. 27 (first emphasis added). The treaty also allows optional exclusions for medical methods, for animals, and for plants other than plant varieties, which must remain patentable. *Id.*

107. *Id.* (emphasis added).

108. See WTO, Intellectual Property (TRIPS), Frequently Asked Questions, http://www.wto.org/english/tratop_e/trips_e/tripfq_e.htm (last visited Nov. 14, 2006) [hereinafter WTO TRIPS FAQ] (noting that the TRIPs Agreement “applies to all WTO members”).

109. See WTO, Understanding the WTO, Members, http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (last visited Nov. 14, 2006) (providing lists of current members and observers, and noting that “observers must start accession negotiations within five years of becoming observers”).

110. Note that NAFTA applies only to the United States, Canada, and Mexico. See NAFTA, *supra* note 95.

exclusions designed to counteract monopoly pricing of beneficial inventions, in virtually every country in the world.¹¹¹

Not surprisingly, developing nations have searched for loopholes in the TRIPs Agreement that might allow them to continue the practice of excluding some beneficial products, particularly pharmaceuticals, from patentability.¹¹² One possibility is to characterize the exclusions as necessary for public health, thus bringing them within the scope of the optional exclusions explicitly allowed by the TRIPs Agreement.¹¹³ However, proving that limits to patentability are “necessary” may be difficult or impossible, and nations may not want to risk possible WTO trade sanctions if a dispute arises. A second option is compulsory licensing, which is authorized by the TRIPs Agreement in cases of “a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use,”¹¹⁴ or if “the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions.”¹¹⁵ These conditions also may be difficult to meet, or may result in high prices for the product despite the compulsory license. Furthermore, a license is useless to a nation that lacks the capability to manufacture the invention. Finally, parallel imports are allowed by the TRIPs Agreement,¹¹⁶ enabling developing nations to import products from international resellers rather than exclusively from the patent holder, thus providing

111. One exception is that “least developed countries” have been granted an extension until 2016 to provide for patentability of pharmaceuticals. WTO TRIPs FAQ, *supra* note 108.

112. In fact, developing nations attended the WTO Ministerial Conference in Doha, Qatar, in November 2001, for the express purpose of finding legal strategies to mitigate the harmful effects of the TRIPs Agreement to their citizenry. The result was the Doha Declaration, a political statement that affirmed that the TRIPs Agreement allows both compulsory licensing and parallel imports. World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/1, 41 I.L.M. 746 (2002) [hereinafter Doha Declaration].

113. See TRIPs Agreement, *supra* note 96, art. 27. The TRIPs Agreement also explicitly provides that “[m]embers may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socioeconomic and technological development, provided that such measures are consistent with the provisions of this Agreement.” *Id.* art. 8(1).

114. *Id.* art. 31.

115. *Id.*

116. See Doha Declaration, *supra* note 112; see also TRIPs and Public Health: The Situation Before Cancún, http://www.wto.org/English/tratop_e/trips_e/health_background_e.htm (last visited Nov. 14, 2006) (noting that the TRIPs Agreement allows parallel imports).

competition between sources of the same product. However, despite the presence of these various loopholes in the TRIPs Agreement, its general effect has been to broaden the worldwide scope of patentability and to raise pharmaceutical prices in developing nations.¹¹⁷

III. A PROPOSED INTERNATIONAL STANDARD FOR THE SCOPE OF PATENTABILITY¹¹⁸

From a purely economic standpoint, providing the broadest possible scope of patentability makes sense because it provides the greatest range of incentives and profits to inventors and to the manufacturers who fund their research. However, as described above, this can have undesirable non-economic consequences, including damaging impacts to the environment and public health. As has been illustrated, to counteract the undesirable consequences of incentivizing harmful inventions and offering monopolies that limit access to beneficial inventions, some national laws and international treaties have limited the permissible scope of patentability to exclude both harmful and beneficial inventions in various circumstances. The scope of patentability should be limited still further. This section provides a proposal for the appropriate scope of patentability in international law. The proposed scope would require utility, novelty, and nonobviousness, would uniformly exclude from patentability sufficiently harmful inventions, and would selectively exclude sufficiently beneficial inventions only in qualifying developing nations.

A. Harmful Inventions: What to Exclude

I propose that provisions be added to domestic laws and international treaties to universally remove the incentive to create

117. In India, implementation of the TRIPs Agreement will likely cause drug prices to rise dramatically. For example, in 1995 the drug Zantac (generically known as ranitidine) retailed in India for 18.53 rupees, in the United Kingdom at the equivalent of 484 rupees (26.1 times as much), and in the United States at the equivalent of 1050 rupees (56.7 times as much). In Pakistan, which has an economy similar to India but allows pharmaceutical patents, Zantac retailed in 1992 for the equivalent of 261 rupees, 14.1 times the price in India three years later. See Jean O. Lanjouw, *The Introduction of Pharmaceutical Product Patents in India: "Heartless Exploitation of the Poor and Suffering"?* 37 (Nat'l Bureau of Econ. Res., Working Paper No. 6366, 1998), available at <http://www.oiprc.ox.ac.uk/JLWP0799.pdf>.

118. In an earlier work, I outlined a related proposal for incorporating a precautionary principle into the patent laws of the United States. See Shawn Kolitch, Comment, *The Environmental and Public Health Impacts of U.S. Patent Law: Making the Case for Incorporating a Precautionary Principle*, 36 ENVTL. L. 221, 249–55 (2006). Portions of Part III are gleaned from that work.

harmful inventions. In the United States, for example, this would require amendment to the applicable patent statutes. The U.S. Congress would need to amend 35 U.S.C. § 101, which 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.”¹¹⁹ For purposes of U.S. law, I propose that Congress add to § 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.” Likewise, comparable provisions should be added to the domestic laws of other nations, and international treaties should be modified to allow these domestic provisions.

The essential policy question for undertaking to devise and implement provisions limiting the scope of patentability for harmful inventions is exactly what would be the new legal limits of patentable subject matter. In other words, *how* detrimental is “sufficiently detrimental” to exclude an invention from patentability? Presumably the answer to this question should balance environmental and public health interests on one hand, with both the development incentive and the economic interests of potential inventors and other would-be patent owners on the other hand.¹²⁰ It is important to consider the policy question of where to draw the line for precautionary exclusion from patentability, while still maintaining a sufficient economic patent incentive to promote technological progress and innovation in appropriate areas.

1. Banned Substances

No reasonable justification exists for maintaining the patent incentive to develop inventions involving substances that a government has clearly indicated should be removed from domestic production and use. Therefore, as a matter of public policy, patent provisions should exclude from patentability all inventions claiming substances facing an imminent domestic production ban or phase out at the time of the patent application.¹²¹

119. 35 U.S.C. § 101 (2000).

120. 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.

121. 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

Excluding banned (or nearly banned) substances from patentability would merely remove the patent incentive to invent in areas where regulatory action leading toward a ban already clearly indicates government recognition that a substance is harmful. Because bans are typically enacted only in the face of incontrovertible evidence regarding the harmful effects of a substance, placing such limits would essentially allow removal of the patent incentive at least for inventions known *with scientific certainty* to be harmful. More generally, the practice would close an existing loophole that maintains the patent incentive during the interval between regulatory action leading towards a ban on production of a substance, and the production ban taking final effect. Removing the patent incentive in such cases is inherently reasonable because an imminent ban or phase out of production strongly suggests that use of the banned substance in a proposed invention is “sufficiently detrimental” to exclude the invention from patentability.

Similarly, patentable subject matter should exclude inventions involving substances facing an imminent ban or phase out on domestic *use*—as opposed to production—at the time of the patent application. Typically, a ban on domestic use will be accompanied by a production ban, but in rare cases a regulation may ban domestic use of a substance without a commensurate ban on domestic production, indicating that the substance still may be used in other nations. One might argue that the patent incentive in such cases should be preserved to induce prospective inventors to “improve” these fields of invention for the benefit of companies producing and exporting the related products. However, inducing research in alternative technologies by removing the patent incentive for clearly harmful substances would better serve ultimate policy goals, including the articulated purpose of patents under U.S. law to promote the “Progress of Science and useful Arts.”¹²² Of course, removing the patent incentive does not in and of itself constitute a ban of any sort, and excluding from patentability a substance whose domestic use is banned would in no way affect either domestic production or foreign use of previously patented inventions related to the substance. Rather, limiting the patent incentive would serve only as

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.

122. U.S. CONST. art. I, § 8, cl. 8.

a subtle force to move future technological development in a more beneficial direction.

2. Other Inherently Reasonable Exclusions

Aside from imminent regulatory bans on production and use of a substance, other indicators of scientific certainty regarding the harmful impacts of the substance should be used to exclude related inventions from patentability as “sufficiently detrimental.” Such alternative indicators, which often serve as the precursors of bans, could include reports by scientific panels, scientific review articles, conference proceedings, and so forth. While such a change in our patent incentive scheme might not *prevent* the production and use of some products containing undesired substances, development of those products might be significantly decreased in favor of safer alternatives for which the patent incentive remains intact. In general, removing the patent incentive immediately upon the arrival of scientific consensus regarding a substance’s harmful impacts, rather than waiting years or decades for the announcement of a regulatory ban or phase out of the substance, seems most consistent with the notion of using patents to promote developments and advancements.

3. Scientific Uncertainty and True Precaution

Most controversially, but also perhaps most importantly, a truly precautionary step would be to exclude from patentability inventions merely *suspected* of causing sufficient harm to the environment or public health. For instance, an invention’s potential harm could be assessed in consultation with the agencies that provide lists of substances that are banned or otherwise known with relative certainty to have “sufficiently detrimental” environmental or public health effects. In borderline cases, risk assessments could be performed with appropriate domestic agencies. Although the precise standards for such assessments would have to be defined with regard to patentability, these details could presumably be promulgated by appropriate agency regulations. Whereas the political climate might make compromising patent rights in favor of environmental concerns an unpopular notion, the practical obstacles to instituting a well-defined precautionary standard of patentability seem to be surmountable.

B. Beneficial Inventions and Selective Exclusion

While it is beyond the scope of this Article to discuss in detail the economic and social effects of granting patents for *beneficial* inventions, both common sense and available data indicate that doing so will increase prices, limiting availability of beneficial products in developing nations, while providing greater profits to manufacturers in developed nations. To counteract this, domestic and international laws should selectively allow developing nations to exclude certain classes of inventions from patentability. Excluded categories should include, at a minimum, agricultural methods and products, and medical methods and products, but should preferably be extended to all inventions sufficiently beneficial to public welfare. Nations allowed to make these exclusions should include at least those thirty-two member nations recognized as “least-developed” by the WTO,¹²³ and should preferably include all nations whose GDP falls below a certain threshold level. For example, the exclusions could be allowed to all nations having a GDP less than the worldwide mean or median GDP, which would effectively limit monopoly pricing to only wealthier nations. Figure 4 illustrates the proposed scope of patentability with sufficiently harmful inventions universally excluded and with sufficiently beneficial inventions selectively excluded.

Unfortunately, as indicated by the advent of the TRIPs Agreement, international law appears to be evolving towards a broader scope of patentability rather than a narrower one. This is due primarily to the influence of the United States and other developed nations, which have the most to gain from a worldwide policy of broad patentability. Although the language of the TRIPs Agreement allows some flexibility in national laws that seek to preclude patentability of harmful inventions, this language should be mandatory rather than optional. Furthermore, rather than preventing developing nations from excluding pharmaceuticals and other beneficial inventions from patentability, the TRIPs Agreement and other international treaties should explicitly allow these exclusions. This would effectively require developed nations to recoup research and development costs from within their own ranks, while providing the benefits of the research to rich and poor countries alike. However, so long as the wealthiest and most developed nations continue to set the policy agenda of the WTO and other

123. See WTO, Understanding the WTO, Least Developed Countries, http://www.wto.org/English/thewto_e/whatis_e/tif_e/org7_e.htm (last visited Nov. 14, 2006) (providing a list of these nations).

international trade organizations, such beneficial reforms to international patent law are unlikely to occur.

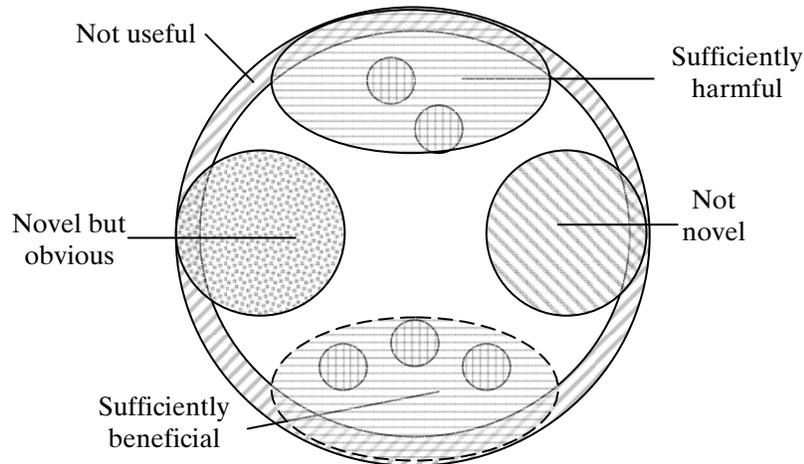


Figure 4

The author's proposed patentability scope. The proposed scope would require utility, novelty, and nonobviousness, would uniformly exclude sufficiently harmful inventions, and would selectively exclude sufficiently beneficial inventions only in qualifying developing nations (as indicated by the dashed boundary line).

CONCLUSION

Patent law purports to be an incentive system, in which the lure of temporary monopoly power spurs both the development of new technologies and public disclosure of the resulting innovations. However, if the patent incentive is offered indiscriminately, both the development and the monopoly power may come at a high domestic and international price. Some innovation has undesirable consequences, and maintaining the patent incentive without regard to the harmful impacts of an invention may result in the development of harmful technologies and may slow the development of safer alternatives. On the other hand, some innovation is so *beneficial* that the grant of even a temporary monopoly may limit access to an invention to the wealthy, and thus conflict with basic notions of fairness

and human rights. This is particularly true with respect to pharmaceuticals, medical methods and devices, and agricultural methods and products.

The scope of patentable subject matter can—and should—be shaped to counteract the problems described above. In the domestic laws of all nations, the patent incentive should be removed for many harmful inventions by excluding from patentability all subject matter known or suspected to have sufficiently detrimental impacts on the environment or public health. Furthermore, to give universal access to beneficial medical and agricultural advances, the patent incentive for this subject matter should be retained only in nations whose citizens can afford to pay the resulting monopoly prices. In other nations, and particularly in the thirty-two member nations recognized as “least-developed” by the WTO, this beneficial subject matter should be excluded from patentability. Finally, all relevant international treaties, particularly the TRIPs Agreement, should be amended to allow these exclusions from patentable subject matter. Unfortunately, this would require a reversal of the current trend of expanding patentable subject matter for the primary benefit of industrialized nations.