

1997

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Recommended Citation

Charles Vorndran, *Biotechnology and Intellectual Property Protection from U.S. Law through NAFTA*, 3 LAW & BUS. REV. AM. 103 (1997)
<https://scholar.smu.edu/lbra/vol3/iss3/6>

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Biotechnology and Intellectual Property Protection from U.S. Law through NAFTA.

Charles Vorndran*

The transition of the U.S. economy from an industrial base to a high technology base shifts the focus of global competitiveness from the availability of natural resources to the international protection of intellectual property rights.¹ The North America Free Trade Agreement² (NAFTA) between the United States, Mexico, and Canada specifically addresses and increases intellectual property protection.³ Moreover, the protection of intellectual property rights under the NAFTA will assist U.S. companies dependent on intellectual property rights to maintain their competitive edge.⁴

This comment focuses on intellectual property as it applies to the biotechnology industry, specifically patent protection. First, Part I includes a discussion of what intellectual property and biotechnology are and how biotechnology relates to the pharmaceutical industry, providing a foundation for following sections. Because of the importance biotechnology is expected to have on international trade, Part II covers generally U.S. patent law concerning biotechnology. Part III examines in detail patent protections under the NAFTA. Part IV discusses the controversy between developing countries and intellectual property protection. Part V concludes that the NAFTA has not dramatically changed substantive patent protection and that additional harmonization of domestic laws is needed to adequately protect biotechnology inventions.

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1. Bruce A. Lehman, *Intellectual Property: America's Competitive Advantage in the 21st Century*, 31 COLUM. J. WORLD BUS. 6, 15 (1996). The development of new technologies has transformed the

U.S. economy into one based on ideas and the implementation of these ideas and U.S. economic growth and competitiveness will largely be determined by the extent to which the United States creates, owns, preserves and protects its intellectual property, and the extent to which the federal government can foster economic growth by creating incentives for private sector investment in research and development, promoting stronger intellectual property protection abroad, reducing barriers to trade and serving U.S. business interests throughout the world. *Id.* at 7.

Additionally, in 1993 a columnist for the Washington Business Journal advised a way to stay in front of the global pack was "getting more people than our principal competitors out of hog farming and broom making and into higher value arenas such as computers, aerospace, financial services, media and biotech." *The Way To Stay in Front of the Global Pack*, WASH. BUS. J., Oct. 1, 1993, available in 1993 WL 5818809.

2. North American Free Trade Agreement, drafted Aug. 12, 1992, revised Sept. 6, 1992, U.S.-Can.-Mex, 32 I.L.M. 605 (entered into force Jan. 1, 1994) [hereinafter "NAFTA"].

3. *The North American Free Trade Agreement Implementation Act Statement as to How the NAFTA Serves the Interests of United States Commerce*, available in 1993 WL 561219.

4. *Id.*

I. Intellectual Property, Biotechnology, and the Pharmaceutical Industry.

A. SCOPE OF INTELLECTUAL PROPERTY.

Intellectual property includes primarily copyrights, trademarks, patents, service marks, and trade secrets.⁵ This broad term is also used to describe the many "rights associated with inventions, discoveries, writings, artistic works, product designs, and designations of the source of goods and services."⁶ The importance of the protection of intellectual property rights is evidenced by the many international trade conventions and treaties ranging from the Paris Convention for the Protection of Industrial Property Rights of 1883⁷ to the NAFTA.⁸ Some of the industries that rely on the protection of intellectual property include: "movies, TV programs, home video, books, music, sound recordings, and computer software."⁹ Pharmaceutical and biotechnology industries also depend heavily on the protection of intellectual property rights.¹⁰ In fact, "[the biotech] industry would not exist in America today without strong patent protection."¹¹ Moreover, "[t]he future of the pharmaceutical industry hinges largely on the results of the North American Free Trade Agreement and the General Agreement on Tariffs and Trade."¹²

Since 1992 global trade arrangements have significantly increased, demonstrating the importance of world-wide trade in today's economy.¹³ Of the many agreements, the

5. Margaret A. Boulware et al., *An Overview of Intellectual Property Rights Abroad*, 16 Hous. J. INT'L L. 441, 445 (1994).
6. Rebecca Eisenberg, *Patents: Help or Hindrance to Technology Transfer*, in BIOTECHNOLOGY SCIENCE, ENGINEERING, AND ETHICAL CHALLENGES FOR THE TWENTY-FIRST CENTURY 161 (Frederick B. Rudolph & Larry V. MacIntire eds., 1996).
7. Paris Convention for the Protection of Industrial Property, July 14, 1967, 21 U.S.T. 1538, 828 U.N.T.S. 305.
8. NAFTA, *supra* note 2. Some other important U.S. treaties include: (1) Patent Cooperation Treaty, June 19, 1970, 28 U.S.T. 7645; (2) Berne Convention for the Protection of Literary and Artistic Works, as revised July 24, 1971, 102 Stat. 2853, U.N.T.S. 221; and (3) Universal Copyright Convention, as revised July 24, 1971, 25 U.S.T. 1341, 943 U.N.T.S. 178. Boulware, *supra* note 5, at 507 & n.1.
9. *Remarks of the Honorable Carlos J. Moorhead Before the Patent and Trademark Office Society*, 78 J. PAT. & TRADEMARK OFF. SOC'Y 225, 228 (1996) [hereinafter Moorhead].
10. James Silbermann, Comment, *The North American Free Trade Agreement's Effect on Pharmaceutical Patents: A Bitter Pill to Swallow or a Therapeutic Solution?*, 12 J. CONTEMP. HEALTH L. & POL'Y 607, 635 (1996). One commentator has suggested that without patent protection, the pharmaceutical industry will become a governmental entity which would "erode our capitalist society into a socialist system where there are no entrepreneurs willing to risk the often enormous costs in terms of time, research, and development if order to bring a new invention to market." *Id.*
11. Moorhead, *supra* note 9, at 227.
12. Mark Perkies, *Bitter Pills: Mergers, Price Cuts, Layoffs the Medicine for Pharmaceutical Companies*, PLANT SITES & PARKS 107, available in 1995 WL 14088934.
13. Ralf Boscheck, *Mastering Management - Part 18 (9): Managed Trade and Regional Choice - Ralf Boscheck Examines Regional Trade Blocs, a Rapidly Growing Phenomenon. Are They, as Many Fear, Barely Disguised Protectionism or a Step Towards Global Free Trade?*, FIN. TIMES, Mar. 8, 1996, available in 1996 WL 6148707.

NAFTA is "probably the strongest intellectual property agreement and trade agreement ever. . ."¹⁴ Future implications of the drive toward consensual global regulation of intellectual property on the biotech industry are difficult to predict.¹⁵

B. DEPENDENCE OF INDUSTRIES ON INTELLECTUAL PROPERTY PROTECTION.

High-tech industries incur extremely high costs in research and development (R&D), resulting in the necessity of intensive investment.¹⁶ For example, "[i]n 1995 the biotech industry spent \$7.7 billion on research and development."¹⁷ Unauthorized copying of new technologies avoids the investment of R&D, thereby preventing the inventor from recouping its initial investment.¹⁸ Therefore, the protection of intellectual property prevents unauthorized copying and is the cornerstone of high-tech industries.¹⁹

American businesses lose approximately \$200 billion to counterfeiters annually, and biotechnology and pharmaceuticals are becoming popular targets.²⁰ It is believed this trend will continue in the future, despite the danger some counterfeit goods pose to public safety.²¹ Although stronger protections for intellectual property will help alleviate some of the counterfeiting by making it less profitable, trade agreements alone may not afford adequate protection.²² In fact, some suggest businesses take proactive steps to avoid counterfeiting, such as: legitimizing offenders; educating stockholders; advertising; and high-tech labeling.²³

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14. *Hearing Before the Committee on Finance United States Senate*, 104th Cong., 1st Sess. (1995) (Statement of Rebecca Maynard, Professor of Education and Social Policy, Univ. Of Pennsylvania). See also *Pharmaceuticals*, 4 MEX. TRADE & LAW REP. 24, 26 (1994); Bruce Zagaris & Alvaro J. Aguilar, *Enforcement of Intellectual Property Protection Between Mexico and the United States: A Precursor of Criminal Enforcement for Western Hemispheric Integration?*, 5 FORDHAM INTELL. PROP. MEDIA. & ENT. L.J. 41, 107 (1994).
 15. Louis Lasagna, *Comparison of U.S., European, and Japanese Policies Affecting Pharmaceutical and Biotechnology Development*, in *BIOTECHNOLOGY SCIENCE, ENGINEERING, AND ETHICAL CHALLENGES FOR THE TWENTY-FIRST CENTURY*, *supra* note 6, at 225, 227. See also Kenneth D. Sibley, *Introduction to THE LAW AND STRATEGY OF BIOTECHNOLOGY PATENTS I* (Kenneth D. Sibley ed., 1994) (writing "it is often felt that the patent system itself, at least in the area of biotechnology, is capricious and unpredictable").
 16. Lehman, *supra* note 1, at 10. The author continues by writing "[a]lthough investment leads to innovation, to take these ideas form a laboratory or a studio to the marketplace requires a critical next step, gaining protection for this new intellectual property." *Id.* at 10-11.
 17. Kate H. Murashige, *Genome Research and Traditional Intellectual Property Protection-A Bad Fit?*, 7 RISK: HEALTH SAFETY & ENV'T 231, 232 (1996).
 18. Lehman, *supra* note 1, at 14.
 19. Gerald J. Mossinghoff & Thomas Bombelles, *The Importance of Intellectual Property Protection to the American Research Intensive-Pharmaceutical Industry*, 31 COLUM. J. WORLD BUS. 38 (1996).
 20. Clifford J. Shultz II & Bill Saporito, *Protecting Intellectual Property: Strategies and Recommendations to Deter Counterfeiting and Brand Piracy in Global Markets*, 31 COLUM. J. WORLD BUS. 18, 19 (1996).
 21. *Id.*
 22. *Id.* at 26.
 23. *Id.* at 22-26.
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C. MERGING OF PHARMACEUTICAL AND BIOTECHNOLOGY INDUSTRIES.

The pharmaceutical industry has become one of the most competitive and successful high-technology industries in the United States.²⁴ In 1994 this industry had a trade surplus of exported US \$525 million.²⁵ As a result, U.S. pharmaceutical industries are very concerned with the global harmonization of intellectual property protection.²⁶ Because of the limited availability of new drugs coming directly out of nature and the rapid advancement in the area of biotechnology, many of the large pharmaceutical firms are turning to biotechnology to help identify new drugs.²⁷ By September 1996 sixteen biotechnology based pharmaceuticals had been approved by the Food and Drug Administration (FDA) for that year.²⁸

The U.S. biotech industry has grown tremendously in the last fifteen years.²⁹ In fact, the industry has blossomed into one producing almost \$8 billion in revenues in the United States and creating 103,000 new jobs.³⁰ Moreover, global markets for biotechnology based products are expected to grow to US \$30-\$50 billion per year in the next ten years.³¹ As a result, biotechnology and the biotech industry are expected to have a great impact on international trade.³²

24. *Prepared Testimony of Robert Neimeth Charirman, Intellectual Property Task Force International Section Pharmaceutical Research and Manufacturers of America and President, International Pharmaceuticals Group Pfizer, Inc. Before the Committee on Ways and Means Subcommittee on Trade and the Committee on Rules Subcommittee on Rules and Organization United States House of Representatives Keeping Trade with Latin America on the Fast Track*, Fed. News Service - Cong. Hearings Testimonies, May 17, 1995, available in 1995 WL 10386192.
25. *Id.*
26. Bruce Rubenstein, *Latin America Slow to Protect Patents under NAFTA*, 6 CORP. LEGAL TIMES 14 (1996).
27. Philip H. Abelson, *Pharmaceuticals Based on Biotechnology*, 273 SCIENCE 719 (1996) (Approximately 170 collaborative arrangements between pharmaceutical and biotech companies were established in 1995). However, at least one new company, Vertex Pharmaceuticals, has adopted the "rational" approach to developing new drugs. The Pizzaz Factor (U.S. business system)(A Survey of American Business: Back on Top), ECONOMIST, Sept. 16, 1995, Vol. 336, available in 1995 WL 9570600. The rational approach attempts to design new drugs chemically rather than testing them by trial and error. *Id.*
28. Ableson, *supra* note 27, at 719. "[t]he U.S. Food and Drug Administration is receiving more new drug applications from the biotech industry than from big pharmaceutical companies." Jennifer Lanthier, *Visionary With Clout: Ed Rygiel Thinks Biotech Can Make Canada and the World a Better Place, and as MDS Health Group's Venture Capital Guru, He's in a Position to Help Make it Happen*, FIN. POST, Sept. 17, 1996, at 62.
29. Moorhead, *supra* note 9, at 226. Biotechnology has been heralded as "one of the most significant developments of this century." Lanthier, *supra* note 28 (quoting Ed Rygiel, vice-president of corporate development with MDS Health Group Ltd.).
30. Moorhead, *supra* note 9, at 226 (stating the biotech industry "has created more nutritious foods and vital medical treatments for cancer and heart patients than all other research industries combined. And, it's almost exclusively, an American industry." *Id.*).
31. NATURAL RESOURCE COUNCIL, *PUTTING BIOTECHNOLOGY TO WORK*, BIOPROCESS ENGINEERING, 9, 10 (1992)[hereinafter Natural].
32. Gerd Junne, *The Impact of Biotechnology on International Trade*, in BIOTECHNOLOGY: ECONOMIC AND SOCIAL ASPECTS, ISSUES FOR DEVELOPING COUNTRIES, 165, 185 (E. J. Da Silva et al. eds., 1992)(predicting "[t]he impact of biotechnology on trade flows is hard to measure." Moreover, "[a]pplications of biotechnology will first of all affect [international] trade in agricultural products." *Id.*).

D. DEFINING BIOTECHNOLOGY.

Biotechnology means different things to different people.³³ The National Resource Council defines biotechnology as "the application of science and engineering to the use of living organisms or substances derived from them, to generate products or to perform functions that can benefit the human condition."³⁴ Biotechnology, therefore, is not a science in itself; rather, it is the application of science used to either make money or to save it.³⁵

Biotechnology as a business begins with the successful translation of basic research in the life sciences into very high-value-added products, including biopharmaceuticals for the treatment of diseases such as heart disease, cancer, and kidney diseases.³⁶ In so doing, the distinction between biotechnology and pharmaceuticals begins to blur. Pharmaceutical products now include those derived from biotechnology, giving birth to the term biopharmaceutical.³⁷ Some biopharmaceuticals are products of new recombinant deoxyribonucleic acid (DNA)³⁸ and hybridoma technology,³⁹ vaccines, and therapeutic proteins.⁴⁰ These "[b]iotechnology-derived products are an important source of revenue and commercial growth throughout the world and hence are related to issues of international competitiveness."⁴¹

An additional reason pharmaceutical industries and biotech industries are combining forces is the interest the pharmaceutical industry has in using biological synthesis of products rather than traditional chemical synthesis.⁴² Chemical synthesis typically results in a mixture of product.⁴³ The mixture contains enantiomers, left and right-handed versions

33. Colin Ratledge, *Biotechnology: The Socio-economic Revolution? A Synoptic View of the World Status of Biotechnology*, in BIOTECHNOLOGY: ECONOMIC AND SOCIAL ASPECTS, ISSUES FOR DEVELOPING COUNTRIES, *supra* note 32, at 1. The author traces the practice of biotechnology techniques from the first production of wines to the advent of recombinant DNA technology and concludes both the traditionalist view and the modern view of biotechnology are interdependent. *Id.*

34. Natural, *supra* note 31, at 9.

35. Ratledge, *supra* note 33, at 1. A more descriptive definition of biotechnology is a collection of scientific techniques applicable to several industries. TREVOR COOK ET AL., PHARMACEUTICALS BIOTECHNOLOGY AND THE LAW 5 (1991).

36. Natural, *supra* note 31, at 13.

37. *Id.* at 16.

38. Recombinant DNA technology is "a laboratory technique used to join deoxyribonucleic acid from different sources to produce an individual with a novel gene composition." MCGRAW-HILL DICTIONARY OF SCIENTIFIC AND TECHNICAL TERMS 1576 (4th ed. 1989)[hereinafter McGraw-Hill].

39. Hybridoma technology is used for the production of monoclonal antibodies. Cook, *supra* note 35, at 114. Antibodies are proteins produced by immune cells that bind to sites on foreign agents (antigens) in the body as part of the immune response. *Id.* Monoclonal antibodies bind to the same antigenic site, giving them extreme sensitivity, and can be produced in large quantities. *Id.* They have important uses in diagnostics, e.g. home pregnancy tests. *Id.* Monoclonal antibodies can also be important in the "targeted delivery of toxic drugs" in the treatment of cancer. *Id.*

40. Natural, *supra* note 31, at 16. A protein is "[a]ny of a class of high molecular weight polymer compounds composed of a variety of -amino acids joined by peptide linkages." McGraw-Hill, *supra* note 37, at 1510. Amino acids are the building blocks of proteins. *Id.* at 74.

41. Natural, *supra* note 31, at 38.

42. Michael Shuler, *Development of Biopharmaceuticals: An Engineering Perspective*, in BIOTECHNOLOGY SCIENCE, ENGINEERING, AND ETHICAL CHALLENGES FOR THE TWENTY-FIRST CENTURY, *supra* note 6, at 100, 106.

43. *Id.*

of the same molecule; hopefully one enantiomer will have the desired effect and the other will have no effect.⁴⁴ Occasionally, however, one of the enantiomers can have harmful effects.⁴⁵ The advantage of biological synthesis is that only the beneficial enantiomer is produced, thereby avoiding contamination of the product with deleterious enantiomers.⁴⁶

Finally, pharmaceutical firms are entering the biotech industry because many of the molecules that produce physiological responses useful in the treatment of disease are not simple chemicals.⁴⁷ Rather, these molecules are often complex proteins or fragments of proteins that require complex chemistry to synthesize, and the yield of the synthesis is often very low.⁴⁸ Biotechnology can use nature's own machinery to produce these complex molecules in sufficient quantities to make the product economically profitable.⁴⁹

When thinking of biotechnology, most people quickly begin to imagine genetics and DNA.⁵⁰ The development of technology allowing the manipulation of genes to produce designed changes in living organisms has resulted in the production of several products used to treat human disease.⁵¹ For example, insulin,⁵² human growth hormone,⁵³ and erythropoietin⁵⁴ can now be produced in bacteria or yeast and can be used to treat humans.⁵⁵ The key to the successful production of a therapeutic protein is making sure the recombinant protein is modified in the same manner in bacteria as it would be in humans. Simply knowing the genetic code of the protein may not be sufficient to produce a marketable product.

Other products of biotechnology include genetically engineered animals and plants.⁵⁶ Genetically engineered (transgenic) animals can be used in the research and development of additional products.⁵⁷ Additionally, transgenic animals can be designed to provide

44. *Id.*

45. *Id.*

46. *Id.*

47. Cook, *supra* note 35, at 7.

48. *Id.*

49. *Id.*

50. See generally Anita Varma & David Abraham, *DNA is Different: Legal Obviousness and the Balance Between Biotech Inventors and the Market*, 9 HARV. J.L. & TECH. 53 (1996) and Murashige, *supra* note 17.

51. Teresa Pechulis Buono, Note, *Biotechnology-Derived Pharmaceuticals: Harmonizing Regional Regulations*, 18 SUFFOLK TRANSNAT'L L. REV. 133, 137 (1995).

52. Natural, *supra* note 31, at 14. Recombinant insulin became rapidly available after the discovery of Type II restriction endonucleases, enzymes used to cut DNA. *Id.*

53. Murashige, *supra* note 17, at 231.

54. *Id.*

55. Shuler, *supra* note 42, at 101. Once the protein is formed it may undergo some of the following modifications to produce a functional protein: folding, addition of sugars, disulfide bond formation, and the addition of phosphate groups. *Id.*

56. See generally Elisabeth T. Jozwiak, Comment, *Worms, Mice, Cows and Pigs: The Importance of Animal Patents in Developing Countries*, 14 NW. J. INT'L L. & BUS. 620; Mark Hanning, *An Examination of the Possibility to Secure Intellectual Property Rights for Plant Genetic Resources Developed by Indigenous Peoples of the NAFTA States: Domestic Legislation Under the International Convention for the Protection of New Plant Varieties*, 13 ARIZ. J. INT'L & COMP. L. 175 (1996).

57. Jozwiak, *supra* note 56, at 623. Transgenic animals can be used to produce vaccines or to test available drugs for effectiveness. *Id.*

more food than unaltered animals or can be designed to grow faster on lower levels of nutrition.⁵⁸ With increasing demand for food production, these animals may be important in preventing starvation.⁵⁹

II. U.S. Patent Law and Biotechnology.

A. SUBJECT MATTER.

In the United States, the patent statute is found in Title 35 of the U.S. Code.⁶⁰ Section 101 provides "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."⁶¹ The courts have interpreted this language as requiring three elements necessary for an invention to be patentable: (1) novelty; (2) utility; and (3) statutory subject matter.⁶² The requirement for statutory subject matter means an invention must fall within one of the enumerated categories listed in the statute.⁶³ Because biotechnological inventions by definition are concerned with living matter and nature, the patentability of biotechnological products must fall in the composition of matter or process elements of the statute.⁶⁴ Generally, patent applications contain claims that reflect the subject matter of the invention.⁶⁵

Despite the seemingly narrow scope of patentable subject matter, the U.S. Supreme Court determined Congress' intent was that "anything under the sun that is made by man" is patentable subject matter. Still, the product of nature doctrine serves as "a limitation on patentable subject matter," but it does not distinguish between "animate and inanimate naturally occurring products."⁶⁷

58. *Id.*

59. *Id.*

60. The sections of the statute discussed in this comment are 35 U.S.C. §§ 101-104 (1994). The patent statute was originally enacted in 1952.

61. 35 U.S.C. § 101.

62. *In re Bergy*, 596 F.2d 952, 960 (C.C.P.A. 1979). See also Boulware, *supra* note 5, at 465; Robert Patrick Merges, *PAT.L. & POL'Y* 147 (1992) (writing the three requirements are novelty, utility and non-obviousness).

63. Brian P. O'Shaughnessy, *Patentable Subject Matter*, in *THE LAW AND STRATEGY OF BIOTECHNOLOGY PATENTS*, *supra* note 15, at 62 citing *In re Pardo*, 684 F.2d 912, 916 (C.C.P.A. 1982) ("[a]ny process, machine, or composition of matter constitutes statutory subject matter unless it falls within a judicially determined exception to section 101.").

64. But see *id.* at 62, writing that "[t]he four [statutory] categories are somewhat ambiguous" and determining "whether a genetically altered cell that manufactures recombinant human proteins is a machine or composition of matter" is an issue on which reasonable minds may differ. *Id.*

65. Stephen G. Whiteside, Note, *Patents Claiming Genetically Engineered Inventions: A Few Thoughts on Obtaining Broad Property Rights*, 30 *NEW ENG. L. REV.* 1019, 1024 (1996). The claims define the invention. *Id.* at 1023.

66. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

67. KENNETH J. BURCHFIELD, *BIOTECHNOLOGY AND THE FEDERAL CIRCUIT* 41 (1995). The product of nature doctrine establishes that a product of nature, whether living or not, cannot be the subject matter of a patent. *Id.* at 40-41. Additionally, scientific principles and mathematical methods are not patentable. Boulware, *supra* note 5, at 459.

Although a naturally occurring product is typically not patentable, some ways to secure a patent for such a product may exist.⁶⁸ The isolation and purification of a natural product may be patentable by the claims of the patent even if the subject matter is one occurring in nature.⁶⁹ A simple but "affirmative manipulative step" can secure a patent on a natural product under the U.S. patent statute.⁷⁰

Living organisms were declared patentable in the landmark decision of *Diamond v. Chakrabarty*.⁷¹ Although a process involving living organisms such as bacteria has generally been accepted as patentable, the patenting of the living thing itself has spawned controversy.⁷²

In *Chakrabarty*, the Supreme Court reversed the rejection of a patent application on a "human-made, genetically engineered bacterium capable of breaking down multiple components of crude oil."⁷³ The Court held the invention constituted a manufacture or composition of matter within the meaning of the statute.⁷⁴ The recognition of micro-organisms as patentable subject matter led to the patentability of multicellular organisms.⁷⁵ On April 21, 1987, the Patent and Trademark Office (PTO) released a notice recognizing the patentability of "nonnaturally occurring nonhuman multicellular living organisms."⁷⁶ Despite the recognition of multicellular organisms as patentable subject matter, one scholar has suggested the PTO has effectively imposed a moratorium on patents for higher vertebrates.⁷⁷

B. UTILITY.

In addition to being within the statutory subject matter, a biotechnological invention, as with any invention, must also be useful to secure a patent.⁷⁸ Two requirements fall within the standard of utility: (1) operability and (2) practical utility.⁷⁹ Operability refers

68. O'Shaughnessy, *supra* note 63, at 63 citing *Ex Parte Prescott*, 19 U.S.P.Q. 178 (Bd. Pat. App. 1932) for the proposition that a patent may be granted for a product of nature if it involves: "(1) isolation or purification to yield products not otherwise useful in their natural state, and (2) the use of a product in a novel and non-obvious process." *Id.*

69. *Id.* at 64. The claims can define the invention as not being a product of nature. *Id.*

70. *Id.* at 65.

71. *Chakrabarty*, 447 U.S. at 303.

72. O'Shaughnessy, *supra* note 63, at 65. See also BURCHFIEL, *supra* note 67, at 42, noting that the grant of a patent on the "Harvard mouse" resulted in legislative proposals to remove higher animals from patentable subject matter and legal action against the Commissioner of Patents and Trademarks.

73. *Chakrabarty*, 447 U.S. at 305. The invention was to be used in treating oil spills. *Id.*

74. *Id.* at 309. "[t]he patentee has produced a new bacterium with markedly different characteristics from any found in nature and on having the potential for significant utility. His discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter under § 101." *Id.*

75. BURCHFIEL, *supra* note 67, at 41.

76. O'Shaughnessy, *supra* note 63, at 67.

77. BURCHFIEL, *supra* note 67, at 43. In 1991 approximately 157 animal patents had not issued. *Id.* Recently, a petition was filed with the PTO to "impose a moratorium on the issuance of patents for living organisms" by Jeremy Rifkin's Foundation for Economic Trends, joined with mainstream religious leaders. Brian C. Cunningham, *Impact of the Human Genome Project at the Interface Between Patent and FDA Laws*, 7 RISK: HEALTH SAFETY & ENV'T 253, 262 (1996).

78. 35 U.S.C. § 101.

79. BURCHFIEL, *supra* note 67, at 47.

to "whether the invention works."⁸⁰ Practical utility is whether the invention is useful.⁸¹ The requirement that an invention be useful does not generally become an issue for mechanical and electrical inventions, but biotechnological inventions are occasionally challenged on this basis.⁸² Since the mid-1960s, the element of practical utility has spawned controversy.⁸³

In *Brenner v. Manson*, the U.S. Supreme Court recognized the "everyday word [utility] can be pregnant with ambiguity when applied to the facts of life."⁸⁴ The process patent at issue concerned a chemical process for producing steroids.⁸⁵ The patent application did not include any utility for the compounds produced by the process; however, the applicant argued the process patent produced a homologue⁸⁶ to steroids demonstrated to have tumor-inhibiting effects in mice.⁸⁷ Although the Court recognized the process had some utility because the process worked and the products could be used for future testing, the Court held this alone was insufficient to grant a patent.⁸⁸ The Court reasoned that "until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly [of knowledge] are not capable of precise delineation."⁸⁹ As a result, the benefit to the public would not be commensurate with the benefit resulting from the granting of such a broad patent. Because the Court also included that the "patent system must be related to the world of commerce rather than the realm of philosophy. . .,"⁹⁰ the determination of practical utility encompasses a chemical or chemical process' commercial applicability.⁹¹

Commercial applicability could present a problem for biotechnology since it generates many inventions that do not have immediate commercial use but are useful in research.⁹² In fact, the PTO "has frustrated the full realization of patenting pharmaceutical biotechnology

80. O'Shaughnessy, *supra* note 63 at 71; BURCHFIEL, *supra* note 67, at 48.

81. O'Shaughnessy, *supra* note 63, at 69.

82. Boulware, *supra* note 5, 467-68.

83. O'Shaughnessy, *supra* note 63, at 69.

84. *Brenner v. Manson*, 383 U.S. 519, 529 (1966).

85. *Id.* at 520.

86. "A homologous series is a family of chemically related compounds, the composition of which varies from member to member by CH(2)(one atom of carbon and two atoms of hydrogen). . ."
Id. at 522 & n.3 (quoting *Application of Henz*, 181 F. 2d 196, 200-201 (C.C.P.A.)).

87. *Id.* at 521-22.

88. *Id.* at 535.

89. *Id.* at 536.

90. *Id.* (quoting *Application of Ruschig*, 343 F. 2d 970 (C.C.P.A.)).

91. BURCHFIEL, *supra* note 67 at 51. Additionally, this interpretation of the utility requirement was extended in *Application of In re Kirk*, 376 F.2d 936, 942 (C.C.P.A. 1967)(holding that claims describing the invention as having biological activity and usable to prepare compounds with biological properties did not meet the utility requirement). O'Shaughnessy, *supra* note 63, at 69; Merges, *supra* note 62, at 152. It should be noted that claims of inventions in humans may require clinical trials to establish utility. O'Shaughnessy, *supra* at 72 (citing *Ex parte Balzarini*, 21 U.S.P.Q. 2d 1892, 1897 (Bd. Pat. App. 1991)).

92. BURCHFIEL, *supra* note 67, at 57.

inventions by rejecting inventions on the grounds that they do not meet the § 101 requirement that the invention be 'useful' because they do not recite human clinical *in vivo* data."⁹³

A specific example of how the controversy with utility affects the biotechnology industry is the attempt of the National Institutes of Health to patent expressed sequence tags.⁹⁴ Expressed sequence tags are stretches of DNA sequenced from randomly selected complementary DNAs that correspond to small coding regions of genes without knowing the function of the genes.⁹⁵ The argument against the utility of the patent was basically that the utility of the patent would not be known until the full sequence of the gene and the structure and function of the proteins the genes encode was known.⁹⁶ The patent application was abandoned for fear the grant of the patent would hinder further research and/or hinder the Human Genome Project.⁹⁷

C. NOVELTY.

The novelty requirement is located in 35 U.S.C. § 102.⁹⁸ The information in section

93. Garth Butterfield et al., *Biotechnology Protection and Licensing*, 431 PLI/PAT 235, 244 (1996). The PTO has adopted guidelines for establishing a *prima facie* case of lack of utility. A *prima facie* case for no utility must establish that a person skilled in the art would not consider credible any specific utility asserted by the applicant for the claimed invention. *Id.* at 244. The following elements must be included: "(i) [a] well reasoned statement that clearly sets forth the reasoning used in concluding that the asserted utility is not credible; (ii) [s]upport for factual findings relied upon in reaching this conclusion; and (iii) [s]upport for any conclusions regarding evidence provided by the applicant in support of an asserted utility." *Id.* at 245.

94. BURCHFIEL, *supra* note 67, at 58; Murashige, *supra* note 17, at 235-36.

95. BURCHFIEL, *supra* note 67, at 58.

96. *Id.*

97. *Id.* "The Human Genome (Project) is an international effort to complete the sequencing of the 100,000 genes that comprise the human genome." Cunningham, *supra* note 77, at 253.

98. 35 U.S.C.A. § 102 (1984) provides:

A person shall be entitled to a patent unless--

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or

(c) he has abandoned the invention, or

(d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States, or

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent, or

(f) he did not himself invent the subject matter sought to be patented, or

102 has been described as being presented in a "convoluted fashion."⁹⁹ Basically, the novelty requirement is meant to ensure the invention described in a patent application has not been known, used, patented, or described in a publication.¹⁰⁰ Unlike most other industrialized countries, the United States allows a one year grace period to file a patent application after public disclosure or sale of the invention.¹⁰¹

If an invention has been publicly disclosed, sold, known, used, or patented more than a year before filing a patent application, the invention is said to be "anticipated" and is denied patent protection.¹⁰² The application of the novelty requirement coupled with the products of nature doctrine poses potential problems for biotechnological inventions.¹⁰³

The reason some biotechnological inventions may not appear to be novel stems from the similarity of a genetically engineered product compared to its natural form. For example, a recombinant protein is produced to perform the same function as the naturally occurring protein. Consequently, the recombinant protein closely resembles the structural and chemical identity of the natural protein.

Despite this high degree of similarity, biotechnology products have been held to be novel on several different grounds.

First, anticipation can be avoided if the recombinant protein product is of more increased purity than the unpurified form found in nature.¹⁰⁴ Moreover, as long as one amino acid of the recombinant protein is different than the natural protein, the recombinant protein will be novel.¹⁰⁵ Second, a biotechnological invention will be novel if it has increased biological activity over its naturally occurring counterpart.¹⁰⁶ Lastly, artificial

(g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

99. James R. Cannon, *Novelty and the Public Domain*, in *THE LAW AND STRATEGY OF BIOTECHNOLOGY PATENTS*, *supra* note 15, at 75.

100. 35 U.S.C.A. § 102; Merges, *supra* note 62, at 162; Boulware, *supra* note 5, at 465 (writing that "[m]ost countries require absolute novelty," which means there must be no public disclosure or commercial exploitation of the invention before the patent application is filed). Cannon notes a one year grace period is useful because it gives the inventor time to investigate the commercial use of the invention and whether pursuing a patent application is economically justified. Cannon, *supra* note 99, at 80.

101. 35 U.S.C.A. § 102(b); Boulware, *supra* note 5, at 465.

102. Cannon, *supra* note 99, at 75. For prior art to anticipate an invention, it must: (1) disclose each element of the claimed invention; (2) be enabling in that a person skilled in the art could make and use the invention based on the prior art; and (3) not fall within the "accidental anticipation" exception." *Id.* at 76. For an analysis of the accidental anticipation exception see *id.* at 79.

103. BURCHFIELD, *supra* note 67, at 60-61.

104. *Id.* at 65.

105. *Id.* at 66. The same reasoning can be applied to cloned genes in which the cloned sequence differs from the naturally occurring sequence. Importantly, this differences must be claimed in the patent application. *Id.*

106. *Id.*

biological constructs such as plasmids, vectors, and transformed cells do not occur naturally and are, therefore, novel.¹⁰⁷

D. NONOBVIOUSNESS.

In addition to novelty, utility, and statutory subject matter, an invention must not be obvious to one skilled in the art in order to become patented.¹⁰⁸ The nonobviousness requirement is premised on the concept that an invention that is "merely a trivial step for-

107. *Id.*

108. 35 U.S.C.A. § 103 (West Supp. 1996) which provides:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

(b)(1) Notwithstanding subsection (a), and upon timely election by the applicant for patent to proceed under this subsection, a biotechnological process using or resulting in a composition of matter that is novel under section 102 and non-obvious under subsection (a) of this section shall be considered non-obvious if--

(A) claims to the process and the composition of matter are contained in either the same application for patent or in separate applications having the same effective filing date; and

(B) the composition of matter, and the process at the time it was invented, were owned by the same person or subject to an obligation of assignment to the same person.

(2) A patent issued on a process under paragraph (1)--

(A) shall also contain the claims to the composition of matter used in or made by that process, or

(B) shall, if such composition of matter is claimed in another patent, be set to expire on the same date as such other patent, notwithstanding section 154.

(3) For purposes of paragraph (1), the term "biotechnological process" means--

(A) a process of genetically altering or otherwise inducing a single- or multi-celled organism to--

(i) express an exogenous nucleotide sequence,

(ii) inhibit, eliminate, augment, or alter expression of an endogenous nucleotide sequence, or

(iii) express a specific physiological characteristic not naturally associated with said organism;

(B) cell fusion procedures yielding a cell line that expresses a specific protein, such as a monoclonal antibody; and

(C) a method of using a product produced by a process defined by subparagraph (A) or (B), or a combination of subparagraphs (A) and (B).

(c) Patentability shall not be negated by the manner in which the invention was made. Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. [See Butterfield, *supra* note 93, at 256-72 for a detailed discussion of the relevant case law in the area of biotechnology and the issue of obviousness.]

ward in the art" does not contribute enough benefit to the public to justify the issuance of a patent.¹⁰⁹ Determining exactly what is obvious is not a simple matter.¹¹⁰ Moreover, the requirement of nonobviousness can present more problems for biotechnology inventions than other types of inventions because rejections of biotechnology based patent applications are based on both obviousness and the lack of enablement.¹¹¹ Defending the application against obviousness may result in conceding the lack of enablement because of the complexity of the techniques involved.¹¹²

After the enactment of section 103, an invention is not required to demonstrate a "flash of creative genius."¹¹³ Rather, the statute sets out a test that has been interpreted as having the following elements: (1) determination of the scope and content of the prior art; (2) determination of the differences in the prior art and the claims in the patent application; (3) determination of the level ordinary skill in the art; and (4) secondary considerations such as commercial success.¹¹⁴ These determinations must be based on information available at the time the invention was made.¹¹⁵ In addition, the prior art must suggest or motivate a change in the prior art to render the invention at issue obvious.¹¹⁶ The general test for obviousness has been described as "whether an average person who works in the particular field would deduce, realize, or discover the invention from information in the public domain."¹¹⁷

The determination of the level of skill of the average person working in the particular field is made using several factors.¹¹⁸ Some of these factors include: "(1) the educational level of the inventor; (2) the type of problems encountered in the art; (3) the prior art solutions to those problems; (4) the speed with which the innovations are made; (5) the sophistication of the technology; and (6) the educational level of active workers in the field."¹¹⁹

109. *Merges*, *supra* note 62, at 379. Nonobviousness attempts to measure the technical accomplishment of the invention. *Id.*

110. BURCHFIELD, *supra* note 67, at 78. "[T]he statutory obviousness standard reflects more than a hundred years of shifting precedent defining the minimum quantum of creativity which must distinguish a patentable invention from prior knowledge of those most familiar with the technical field of endeavor." *Id.*

111. Shawn P. Foley, *Nonobviousness*, in *THE LAW AND STRATEGY OF BIOTECHNOLOGY PATENTS*, *supra* note 15, at 93-94. The PTO may be applying a stricter standard for inventiveness for biotechnology inventions because more biotechnology based patents are rejected than those based on other technologies. *Id.*

112. *Id.*

113. *Graham v. John Deere Co.*, 383 U.S. 1, 15 (1966)(citing *Cuno Corp. v. Automatic Devices Corp.*, 314 U.S. 84 (1941)).

114. *Id.* at 17. The fourth element is also called objective evidence of nonobviousness. Foley, *supra* note 111, at 94; Varma, *supra* note 50, at 66.

115. 35 U.S.C. § 103(a).

116. BURCHFIELD, *supra* note 67, at 79 (citing *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1051 (Fed. Cir.) cert-denied 488 U.S. 825 (1988)).

117. Boulware, *supra* note 5, at 467.

118. Foley, *supra* note 111, at 96.

119. *Id.* (citing *Orthopedic Equipment Co., Inc. v. All Orthopedic Appliances, Inc.*, 707 F.2d 1376 (Fed. Cir. 1983)).

In determining whether an invention is obvious, the PTO employs a procedural tool, the prima facie case of obviousness.¹²⁰ The concept of prima facie obviousness is predicated on the "assumption that chemical compounds having similar structures will have similar properties."¹²¹ Once a patent is filed, it is presumed patentable unless the PTO can establish a case of prima facie obviousness or otherwise defeat the claims of the patent.¹²²

The requirements for a prima facie case of obviousness are:

1. The prior art must disclose or suggest the modification in the prior art process that is required for the invention, without reference to the applicant's specification.
2. The references must convey to one skilled in the art that there is a reasonable expectation of success if the modification is made.
3. The reference must provide detailed enabling methodology for practicing the claimed invention.¹²³

With the recent amendments to section 103, a biological process patent is novel and non-obvious if: "1) the product and the process claims are in the same application and have the same filing date; and 2) the product and the process claims were owned by the same person when invented."¹²⁴ The amendment was intended to overrule *Durden*,¹²⁵ which provided the foundation for the PTO's position that when "a genetically engineered cell has been 'programmed' to make a known protein, use of the cell to manufacture the protein by fermentation would be obvious."¹²⁶ The effect of *Durden* was a massive rejection of biotechnology process claims.¹²⁷ The amendment has the potential for producing a class of very broad biotechnology patents that may be removed from ordinary statutory scrutiny.¹²⁸

The suggestion has recently been made that "[t]he current state of biotechnology DNA patent case law has shifted the balance undesirably in favor of the patent applicant by applying ill-fitting and inapplicable traditional chemical patent law doctrines."¹²⁹ The use of chemical patent law or structural similarity may not be useful in determining obviousness in complex molecules such as DNA and proteins.¹³⁰ Biotechnology can alter proteins and genes in numerous ways, resulting in a product that although structurally similar, may have unique biological properties.¹³¹ In an attempt to create parity between biotechnology patents and the public benefit, Varma and Abraham suggest a variation on the test for

120. Varma, *supra* note 50, at 66.

121. BURCHFIEL, *supra* note 67, at 91.

122. Varma, *supra* note 50, at 66.

123. BURCHFIEL, *supra* note 67, at 107.

124. Butterfield *supra* note 93, at 270. Pub.L. No. 104-41 amended § 103(b) in 1995. *Id.* at 269.

125. *In re Durden*, 763 F.2d 1406 (Fed. Cir. 1985). The court held that even if the starting material or product nonobvious, the steps of the chemical process may be obvious. Butterfield, *supra* note 93, at 268.

126. Butterfield, *supra* note 93, at 268.

127. BURCHFIEL, *supra* note 67, at 131. Process patents or claims are very important to biotechnology because the invention usually includes the process for producing the desired product. *Id.* at 130.

128. BURCHFIEL, *supra* note 67, at 133.

129. Varma, *supra* note 50, at 85.

130. BURCHFIEL, *supra* note 67, at 117.

131. *Id.*

obviousness.¹³² Their "suggestion test" imposes the certain criteria on the prior art; the prior art must:

- (1) suggest the claimed subject matter to a person of ordinary skill in the art; and to
- (2) demonstrate a reasonable expectation of success by:
 - (a) providing specific guidance as to how to modify the teachings of the prior art to arrive at the claimed invention; and
 - (b) providing evidence that the suggested modification would be successful.¹³³

Although the authors suggest this test may raise controversy in the biotechnology industry, they emphasize any test for *prima facie* obviousness can be overcome by objective evidence.¹³⁴ The application of their test would significantly reduce the number of patents issued for genetic sequences.¹³⁵ Whether the PTO will employ such a test remains to be seen.

III. NAFTA Patent Provisions.

A. SCOPE OF PROTECTION.

Article 1701 requires the signatory Parties to conform to a prescribed level of protection for intellectual property rights.¹³⁶ Specifically, the NAFTA provides that "[e]ach Party shall provide in its territory to the nationals of another Party adequate and effective protection and enforcement of intellectual property rights, while ensuring that measures to enforce intellectual property rights do not themselves become barriers to legitimate trade."¹³⁷ The enforcement of these rights has been a source of contention, and may continue to cause difficulties in the future.¹³⁸ Although a Party may implement more stringent protection under its domestic laws than that contained in the NAFTA,¹³⁹ the Parties must adhere to several existing international agreements for the protection of intellectual

132. Varma, *supra* note 50, at 81.

133. *Id.*

134. *Id.*

135. *Id.* at 82-84. In applying their test, the authors conclude that several patents issued for genetic sequences would have been rendered obvious, thereby excluding them from patentability. *Id.*

136. NAFTA, *supra* note 2, art. 1701.

137. *Id.*

138. Zagari, *supra* note 14, at 123.

139. NAFTA, *supra* note 2, art. 1702. Increased protection of intellectual property rights must be consistent with the NAFTA. *Id.* However, one commentator points out that "domestic protection of intellectual property is directly tied to the quality of international intellectual property protection." Lehman, *supra* note 1, at 11-12.

property.¹⁴⁰ The NAFTA further provides that if a Party has not acceded to the stipulated international agreements, that Party must make every effort to do so.¹⁴¹

B. REQUIREMENTS FOR PATENTABILITY: PATENTABILITY: ARTICLE 1709(1).

Article 1709(1) defines which inventions are eligible for a patent.¹⁴² The necessary requirements each invention must possess to successfully receive a patent under the NAFTA reflect the requirements under the laws of the member countries.¹⁴³ Specifically, the NAFTA provides a patent must be available for "any inventions, whether products or processes, in all fields of technology, provided that such inventions are new, result from an inventive step and are capable of industrial application."¹⁴⁴ To harmonize this language with U.S. law, the terms "inventive step" and "capable of industrial application" are defined in the NAFTA as synonymous with the terms "non-obvious" and "useful," respectively.¹⁴⁵ In addition to delineating those inventions subject to a patent, the NAFTA also specifically excludes certain inventions from becoming patented.¹⁴⁶

C. EXCLUSIONS FROM PATENTABILITY.

1. *Article 1709(2): Ordre Public and Morality Exclusions.*

Some of the most controversial sections regarding intellectual property protection under the NAFTA concern the exclusion of certain inventions from patentability.¹⁴⁷ Under Article 1709(2), a Party may exclude from patentability inventions to protect the "ordre public or morality."¹⁴⁸ These terms are not explicitly defined,¹⁴⁹ however because these terms are not specifically defined, they are subject to interpretation by each Party and

140. NAFTA, *supra* note 2, art. 1701(2). Specifically, a party must, at a minimum, give effect to the substantive provisions of: "(a) the Geneva Convention for the Protection of Producers of Phonograms Against Unauthorized Duplication of their Phonograms, 1971 (Geneva Convention); (b) the Berne Convention for the Protection of Literary and Artistic Works, 1971 (Berne Convention); (c) the Paris Convention for the Protection of Industrial Property, 1967 (Paris Convention); and (d) the International Convention for the Protection of New Varieties of Plants, 1978 (UPOV Convention), or the International Convention for the Protection of New Varieties of Plants, 1991 (UPOV Convention)". *Id.*

141. *Id.*

142. See NAFTA, *supra* note 2, art. 1709(1).

143. RICHARD E. NEFF & FRAN SMALLSON, NAFTA: PROTECTING AND ENFORCING INTELLECTUAL PROPERTY RIGHTS IN NORTH AMERICA 70 & n.4 (1994).

144. NAFTA, *supra* note 2, art. 1709(1).

145. *Id.* Compare with 35 U.S.C. § 101 (1994) which provides, "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." Sections 102-103 additionally require that the invention be novel and nonobvious, respectively. See 35 U.S.C. §§ 102-03 (1994).

146. NAFTA, *supra* note 2, art. 1709(2)-(3).

147. NEFF, *supra* note 143, at 70.

148. NAFTA, *supra* note 2, art. 1709(2).

149. See *id.*

may lead to the exclusion of inventions that are politically sensitive.¹⁵⁰

Article 1709(2) does provide limited guidance in interpreting "ordre public" by listing some instances in which the exclusion may be invoked.¹⁵¹ For example, a Party may exclude an invention from patent protection to "protect human, animal or plant life or health or to avoid serious prejudice to nature or the environment. . ."¹⁵² The only apparent limitation on this exclusion is that a Party may not exclude an invention from patent protection solely on the grounds the particular subject matter of the invention in question is one the excluding Party specifically prevents commercial exploitation of in its territory.¹⁵³ Commercial exploitation by definition includes the sale of a product; therefore, a member country cannot exclude patent protection of a product simply because it is not legally for sale in that country.¹⁵⁴ Despite this limitation, some commentators have asserted that the ordre public and morality exclusions create a large loophole by which parties may maintain barriers to trade specifically in the pharmaceutical industry.¹⁵⁵

2. Exclusions under Article 1709(3).

Additional exclusions from patentability are detailed in Article 1709(3).¹⁵⁶ Under this section, a Party may deny patent protection to the following: "(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; (b) plants and animals other than microorganisms; and (c) essentially biological processes for the production of plants or animals, other than non-biological and microbiological processes for such production."¹⁵⁷

The language of the exclusions under Article 1709(3) provides for a broad range of exclusions.¹⁵⁸ Because medical devices and diagnostic devices are patentable in the United States, there was initial concern devices already patented in the United States would not receive patent protection in Mexico and Canada if this exclusion was invoked.¹⁵⁹ Moreover, the exclusions of Article 1709(3)(b) and (c) encompass many biotechnology inventions and could prove to be problematic until the patent laws of each Party are com-

150. NEFF, *supra* note 143, at 71, n.7, citing reports indicating the use of the ordre public exclusion could be used to prevent patentability of inventions ordinarily patentable in the United States.

151. NAFTA, *supra* note 2, art. 1709(2).

152. *Id.*

153. *Id.*

154. NEFF, *supra* note 143, at 71. One negotiator said "there is no poor taste exception," meaning that simply because a Party does not approve of a product and therefore prohibits the sale of the product based on that subjective dislike, the Party cannot invoke the ordre public exclusion to deny that product patent protection. *Id.* Moreover, the author concludes there must be "a specific finding that the particular product or process would endanger life or health or would seriously prejudice the environment." *Id.*

155. Peggy E. Chaudhry & Michael G. Walsh, *Intellectual Property Rights: Changing Levels of Protection Under Gatt, NAFTA and the EU*, 30 COLUM. J. WORLD BUS. 80, 83 (1995). The authors conclude the pharmaceutical industry will be particularly affected by this exclusion because it is strictly regulated in many countries. *Id.*

156. NAFTA, *supra* note 2, art. 1709(3).

157. *Id.*

158. NEFF, *supra* note 143, at 72.

159. *Id.* at 73.

pletely harmonized.¹⁶⁰ Specifically, "Mexico does not currently [in 1994] provide patent protection for diagnostic, therapeutic, and surgical methods," and Canada's patent laws have been interpreted as "not providing protection for methods of medical treatment."¹⁶¹

a. *Exclusion of Plants and Animals.*

The exclusion of plants and animals as patentable subject matter is also believed to have a chilling effect on the biotechnology industry.¹⁶² As mentioned earlier, the U.S. PTO accepts patent applications for multicellular animals as well as genetically engineered, single-cell organisms.¹⁶³ The U.S. PTO acted in response to the U.S. Supreme Court decision in *Chakrabarty* upholding the patentability of genetically engineered, single-cell organisms not found in nature.¹⁶⁴ Whereas a biotech company may patent a multicellular organism in the United States, that same invention may not receive protection in other countries.¹⁶⁵

b. *Exclusion of Biological Processes in the Production of Plants or Animals.*

Article 1709(3)(c) also affords a Party the option to proscribe the patenting of a biological process used to produce a plant or animal. As with the other exclusions, this exclusion has a potentially broad scope and could be applicable to any biological process used in the production of any plant or animal.¹⁶⁶ Although non-biological processes resulting in the production of plants or animals may be patented,¹⁶⁷ the biological processes of production developed in biotech industries remains excludable.

160. Food and Drug Law Group, Blake, Cassels & Graydon, *Developments in Canadian Law Relating to Food, Drugs, Devices, and Cosmetics as of December 1992*, 49 FOOD & DRUG L.J. 323, 333 (1994).

161. NEFF, *supra* note 143, at 72.

162. *Id.* at 73.

163. Boulware, *supra* note 5, at 462.

164. *Chakrabarty*, 447 U.S. at 309-10.

165. Boulware, *supra* note 5, at 462. A patent was granted for the "Harvard Oncomouse," which is a mouse genetically engineered to be susceptible to cancer.

166. NEFF, *supra* note 143, at 73. Conceivably, this exclusion could apply to processes utilizing naturally occurring viruses for the production of new organisms via fusion of single cells. *Id.*

167. NAFTA, *supra* note 2, art. 1709(3)(c).

D. PIPELINE PROTECTION.

When a member country has granted a patent for pharmaceuticals or agricultural chemicals, and the subject matter of that patent is not recognized as patentable in another member country, the member country not recognizing the subject matter of the patented invention must provide patent protection if two conditions are met.¹⁶⁸ These conditions are: (1) the product must not have been marketed in the country providing the protection; and (2) the person seeking the protection must make a timely request.¹⁶⁹ Article 1709(4) provides what is coined as pipeline protection.¹⁷⁰

E. RIGHTS OF A PATENTEE.

A patent is generally defined as a statutory right to exclude others from practicing or making the invention disclosed in the patent specification.¹⁷¹ The NAFTA confers similar rights to a patentee.¹⁷² Under Article 1709(5), a member country must provide a patentee with "the right to prevent other persons from making, using or selling the subject matter of the patent, without the patent owner's consent."¹⁷³

The NAFTA also distinguishes between a product patent and a process patent.¹⁷⁴ Specifically, Article 1709(5) provides the holder of a process patent the right "to prevent other persons from using that process and from using, selling, or importing at least the product obtained directly by that process, without the patent owner's consent."¹⁷⁵ Because patent rights of the member countries were very similar when the NAFTA was negotiated, the NAFTA did not dramatically change the substantive rights of the patentee; however, the addition of future members to the NAFTA may have a conflict with this provision.¹⁷⁶

168. *Id.* at art. 1709(4). The text of Article 1709(4) is as follows:

If a Party has not made available product patent protection for pharmaceutical or agricultural chemicals commensurate with paragraph 1: (a) as of January 1, 1992, for subject matter that relates to naturally occurring substances prepared or produced by, or significantly derived from, microbiological processes and intended for food or medicine, and (b) as of July 1, 1991, for any other subject matter, that Party shall provide to the inventor of any such product or its assignee the means to obtain product patent protection for such product for the unexpired term of the patent for such product granted in another Party, as long as the product had not been marketed in the Party providing protection under this paragraph and the person seeking such protection makes a timely request.

Id.

169. *Id.*

170. Pipeline provisions are ones without which "a patentee of a drug, patentable in the United States [for example] with a term of one year remaining on the exploitation of the drug, would not enjoy patent protection for the final year in a country that did not recognize the patentability of that drug." NEFF, *supra* note 143, at 74 & n.25.

171. Boulware, *supra* note 5, at 446. The specification must disclose enough information to enable others to make and to use the invention. Whiteside, *supra* note 65, at 1022.

172. NAFTA, *supra* note 2, art. 1709(5).

173. *Id.*

174. *Id.*

175. *Id.*

176. NEFF, *supra* note 143, at 75.

The NAFTA also allows for the limitation of the rights of a patentee "provided that the [limited] exceptions [to the exclusive rights] do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of other persons."¹⁷⁷ The extent of the possible limitations on the rights of a patentee have not been delineated, and this concerns the industries relying on the protection of intellectual property.¹⁷⁸ Finally, the NAFTA provides for the alienability of rights conferred to the patentee.¹⁷⁹

Additional sections of the NAFTA affect the rights of a patentee.¹⁸⁰ In particular, Article 1709(7) prevents a Party from discriminating in the providing of patent protection with regard to: (1) the field of technology; (2) the territory of the Party where the invention was made; and (3) whether the products are imported or locally produced.¹⁸¹

Article 1709(7) was included in the NAFTA to harmonize the patent laws of the member countries.¹⁸² Specifically, Canadian law dealing with compulsory licensing of pharmaceuticals was believed to discriminate against the pharmaceutical industry.¹⁸³ Similarly, prior to the NAFTA, U.S. law was believed to discriminate in that only inventorship within the United States was considered in a patent application.¹⁸⁴ Currently, U.S. patent law does recognize inventorship in NAFTA countries for the purpose of determining the date of invention.¹⁸⁵

177. NAFTA, *supra* note 2, art. 1709(6).

178. NEFF, *supra* note 143, at 75.

179. NAFTA, *supra* note 2, art. 1709(9).

180. *Id.* at art. 1709(7)-(8).

181. *Id.* at art. 1709(7). Article 1709(7) provides "[s]ubject to paragraphs 2 and 3, patents shall be available and patent rights enjoyable without discrimination as to the field of technology, the territory of the Party where the invention was made and whether products are imported or locally produced." *Id.*

182. NEFF, *supra* note 143, at 76.

183. *Id.*

184. *Id.*

185. 35 U.S.C.A. § 104 (1984), It provides:

(A) In general.--

- (1) Proceedings.--In proceedings in the Patent and Trademark Office, in the courts, and before any other competent authority, an applicant for a patent, or a patentee, may not establish a date of invention by reference to knowledge or use thereof, or other activity with respect thereto, in a foreign country other than a NAFTA country or a WTO member country, except as provided in sections 119 and 365 of this title.
 - (2) Rights.--If an invention was made by a person, civil or military--
 - (A) while domiciled in the United States, and serving in any other country in connection with operations by or on behalf of the United States,
 - (B) while domiciled in a NAFTA country and serving in another country in connection with operations by or on behalf of that NAFTA country, or
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F. COMPULSORY LICENSING UNDER ARTICLE 1709(10).

Article 1709(10) provides for the use of a patent without the authorization of the patentee.¹⁸⁶ The use of a patent by a government of persons authorized by a government without the patentee's authorization is known as compulsory licensing.¹⁸⁷ Compulsory licenses are commonly granted in developing countries and are feared by developed countries.¹⁸⁸ Although the NAFTA does allow compulsory licenses, the granting of these licenses is strictly limited.¹⁸⁹

1. *Limitations on the Granting of Compulsory Licenses.*

The first limitation on the granting of a compulsory license is that each grant of a compulsory license must be decided on an individual basis.¹⁹⁰ By restricting the grant of a license to review on an individual basis, the NAFTA prevents a member country from granting a license to an entire industry.¹⁹¹

Additionally, the user of the compulsory license must have attempted to obtain authorization from the patentee "on reasonable commercial terms and conditions and such efforts have not been successful within a reasonable period of time."¹⁹² Importantly, this section of the NAFTA does not define what a reasonable time is.¹⁹³ The requirement

(C) while domiciled in a WTO member country and serving in another country in connection with operations by or on behalf of that WTO member country, that person shall be entitled to the same rights of priority in the United States with respect to such invention as if such invention had been made in the United States, that NAFTA country, or that WTO member country, as the case may be.

- (3) Use of information.--To the extent that any information in a NAFTA country or a WTO member country concerning knowledge, use, or other activity relevant to proving or disproving a date of invention has not been made available for use in a proceeding in the Patent and Trademark Office, a court, or any other competent authority to the same extent as such information could be made available in the United States, the Commissioner, court, or such other authority shall draw appropriate inferences, or take other action permitted by statute, rule, or regulation, in favor of the party that requested the information in the proceeding.

Id.

186. NAFTA, *supra* note 2, art. 1709(10).

187. NEFF, *supra* note 143, at 78-79.

188. Lori M. Berg, Comment, *The North American Free Trade Agreement & Protection of Intellectual Property: A Converging View*, 5 J. TRANSNAT'L L. & POL'Y 99, 119 (1995).

189. NAFTA, *supra* note 2, art. 1709(10).

190. *Id.* Article 1709(10)(a) provides that "authorization of such use shall be considered on its individual merits." *Id.*

191. NEFF, *supra* note 143, at 79.

192. NAFTA, *supra* note 2, art. 1709(10)(b).

193. *Id.*

to negotiate with the patentee for the right to use the patent prior to the granting of a compulsory license can be waived in case of a national emergency, but the patentee must be notified.¹⁹⁴

One of the most important limitations on compulsory licenses is that "the scope and duration of such use shall be limited to the purpose for which it was authorized."¹⁹⁵ By limiting the scope of the compulsory license, the exploitation of the patent by the patentee is preserved as much as possible.¹⁹⁶ Additionally, the use is nonexclusive, nonassignable, and the use of the patent must be for the domestic market.¹⁹⁷

2. Reviewability of Compulsory Licenses.

The granting of a compulsory license is reviewable and can be terminated when the reasons for granting the license are no longer present.¹⁹⁸ Further, the act of granting a compulsory license and the amount of remuneration to the patentee are reviewable by the judiciary or by an appropriate authority.¹⁹⁹ Finally, a compulsory license cannot be granted to allow the exploitation of a different patent.²⁰⁰

G. ENFORCEMENT OF PATENT RIGHTS.

The length of protection for a patent under the NAFTA is twenty years from the date of filing or seventeen years from the date the patent is granted.²⁰¹ During this time, the patentee has the exclusive right to exclude others from using the patent.²⁰² If a patentee

194. *Id.* Article 1709(10)(b) provides in part:

The requirement to make such efforts may be waived by a Party in the case of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly.

Id.

195. *Id.* at art. 1709(10)(c).

196. *Id.* at art. 1709(10)(h). The patentee is compensated for the compulsory license. Article 1709(10)(h) provides "the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization." *Id.*

197. NAFTA, *supra* note 2, art. 1709(10)(d)-(f). A compulsory license may be assignable only "with that part of the enterprise or goodwill that enjoys such use." NAFTA, *supra* note 2, art. 1709(10)(e).

198. *Id.* at art. 1709(10)(g).

199. *Id.* at art. 1709(10)(i)-(j).

200. *Id.* at art. 1709(10)(l). This section allows the granting of a compulsory license for the exploitation of a different patent, but only "as a remedy for an adjudicated violation of domestic laws regarding anticompetitive practices." *Id.*

201. *Id.* at art. 1709(12). Parties are also permitted to extend the term of the patent to account for delays in the approval process. *Id.* The current term of a patent in the United States is twenty years from the date of filing. Uruguay Round of Multilateral Trade Negotiations of 1994, Pub. L. No. 103-465, 108 Stat. 4809.

202. *Id.* at art. 1709(5).

believes his or her patent is being infringed by someone using the patent without authorization, he or she can bring legal action against the infringing Party within the term of the patent.²⁰³

The NAFTA provides that each member must make enforcement measures available under domestic law "so as to permit effective action to be taken against any act of infringement of intellectual property rights. . ."²⁰⁴ These measures must be "fair and equitable," reasonable in cost, and timely.²⁰⁵ Finally, decisions of each case, both judicial and administrative, should be in writing and should include the reasoning of the decision.²⁰⁶

Additionally, Article 1715 provides the framework for civil and administrative procedures available for infringement of a patent.²⁰⁷ Among the procedures included are:

- (a) defendants have the right to written notice that is timely and contains sufficient detail, including the basis of the claims;
- (b) parties in the proceeding are allowed to be represented by independent legal counsel;
- (c) the procedures do not include imposition of overly burdensome requirements concerning mandatory personal appearances;
- (d) all parties in a proceeding are duly entitled to substantiate their claims and to present relevant evidence; and
- (e) the procedures include a means to identify and protect confidential information.²⁰⁸

To facilitate this provision, judicial authorities may: (1) order the production of evidence;²⁰⁹ (2) make preliminary and final determinations on incomplete evidence when a party refused to cooperate; (3) order a Party in a proceeding to desist from infringement;²¹⁰ (4) award damages;²¹¹ (5) award attorney's fees;²¹² and (6) provide compensation to a Party in which the proceeding was brought as an abuse of the enforcement measures.²¹³ Additionally, judicial authorities have powers to deter infringement, including

203. *Id.* at art. 1715.

204. *Id.* at art. 1714(1). These measures must be used to prevent the creation of trade barriers and contain provisions to prevent abuse of the system. *Id.*

205. Specifically, NAFTA, *supra* note 2, art. 1714(2) provides that "[e]ach Party shall ensure that its procedures for the enforcement of intellectual property rights are fair and equitable, are not unnecessarily complicated or costly, and do not entail unreasonable time-limits or unwarranted delays."

206. *Id.* at art. 1714(3). This provision also limits decisions to the evidence adduced at the hearing.

207. *Id.* at art. 1715.

208. *Id.* at art. 1715(1).

209. *Id.* at art. 1715(2)(a).

210. *Id.* at art. 1715(2)(c).

211. *Id.* at art. 1715(2)(d).

212. *Id.* at art. 1715(2)(e).

213. *Id.* at art. 1715(2)(f).

the power to destroy infringing goods.²¹⁴

Lastly, a Party has the option of providing criminal penalties in cases of willful infringement on a commercial scale.²¹⁵ Importantly, the substantive provisions of each member's intellectual property law vary.²¹⁶ As a result, the actual enforcement, or lack of enforcement, of these protections may become problematic in the future.²¹⁷ A Party's willingness to enforce the protection of intellectual property may be linked to how their cultural, moral, and religious beliefs impact their view of intellectual property.²¹⁸

IV. Developing Countries and Intellectual Property Protection.

Biotechnology has attracted the attention of developing countries because of the belief biotechnology can quickly improve the economy and standard of living.²¹⁹ Although developing countries stand to benefit from the advances of biotechnology, many of these countries do not provide adequate intellectual property protection necessary to facilitate the transfer of such technology from developed countries to developing countries.²²⁰

Historically, developing countries have not recognized private property rights such as intellectual property rights.²²¹ In contrast, developed countries such as the United States have a long tradition of protecting private property rights.²²² Unlike many other industrialized nations, the United States recognized the importance of the protection of these

214. These powers are found in NAFTA, *supra* note 2, art. 1715(5) which provides: judicial authorities shall have the authority to order that:

- (a) goods that they have found to be infringing be, without compensation of any sort, disposed of outside the channels of commerce in such a manner as to avoid any injury caused to the right holder or, unless this would be contrary to existing constitutional requirements, destroyed; and
- (b) materials and implements the predominant use of which has been in the creation of the infringing goods be, without compensation of any sort, disposed of outside the channels of commerce in such a manner as to minimize the risks of further infringements.

215. *Id.* at art. 1717(3).

216. Kenneth D. Sibley, *Foreign Patents*, in *THE LAW AND STRATEGY OF BIOTECHNOLOGY PATENTS*, *supra* note 15, at 188.

217. Chaudhry, *supra* note 155, at 91.

218. Zagaris, *supra* note 14, at 123.

219. Unfortunately, developing countries lack both the industrial and economic infrastructure necessary to achieve this goal. Ratledge, *supra* note 33, at 3. "Biotechnology will not create an affluent society but will only help an existing one to become more prosperous." *Id.* at 4.

220. Jozwiak, *supra* note 56, at 622-24 (writing that biotechnology has produced genetically-engineered animals that could alleviate mass starvation and disease).

221. Amy E. Carroll, Comment, *Not Always the Best Medicine: Biotechnology and the Global Impact of U.S. Patent Law*, 44 AM. U.L. REV. 2433, 2465 (1995)[hereinafter Carroll].

222. *Id.*

forms of intangible property in its constitution.²²³ Developed countries recognize the protective regulation of patenting provides incentives for private-sector investments in high-tech, science-based biological technologies.²²⁴

Developing countries, having less technology by definition, have been resigned to purchasing technology from developed countries in an attempt to both reduce the disparity in technology and to improve their economies.²²⁵ Developed countries condition the sale of technology on the forced improvement of the purchasing country's domestic intellectual property law. As a result, developing countries have been hesitant to harmonize their intellectual property laws with those of developed countries.²²⁶

In addition to the historical skepticism of private property rights, two lines of reasoning have developed to explain the resistance developing countries have to adopting strong intellectual property laws.²²⁷ First, developing countries are more likely to view technological advances as public good rather than a private right.²²⁸ Arguably, this view is an altruistic one similar to the concept that the good of the many outweighs the good of the few.²²⁹

Second, developing countries are concerned the granting of patents will increase the cost of needed pharmaceuticals.²³⁰ The increase in costs would adversely affect individuals who need the product by potentially preventing impoverished patients from being able to purchase them.²³¹ Additionally, domestic pharmaceutical industries would be required to purchase licenses from the patentee at prices which could ultimately put them out of business.²³²

Despite the differing views regarding the protection of intellectual property between developed and developing countries, these differences will become moot as more nations sign on to other multilateral trade agreements including the General Agreement on Trade and Tariffs.²³³

223. U.S. CONST. art. I, § 8, cl. 8 commands in part to "promote the Progress of Science and the useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."

224. Harold H. Lee & Fredrick E. Tank, *A Conceptual Framework for Biotechnology Assessment*, in *BIOTECHNOLOGY: A HOPE OR THREAT?* 17, 21 (Ifikhar Ahmed ed., 1992).

225. Caroll, *supra* note 221, at 2466.

226. *Id.* Forcing developing countries to change their domestic laws is tantamount to "technological colonialism." *Id.*

227. Chaudhry, *supra* note 155, at 88; Caroll, *supra* note 221, at 2465.

228. Chaudhry, *supra* note 155, at 88.

229. *Id.* "The idea of a better-ordered world is one in which medical discoveries will be free of all patents and there will be no profiteering from life and death." *Id.* (quoting Indira Ghandi from *STRENGTHENING PROTECTION OF INTELLECTUAL PROPERTY IN DEVELOPING COUNTRIES* (1990)). But see Ratledge, *supra* note 33, at 3, writing "[a]ltruistic biotechnology does not exist or if it does it simply consumes money and does not generate it."

230. Caroll notes that providing increased patent protection would increase administrative costs, which would be absorbed by the domestic economy. Caroll, *supra* note 221, at 2468. Chaudhry quotes Jose Fernando Magalhaes, director of the Brazilian company Sinto Farms, as saying "[p]atients in any country must have the option of buying a drug at the best possible price." Chaudhry, *supra* note 155, at 88.

231. Chaudhry, *supra* note 155, at 88.

232. *Id.*

233. *Id.* at 91. The author points out that future problems are more likely to result from the use of the exclusions of patentability, such as for ordre public, as loopholes. *Id.*

V. Conclusion.

According to Coopers & Lybrand, the most important issue facing the pharmaceutical and biotechnology industries is the timely development of new products.²³⁴ Obviously, the next step would be to protect these new products. Whether this protection is a result of free trade agreements or changes in domestic law, "protecting intellectual property from counterfeiters amounts to protecting American economic well-being."²³⁵

Although the NAFTA has been hailed as providing comprehensive intellectual property protection, it has not changed substantive patent laws; rather, the NAFTA affects trade in patented products.²³⁶ The potential use of the exclusions from patentability for the protection of public order, morality, or public health has specific importance to the biotechnology industry because many biotechnology inventions have the potential to fall within these exclusions.²³⁷ Negotiations for the elimination or restriction of these exclusions should be pursued if the exclusions are frequently used to maintain barriers to free trade.

As more nations become parties to international agreements, the potential use of these exclusions could increase if changes in domestic laws are not harmonized with those of other members. The harmonization of domestic law with the international agreements is generally a prerequisite to joining the agreement,²³⁸ thereby making the use of the exclusions less likely.

Significant changes have occurred in all three of the NAFTA members' domestic laws. For example, as previously described, the United States now recognizes inventorship in member countries. Canada has passed a law, Bill C 91, which gives brand-name drug makers twenty-year patent protection in an effort to conform its compulsory licensing system with the NAFTA.²³⁹ In 1991 Mexico passed the Law for the Promotion and Protection of Industrial Property which revised its laws on intellectual property in anticipation of the NAFTA.²⁴⁰ These changes suggest more are possible and are probably necessary as the courts catch up to the ever advancing field of biotechnology.

234. Johanna Powell, *Biotech Firms See Profit in Rationalization*, FIN. POST, Sept. 26 1996, at 15, available in 1996 WL 5741429.

235. Lehman, *supra* note 1, at 15.

236. Boulware, *supra* note 5, at 505.

237. See Neff, *supra* note 158 and accompanying text.

238. See NAFTA, *supra* note 137 and accompanying text.

239. Jennifer Lanthier, *Trade Boards Lobby for Patent Drug Protection*, FIN. POST, Mar 20 1996, at 9, available in 1996 WL 5726576. Bill C-91 is up for parliamentary review in 1997. *Id.*

240. NEFF, *supra* note 143, at 82.
