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I. Introduction.

Canada and the United States are each other's largest trading partners and have many cultural similarities.[1] Trade relations between the United States and Canada, however, also have many parallels between the United States and developing nations. The net import and export of intellectual property are in opposite directions. Canada is a net importer of intellectual property from the United States,[2] while the United States

1. *See* U.S. Dep't of Commerce, Int'l Trade Admin., U.S. Foreign Trade Highlights, Table 6, U.S. Total Exports to Individual Countries, 1991–98 (visited Sept. 18, 1999), http://www.ita.doc.gov/industry/otea/usfth/aggregate/Hl98t06.txt and Table 7, U.S. Total Imports from Individual Countries, Table 7, 1991–98, http://www.ita.doc.gov/industry/otea/usfth/aggregate/Hl98t07.txt (in 1998, America's imports to and exports from Canada exceeded the total imports and exports to and from all other countries in the western hemisphere combined) [hereinafter Highlights].

2. *See* Allen Z. Hertz, *NAFTA Revisited: Shaping the Trident: Intellectual Property Under NAFTA, Investment Protection Agreements and at the World Trade Organization*, 23 CAN.-U.S. L.J. 261, 304 n. 197 (1997) (citing reports from Consumer and Corporate Affairs Canada and the Canadian Intellectual Property Office that patent registration by Canadian and American inventors were 10 percent and 50 percent, respectively); *id.* at 307 (the United States produces 94 percent and 75 percent of the films and television shows seen in Canada); *id.* at 308 ("Canada is the largest export market for U.S. books which are [79 percent] of all book imports [into Canada]. . . "); John Baldwin, *Innovation and Intellectual Property, Micro-Economics Analysis Division, Statistics Canada* (visited Sept. 19, 1999), http://www.statcan.ca/Daily/English/970317/d970317.htm#ART3 (only a small percentage of Canadian-owned manufacturing firms use trademarks (11 percent), trade secrets (8.3 percent), and patents (7.1 percent)).

is a net exporter.[3] The United States has a growing trade deficit with Canada.[4] Canada and the United States had different priorities when negotiating the North American Free Trade Agreement (NAFTA).[5] For Canada, the U.S.–Canada Free Trade Agreement secured access to the U.S. market in 1988.[6] Continued access to that market while preserving Canada's cultural identity and obtaining U.S. national treatment were important negotiating points.[7] For the United States, provisions to ensure intellectual property protection and their enforcement were key points.[8] The same issues were negotiated for the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).[9]

As the United States shifts from a manufacturing-based to a knowledge-based economy, protecting intellectual property rights through international agreements takes on increasing importance.[10] NAFTA and TRIPS are hailed as major advances in international intellectual property protection. Both treaties are subject to state dispute settlement proceedings with compulsory third-party arbitration, a final ruling requiring compliance, and procedures to enforce decisions.[11] International dispute resolution mechanisms are important last resorts to address treaty violations under NAFTA and TRIPS that were absent in previous treaties. The routine enforcement of treaty obligations, however, falls to each country's judicial system.

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3. *See* Highlights, *supra* note 1, Table 2, U.S. Trade in Services by Major Category, 1975–98, http://www.ita.doc.gov/industry/otea/usfth/aggregate/Hl98t02.txt (the net balance for U.S. royalties and license fees exports in 1998 was $25.5 billion worldwide, up 52 percent from 1993).
4. *See Trade Surplus Just Keeps Rising*, THE TORONTO STAR, Aug. 20, 1999 (the U.S. trade deficit with Canada is at a record $24.6 billion (U.S.)).
5. *See generally* North American Free Trade Agreement, drafted Aug. 12, 1992, revised Sept. 6, 1992, U.S.-Can.-Mex., 32 I.L.M. 289, 297 (entered into force Jan. 1, 1997) [hereinafter NAFTA].
6. *See* Canada-U.S. Free Trade Agreement, Jan. 2, 1988, 27 I.L.M. 281 (1988) [hereinafter FTA]; Jean Raby, *The Investment Provisions of the Canada–United States Free Trade Agreement: A Canadian Perspective*, 84 AM. J. INT'L L. 394, 443 (1990) (for a minor loosening in the regulation of foreign direct investment, Canada secured investment access to the United States).
7. *See* Hertz, *supra* note 2, at 310; Eileen McMahon, *NAFTA and the Biotechnology Industry*, 33 CAL. W. L. REV. 31, 31–32 (1996) (under article 1703(1), each Party must treat foreigners no worse than its own nationals in protecting and enforcing intellectual property rights).
8. *See* Joseph S. Papovich, *NAFTA's Provisions Regarding Intellectual Property: Are They Working as Intended?*, 23 CAN.-U.S. L.J. 253, 254–55 (1997) (recounting the negotiations for intellectual property rights provisions in NAFTA); McMahon, *supra* note 7, at 31 (same).
9. *See generally* Agreement on Trade-Related Aspects of Intellectual Property Rights, 33 I.L.M. 1197 (1994), *in* General Agreement on Tariffs and Trade: Multilateral Trade Negotiations Final Act Embodying the Results of the Uruguay Round of Trade Negotiations, Apr. 15, 1994, 33 I.L.M. 1125, Annex 1C (1994) [hereinafter TRIPS]; Papovich, *supra* note 8, at 254.
10. *See* Gregory J. Maier, *High-Tech Economy Is Propelled by IP*, 21 NAT'L L.J. B10 (1999).
11. *See* Hertz, *supra* note 2, at 267; Papovich, *supra* note 8, at 255; NAFTA, *supra* note 5, ch. 20, section B; TRIPS, *supra* note 9, art. 64 (dispute settlement).

The extent to which NAFTA and TRIPS protect intellectual property rights ultimately depends on how they are codified and then enforced by the parties.[12] Statutes are interpreted by courts against a background of prior case law, current political atmosphere, and long-standing cultural influences. A treaty's impact becomes clear only after being interpreted by each nation's law making and judicial system. Given the trade volume between the two nations, analyzing America's and Canada's implementation and interpretation of the NAFTA and TRIPS agreements is important in its own right. This analysis also provides insights into the differences in protections likely to arise between the United States and developing nations making similar agreements.

As shown below, despite similarly worded statutes purporting adherence to the NAFTA and TRIPS treaties, the scope of protection and enforcement of intellectual property rights differs substantially between Canada and the United States. I have investigated selected areas where significant disparities in protection exist in the four major categories of intellectual property law. Part II looks at copyright protection for databases and sound recordings, moral rights, and the fair use defense. Part III examines patent protection for life forms and compulsory licensing for drugs. Part IV compares trade secret protections for data submitted to government agencies for obtaining approval to market drugs. Part V considers trademark protection for well-known marks. These are all the areas recently addressed by statutory revisions or interpretations by courts in one or both countries. My focus is to determine the basis for disparities and the harmonizing effect of the NAFTA and TRIPS agreements, if any. Each part surveys the pertinent provisions in NAFTA and TRIPS, statutory changes in intellectual property law, and courts' interpretations of their nation's treaty obligations. In Part VI, I summarize the foregoing analysis and the implications for future international treaties designed to enforce intellectual property rights.

II. Copyright Law.[13]

A. Database Protection.

1. NAFTA.

NAFTA protects works described in Article 2 of the Berne Convention, "including any other works that embody original expression . . . ."[14] Article 2(1) of the Berne

12. *See* Sharon L. Goolsby, *Protection of Intellectual Property Rights under NAFTA*, 4 NAFTA L. & Bus. Rev. Am. 5, 92 (1998) (NAFTA's provisions are ambiguous enough to allow any Party to avoid protecting intellectual property rights while apparently complying with the treaty).

13. *See generally* Kimberly Hancock, *Canadian Copyright Act Revisions*, 13 Berkeley Tech. L.J. 517 (1998); Sunny Handa, *A Review of Canada's International Copyright Obligations*, 42 McGill L.J. 961 (1997); Bob H. Sotiriadis, *A Summary of Some Distinctions between Canadian and American Copyright Law and Practice* (visited Sept. 2, 1999), http://www.robic.ca/publications/228.htm (material delivered in a lecture to during the annual meeting of the Section of Intellectual Property of the American Bar Association on August 1, 1998).

14. *See* NAFTA, *supra* note 5, art. 1705(1); Berne Convention for the Protection of Literary and Artistic Works, Sept. 9, 1886, completed Paris, May 4, 1896, last revised Paris, July 24, 1971, S. Treaty Doc. No. 27, 99th Cong., 2d Sess. (1986) [hereinafter Berne Convention].

Convention "include[s] every production in the literary, scientific and artistic domain, whatever may be the mode or form of its expression . . . ."[15] NAFTA extends protection to "compilations of data . . . which by reason of the selection or arrangement of their contents constitute intellectual creations . . . ."[16] But "protection . . . shall not extend to the data or material itself, or prejudice any copyright subsisting in that data or material."[17]

2. TRIPS.

Article 10(2) of TRIPS specifically protects compilations of data, using nearly identical language as NAFTA.[18]

3. United States.

a. Statutory Law.

The United States made no major changes in its laws covering copyright subject matter to comply with NAFTA or TRIPS.[19] Section 102 of the U.S. Copyright Act defines the scope of subject matter protected as "original works of authorship fixed in any tangible medium of expression . . . ."[20] Ideas, procedures, processes, systems, methods of operation, concepts, principles or discoveries cannot be copyrighted.[21] Compilations are included as proper subject matter, but "only to the material contributed . . . as distinguished from the preexisting material employed in the work, and does not imply any exclusive right in the preexisting material."[22] Compilations are "formed by the collection and assembling of preexisting materials or of data that are selected, coordinated or arranged in such a way that the [result] . . . constitutes an original work . . . ."[23]

b. Judicial Interpretations.

In *Feist Publications, Inc. v. Rural Telephone Service Co., Inc.*, the U.S. Supreme Court held that the U.S. Constitution mandates originality as a prerequisite for copyright protection.[24] From Section 103 of the Copyright Act, the Court derived a three-element

15. Berne Convention, *supra* note 14, art. 2(1).
16. NAFTA, *supra* note 5, art. 1705(1)(a–b).
17. *Id.*
18. "Compilations of data . . . by reason of the selection or arrangement of their contents . . . shall be protected . . . [P]rotection . . . shall not extend to the data or material itself . . . "; *see* TRIPS, *supra* note 9, art. 10(2).
19. *See* Goolsby, *supra* note 12, at 55.
20. 17 U.S.C. § 102(a) (1994) [hereinafter Copyright Act]. Fixation occurs when the work is "sufficiently permanent . . . to be perceived, reproduced or otherwise communicated . . . " *Id.* § 101.
21. *Id.* § 102(b).
22. *Id.* § 103(b).
23. *Id.* § 101.
24. 499 U.S. 340, 346 (1991).

test for compilations to be copyrightable: (1) collection and assembly of preexisting material, facts, or data; (2) selection, coordination, or arrangement of the material; and (3) creation, by virtue of the particular selection, coordination, or arrangement, of an "original" work of authorship.[25]

The Court concluded that although facts in a compilation may not be copyrighted, the choice and arrangement of those facts may be.[26] Therefore, copyright extends only to the original components of a compilation made by the compiler.[27] The Court rejected allowing a copyright because of the amount of work done by the compiler. Such a "sweat of the brow" rationale would extend copyright protection of compilations to the facts themselves.[28] Allowing facts to be copyrighted would unreasonably require each new compiler to start from scratch because they would be precluded from relying on a previous compilation.[29] Nevertheless, there is increasing pressure on the United States to increase protection for database owners. U.S. database owners have lobbied the World Intellectual Property Organization (WIPO) for international treaty protections similar to that offered in Europe.[30] The proposed Collections of Information Antipiracy Act addresses these concerns.[31]

4. Canada.

a. Statutory Law.

Section 5(1) of the Copyright Act provides that copyright shall subsist in an exclusive list of "every original literary, dramatic, musical and artistic work."[32] As a result of NAFTA, the Canadian Copyright Act was amended to expressly include compilations as covered works.[33] Original literary works "include[s] every original production in the literary, scientific or artistic domain, whatever may be the mode or form of its expression."[34] Compilations are defined as resulting from the selection or arrangement of literary, dramatic, musical or artistic works, or the selection or arrangement of data.[35] Unlike the U.S. copyright law, however, there is no express restriction on protecting only those aspects of the compilation uniquely added by the compiler.

25. *Id.* at 357.
26. *Id.* at 348.
27. *Id.*
28. *Id.* at 353.
29. *Id.* at 359.
30. *See* Robert P. Merges et al., *Intellectual Property in the New Technological Age* 340 (1997).
31. The Act proposes fifteen years of protection for "all or a substantial part . . . of a collection of information gathered, organized, or maintained by another person through the investment of substantial monetary or other resources, so as to cause harm to the actual or potential market of that other person . . . " H.R. 354, 106th Cong. § 1402 (1999).
32. Copyright Act, R.S.C., ch. C-30 (1985), § 5(1) (1985) (Can.) [hereinafter Canadian Copyright Act] (visited Jan. 11, 2000), http://canada.justice.gc.ca/STABLE/EN/Laws/Chap/C/C-42.html.
33. *Id.* § 25.
34. *Id.* § 2.
35. *Id.*

b. Judicial Interpretations.

Traditionally, courts viewed the Canadian Copyright Act as created for the sole objective of benefiting the authors of covered works.[36] Copyright protection serves to encourage disclosure to advance learning and to reward and protect an author's intellectual efforts.[37] As late as 1995, an author's "sweat of the brow" industriousness was enough to make a work copyrightable.[38] NAFTA, however, prompted courts to reject industriousness as grounds for copyrightability. For example, in *Tele-Direct Inc. v. American Bus. Inform.*, the Federal Court of Appeals upheld a ruling that a compilation devoid of creativity was not protected under copyright law.[39] Because compilations were added to the Copyright Act for the purpose of implementing NAFTA, the court sought guidance from the wording of NAFTA article 1705(1).[40]

The court noted that Article 1701(1) refers to protecting "original expressions" and Article 1705(1)(b) to compilations constituting "intellectual creations." The court concluded that in signing and implementing NAFTA, Parliament intended courts to adopt a creativity requirement for protected works.[41] In dicta, the court also approved of looking to authoritative decisions from U.S. courts for aid in interpreting Canadian statutes implementing NAFTA, when the statute's wording closely tracks a U.S. statute.[42] Thus, NAFTA appears to have swayed the Canadian judiciary to adopt a view of copyright protection for databases that matches the holding in *Feist*. Ironically, this occurs at a time when the United States may expand database protection beyond *Feist*, if the Collections of Information Antipiracy Act is passed.[43]

B. Sound Recordings.

1. *NAFTA.*

NAFTA requires parties to adopt the substantive provisions of the Geneva Convention.[44] The producer of a sound recording has the right to: control; direct or indirect

36. *See, e.g.*, Bishop v. Stevens [1990] 31 C.P.R. (3d) 394, 403 (S.C.C.).
37. *See* Apple Computer Inc. v. Mackintosh Computers Ltd. [1986] 28 D.L.R. (4th) 178, 213 (F.C.T.D.); *aff'd* 18 C.P.R.(3d) 129 (F.C.A.); *aff'd* 30 C.P.R. (3d) 257 (S.C.C.).
38. *See* U & R Tax Services Ltd. v. H&R Block Canada, Inc. [1995] 62 C.P.R. (3d) 257, 264 (F.C.T.D.) (copyright subsists in a compilation where sufficient labor or time has been expended).
39. [1997] 76 C.P.R. (3d) 296, 308 (F.C.A.); *aff'd* [1998] Can. S.C.R. LEXIS 373.
40. *Id.* at 303.
41. *Id.* at 304.
42. *Id.* at 304. nn.8–9.
43. A point of irony not lost on the Canadian judiciary. See Hager v. ECW Press Ltd. [1998] 85 C.P.R. (3d) 289, 309, 309 n.9 (Judge Reed noting the U.S. debate over *Fiest* signaling a change in database protection, and efforts to enact legislation that would overrule the holding).
44. *See* Goolsby, *supra* note 12, at 26–27. Under the Geneva Convention, producers of phonograms are protected from unauthorized duplication, importation, and distribution to the public. *See* also Geneva Convention for the Protection of Producers of Phonograms Against Unauthorized Duplication of Their Phonograms, Oct. 29, 1971, 25 U.S.T. 309, 866 U.N.T.S. 67.

reproductions or sound recordings; the importing of unauthorized recordings; the first public distribution of the original and copies of recordings by sale, rental or otherwise; and the commercial rental of recordings, unless otherwise allowed by contractual agreement between the producer and the author.[45]

Producer's rights are limited only for "special cases that do not conflict with a normal exploitation of the sound recording and do not unreasonably prejudice the legitimate interests of the right holder."[46] Under NAFTA's cultural industries exception,[47] however, parties have no obligations for cultural industries, as defined in NAFTA article 2107, including NAFTA's intellectual property provisions.[48] In addition, the protection given to foreign performers are limited by national reciprocity principles.[49] This differs from NAFTA's general rule to treat another party's nationals no less favorably than one's own nationals.[50]

2. TRIPS.

By incorporating the Berne Convention, TRIPS gives authors of literary and artistic works the exclusive right to allow reproduction of their works in any manner or form.[51] Article 14 gives the producers of phonograms the right to prevent the unauthorized reproduction of sound recordings and broadcasters the right to prevent the unauthorized broadcasting of a performance to the public.[52] Similar to NAFTA, TRIPS gives producers the right to authorize or prohibit direct or indirect reproductions.[53] TRIPS, however, has no cultural industries exception.[54] While TRIPS, like NAFTA, requires national treatment as the general rule, an exception was created for performers and producers of phonograms, with national treatment only applying to the rights enumerated in Article 14.[55]

45. *See* NAFTA, *supra* note 5, art. 1706(1).
46. *Id.* art. 1706(3). This exception has been criticized as poorly drafted because the meanings of "special cases," "normal exploitation," and "legitimate interests" are not defined. *See* Goolsby, *supra* note 12, at 21.
47. *See* NAFTA, *supra* note 5, Annex 2106.
48. *See* Hertz, *supra* note 2, at 313.
49. *See* NAFTA, *supra* note 5, art. 1703(1) ("a Party may limit rights of performers of another Party . . . to those rights its nationals are accorded . . . ").
50. *Id.*; *see* Goolsby, *supra* note 12, at 15.
51. *See* Berne Convention, *supra* note 14, art. 2(1) & 9 (musical compositions are included in the definition of literary and artistic works).
52. *See* TRIPS, *supra* note 9, art. 14(1).
53. *Id.* art. 14(2).
54. *See* Hertz, *supra* note 2, at 313; Robert Eberschlag, Comment, *Culture Clash: Canadian Periodical Policies and the World Trade Organization*, 26 MAN. L.J. 65, 92–93 (1998) (discussing the failure of Canada to gain support for a general cultural exception in early Uruguay Round negotiations).
55. *See* TRIPS, *supra* note 9, art. 3(1).

3. United States.

a. Statutory Law.

Sound recordings are explicitly protected as a work of authorship under the Copyright Act.[56] The unauthorized fixation and trafficking of sound recordings is an infringement entitling performers to the same remedies as any other form of copyright infringement.[57] Traditionally, the United States has no general royalty or tariff system applied to devices and recording media used to copy sound recordings, or for the public performance of sound recordings.

This was partly changed in 1992 with the Audio Home Recording Act (AHRA).[58] The AHRA created a quarterly royalty payment system payable by the first to make or import digital audio recording devices or associated media.[59] Also, covered recording devices must conform to the Serial Copy Management System, designed to prevent serial copying.[60] A covered device is "any machine . . . distributed to individuals . . . for the primary purpose of . . . making a digital audio copied recording for private use."[61] Covered media must be "primarily marketed or most commonly used . . . for the purpose of making digital audio copied recordings" by a covered device.[62] Excluded are analog recording devices or media, and digital recording devices and media for noncommercial use by a consumer.[63] Royalties are paid to a Sound Recordings Fund, administered by representatives from the American Federation of Musicians and the American Federation of Television and Radio Artists,[64] and to a Musical Works Fund, which distributes the proceeds to music publishers and writers with a copyright interest.[65] No restrictions are placed on the citizenship of artists or publishers compensated from these funds.

b. Judicial Interpretations.

In the first case of interpreting the AHRA, the Ninth Circuit affirmed the district court's denial of an injunction against the maker of a digital audio recording device.[66] The plaintiffs, Recording Industry Association of America (RIAA), alleged that Diamond Multimedia Systems violated the AHRA by producing a device allowing the indirect reproduction of digital music from a transmission previously loaded onto a computer.[67]

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56. *See* Copyright Act, *supra* note 20, § 102(a)(7). A sound recording is a work resulting "from the fixation of a series of musical, spoken, or other sounds," except for sounds in audiovisual works, such as movies. *Id.* § 101.
57. *Id.* § 1101(a).
58. *Id.* § 1002(a); § 1001(11) (the Act was directed toward preventing serial copying; the duplication of a copyrighted work from a previous digital copy).
59. *Id.* § 1003(a); § 1004(a).
60. *Id.* § 1002(a).
61. *Id.* § 1001(3).
62. *Id.* § 1001(4)(A).
63. *Id.* § 1008.
64. *Id.* § 1006(b)(1).
65. *Id.* § 1006(b)(2).
66. *See* Recording Indus. Ass'n of Am., Inc. v. Diamond Multimedia Sys., Inc., 180 F.3d 1072, 1081 (9th Cir. 1999).
67. *Id.*

RIAA's goal in enjoining Diamond was to prevent the expansion of sound recording piracy made possible by using digital recording technology and compression algorithms that allow the rapid downloading of digital audio computer files of music from pirate Web sites on the Internet.[68] RIAA asserted that the device in question, the "RIO," allowed downloading and listening on the portable hand-held machine.

The court held that the RIO was not a digital audio recording device within the meaning of the AHRA, "because the RIO cannot make copies from transmissions, but instead, can only make copies from a computer hard drive, it is not a digital audio recording device."[69] Personal computers are exempted from the AHRA as audio recording devices, because their primary purpose is to run programs and record data, not copy digital audio recordings.[70] The court's holding, therefore, suggests that the AHRA covers a narrow scope of devices and media, and is easily circumvented by using a personal computer to transfer digital audio files.

4. Canada.

a. Statutory Law.

Similar to the United States, sound recordings are covered subject matter.[71] In 1997, Canada made two changes to increase protection for the owners of sound recordings.[72] First, royalty rights were extended to performers and sound recording makers for any public communication of their work.[73] But royalties are paid only to makers who are Canadians, permanent residents, or citizens of Rome Convention countries, or to corporations with headquarters in Canada or in a Rome Convention country.[74] In addition, royalties are paid only if the sound recording was fixed in Canada or in a Rome Convention country.[75] Notably, the United States is not a Rome Convention country.[76] The Minister of Industry has the discretion to limit the scope and duration of royalties to any citizen or corporation of a Rome Convention country that, in the Minister's opinion, does not grant rights of similar scope and duration of copyright protection as provided in Section 19.[77]

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68. *Id.* at 1074.
69. *Id.* at 1081.
70. *Id.* at 1078; *see* Copyright Act, *supra* note 20, § 1001(3) (requiring a covered device to be designed or marketed for the primary purpose of making digital audio recordings).
71. *See* Canadian Copyright Act, *supra* note 32, § 2.2(1)(b). Sound recordings are sounds fixed in any material form, excluding the accompanying soundtrack to a cinematographic work. *Id.* § 2.
72. *Id.* §§ 19–20.
73. *Id.* § 19(1).
74. *Id.* § 20(1)(a).
75. *Id.* § 20(1)(b).
76. *See* International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations, adopted at Rome, Italy on Oct. 26, 1961, 496 U.N.T.S. 43 [hereinafter Rome Convention]. Canada joined on June 4, 1998. *See* Contracting Parties of Treaties Administered by WIPO, http://www.wipo.int/eng/ratific/k-rome.htm (Rome Convention, Status on July 15, 1999).
77. *See* Canadian Copyright Act, *supra* note 32, § 20(2).

Second, a blank tape levy was introduced.[78] The levy applies to all manufacturers in Canada, and importers into Canada, of blank audio recording media, both digital and analog, for the purpose of trade.[79] Audio recording media is defined as that "onto which a sound recording may be reproduced and that is of a kind ordinarily used by individual consumers for that purpose."[80] The Copyright Board has the power to set the amount and manner of collecting the tariff, and to designate the collecting body.[81]

On December 17, 1999, the Copyright Board published its decision for a tariff of levies,[82] imposing a tariff measured per time interval of the recording media.[83] The Board further stated that "only Canadian performers and makers are entitled to share in the levy until the Minister issues a statement pursuant to section 85 [reciprocity exception]. . . ."[84] Approximately $9 million in levies will be collected in the year 2000.[85]

The U.S. trade representatives have complained that Canada's blank tape levy and public performance royalty violate TRIPS and NAFTA.[86] Specifically, levy proceeds are distributed only to Canadian or Rome Convention country performers and companies and not to Americans. It is debatable, however, as to whether either provision violates NAFTA.[87] First, NAFTA Article 2107 allows Canada a cultural industries exception, which could include the protection of reproduction rights to sound recordings by Canadian artists and producers.[88] But the United States could bring an action under TRIPS, which does not provide Canada with a cultural industries exception.[89] Second, article 1703(1) of NAFTA allows reciprocal treatment rather than national treatment for sound recordings.[90] Similarly, TRIPS does not require national treatment for the producers and performers of phonograms except as enumerated in article 14.[91] Because the United States does not have a comparable blank tape levy or producers right, Canada is not obligated to provide reciprocal treatment under NAFTA or TRIPS. However, to the extent that the AHRA provides royalties to the artists and producers of digital sound recordings,

78. *See* Canadian Copyright Act, *supra* note 32, §§ 79–88 (Private Copying).
79. *Id.* § 82(1).
80. *Id.* § 79.
81. *Id.* §§ 83(7–8). The Canadian Private Copying Collective serves as the collecting body and decided to delay collecting levies under the Act, which came into effect on Jan. 1, 1999. *See* Newly Formed CPCC Announces Delay in Collecting Levy on Blank Audio Recording Media, Canada News Wire, Jan. 18, 1999.
82. *See* Supplemental Canada Gazette Part I, Dec. 18, 1999 (visited Dec. 22, 1999), http://www.cb-cda.gc.ca/tariffs/c18121999-b.pdf.
83. *See* John H. Gomery, *Copying for Private Use, Decision of the Board Dec. 17, 1999*, at 42 (visited Dec. 22, 1999), http://www.cbcda.gc.ca/decisions/c17121999-b.pdf.
84. *Id.* at 27.
85. *See* Greg Gazin, *New Recording Levy Won't Leave the Chevy Dry: Copyright Board Decision on Recordable Media Not as Stringent as First Expected*, EDMONTON SUN, Dec. 22, 1999, at 71.
86. *See* Papovich, *supra* note 8, at 258; Hancock, *supra* note 13, at 529 (reviewing statements made by U.S. Trade Representative Barshefsky).
87. *See* Hancock, *supra* note 13, at 530–31.
88. *Id.*
89. *Id.* at 532.
90. *Id.* at 530.
91. *Id.*

reciprocal treatment may be required, a decision within the discretion of the Minister of Industry.[92]

b. Judicial Interpretations.

The blank tape levy has also raised concerns from several groups within Canada. In *Evangelical Fellowship of Canada v. Canadian Musical Reproduction Rights Agency*, a coalition petitioned for an injunction to prohibit the Copyright Board from proceeding with implementing the levy on constitutional grounds.[93] The plaintiffs comprised two groups: religious organizations distributing religious information on tapes at no or low cost and commercial companies selling blank tapes wholesale to professional musicians.[94] The principal argument for an injunction was that the levy was a form of taxation, not copyright legislation.[95] Because the appropriate proceeding for introducing a new tax was not complied with, the levy was unconstitutional. The Federal Court of Appeals, however, denied the injunction.

In Canada, interlocutory injunctions based on a challenge to the constitutionality of legislation require proof of three elements: a serious issue, irreparable harm, and balance of inconvenience.[96] While meeting the low bar of a serious issue, the court rejected the argument that religious organizations would suffer irreparable harm by the creation of a gray market with tapes being bought in the United States for use or resale in Canada.[97] But the court did accept the argument that there would be irreparable harm from incurring the costs of participating in the Board's proceedings, if the levy was found unconstitutional.[98] The decision not to grant an injunction hinged on a favorable balance of public interests from the levy over inconvenience to the plaintiffs. In particular, the levy was intended to benefit the public by promoting a "cultural industry by bolstering Canadian identity and encouraging job creation."[99] And exceptions for educational institutions, libraries, archives, museums and the disabled, minimized harm.[100]

C. Moral Rights.

1. *NAFTA.*

As part of their obligations under NAFTA, each party is to give effect to the substantive provisions of the Berne Convention.[101] But the United States is under no obligation

92. The Minister has the power to grant the right to royalties to any performers or makers who are nationals of NAFTA countries. *See* Canadian Copyright Act, *supra* note 32, § 20(3).
93. No. A-371-99, 1999 A.C.W.S.J. LEXIS 9635 at *1 (F.C.A., Aug. 18, 1999).
94. *Id.* at *6. The Attorney General of British Columbia was also a plaintiff, objecting to the levy as a user of blank tapes for a purpose not involving the recording of music. *Id.*
95. *Id.* at *8.
96. *Id.* at *7.
97. *Id.* at *11.
98. *Id.* at *14.
99. *Id.* at *17.
100. *Id.* at *18.
101. *See* NAFTA, *supra* note 5, art. 1701.2(b).

to give effect to Article 6*bis*, giving authors a moral right to prevent modifications or other derogatory actions against their work.[102]

2. TRIPS.

The stated objective of TRIPS is "the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge . . . conducive to social and economic welfare . . . ."[103] This endorses the American view of using copyright law to protect economic rights to promote innovation, rather than protecting an author's moral rights to his creation.[104] Like NAFTA, TRIPS incorporates Articles 1 through 21 of the Berne Convention,[105] with the exception of Article 6*bis*.

3. United States.

a. Statutory Law.

The United States, unlike most countries, bases copyright law on protecting the economic rights of the author as a means to promote creativity and innovation for the benefit of the public.[106] Traditionally, artists transferring their copyright only have limited state statutory and common-law remedies to uphold a moral right to protect the integrity of the work or the artist's association with the work.[107] Moral rights protection under federal law was recently provided under the Visual Artists Rights Act of 1990 (VARA).[108] Authors may prevent the use of their name as the author in visual art in the event the work is distorted, mutilated, or modified and would prejudice their honor or reputation.[109] The author may also prevent intentional distortion, mutilation, or modification of a work prejudicing their honor or reputation or prevent the destruction of a work of recognized stature.[110]

b. Judicial Interpretations.

Although moral rights are limited only to visual works, even this narrow scope has been controversial, as illustrated by commentary following the holding in *Martin v.*

102. *Id.*, Annex 1701.3(2). Article 6*bis* gives authors the right to object to the distortion, mutilation, or modification of their work if this would prejudice their honor or reputation. *See* Berne Convention, *supra* note 14, art. 6*bis*(1).
103. TRIPS, *supra* note 9, art. 7.
104. *See* Handa, *supra* note 13, at 977.
105. *See* TRIPS, *supra* note 9, art. 9.
106. *See* Goolsby, *supra* note 12, at 26.
107. *See* Dana L. Burton, Comment, *Artists' Moral Rights: Controversy and the Visual Artists Rights Act*, 48 SMU L.REV. 639, 650 (1998) (artists rarely receive relief solely on moral rights).
108. *See* Copyright Act, *supra* note 20, § 106A [hereinafter VARA].
109. *Id.* § 106A(a)(2).
110. *Id.* § 106A(a)(3).

City of Indianapolis.[111] *Martin* is the only successful suit brought under VARA.[112] Courts require artists to overcome several defenses that effectively restrict moral rights to a narrower scope than provided under the Berne Convention.[113] For example, an artist must show that the work is of recognized stature, was not used for advertising, was not a work made for hire, and that the artist did not waive his moral rights provided by VARA.[114]

4. Canada.

a. Statutory Law.

Canada grants authors broad moral rights to ensure the integrity of works and the right to reasonably control their association with the work.[115] Though not assignable, moral rights may be waived—a copyright assignment does not constitute a waiver.[116] Moral rights are infringed if the author's reputation or honor is prejudiced because the work is "distorted, mutilated or otherwise modified" or "used in association with a product, service, cause or institution."[117] For paintings, sculptures, or engravings, prejudice occurs if the work is distorted, mutilated, or otherwise modified.[118] But changing the work's location, physical exposure or physical containment, or good faith efforts to restore or preserve "shall not, by that act alone, constitute a distortion, mutilation or other modification of the work."[119]

b. Judicial Interpretations.

The infringement of an author's moral rights is as common a cause of action as copyright infringement and accepted by Canadian courts for a broad scope of subject matter. For example, in *Boudreau v. Lin*, the court recognized that a professor's appropriation and publication of Boudreau's term paper under his own name was both a copyright and moral rights infringement.[120] Damages were awarded based on "indignation at the wrong committed," rather than commercial loss.[121] Similarly, in *Ateliers Tango Argentin Inc. v. Festival d'Espagne et d'Amerique Latine Inc.*, a plaintiff photographer was awarded damages for violation of his moral right to recognition of authorship.[122]

111. 982 F. Supp. 625 (S.D. Ind. 1997). Martin successfully sued Indianapolis for the destruction of his sculpture in violation of his moral rights under VARA. *Id.*; *See* Sonia T. Banerji, *Recent Developments in Law and Policy under the Visual Artists Rights Act of 1990*: Martin v. City of Indianapolis and the Problem of Unwanted Art, 9 W.R.L.S.I. 99, 106-07 (1999) (reviewing litigation arising in the United States from unwanted art).
112. *See* Banerji, *supra* note 111, at 114.
113. *Id.* at 122.
114. *Id.* at 117–26.
115. *See* Canadian Copyright Act, *supra* note 32, § 14.1(1).
116. *Id.* § 14.1(2–3).
117. *Id.* §§ 28.2(1)(a–b).
118. *Id.* § 28.2(2).
119. *Id.* § 28.2(3).
120. [1997] 75 C.P.R. (3d) 1, 10–13 (Ont. Ct. Gen. Div.).
121. *Id.* at 14.
122. [1997] 84 C.P.R. (3d) 56, 81 (Que. Sup. Ct.).

D. Fair Use Defense.

1. NAFTA and TRIPS.

Neither NAFTA nor TRIPS discusses fair use or fair dealing exceptions to infringement.

2. United States.

a. Statutory Law.

The scope of the fair use exceptions is broad. The Copyright Act allows "the fair use of a copyrighted work, *including* ... reproduction ... for purposes *such as* criticism, comment, news reporting, teaching ..., scholarship, or research, is not an infringement..." (emphasis added).[123] Factors to decide if there is fair use include: the purpose and character of the use, the nature of the work, the amount and substantiality of the portion used compared to the work as a whole, and the impact on the work's potential market.[124]

b. Judicial Interpretations.

Parody is a special example of criticism recognized as fair use by U.S. courts. In the leading case defining the scope of the parody defense, the U.S. Supreme Court allowed 2 Live Crew's rap music version of Roy Orbison's song "Pretty Woman" as an exception to infringement under the fair use parody defense despite otherwise unfavorable factors.[125] The Court acknowledged that the parody had a commercial purpose and took a substantial portion of Orbison's work.[126] But a commercial purpose does not presumptively eliminate fair use as a defense and, to be effective, the heart of the work must be copied.[127]

3. Canada.

a. Statutory Law.

The Canadian Copyright Act provides an exception for any fair dealing with any work if the source and author's name is mentioned.[128] The fair dealing exception applies to "research or private study" or "criticism or review" or "news reporting."[129]

b. Judicial Interpretations.

Fair dealing in Canada is not the same as fair use in the United States. Courts have construed the fair dealing exceptions to infringement as only those listed in the

123. Copyright Act, *supra* note 20, § 107.
124. *Id.*
125. *See* Campbell v. Acuff-Rose Music, Inc., 510 U.S. 569, 594 (1994).
126. *Id.* at 587–88.
127. *Id.* at 591.
128. *See* Canadian Copyright Act, *supra* note 32, § 29.1(a–b).
129. *Id.* § 29(1–2).

Canadian Copyright Act.[130] For example, in *Michelin*, the defendants depicted the plaintiff's copyrighted "Bibendum" figure stomping on the heads of union workers.[131] The court rejected the defendant's argument that their use of the Bibendum was fair dealing in the form of parody.[132] The court noted that, unlike the United States' open-ended list of exceptions, the exceptions to infringement are listed exhaustively as a closed set.[133] Since parody was not explicitly mentioned in the Act "parody does not exist as [criticism], an exception to copyright infringement."[134]

Fair dealing also differs from fair use in that the former requires the source to be mentioned and to receive fair treatment by the critic. The *Michelin* court noted that the defendants failed to mention Michelin as the source of the Bibendum, a requirement added to the Canadian Copyright Act pursuant to implementing NAFTA.[135] Parody does not absolve the critic from treating the source fairly, otherwise making "the parody label the last refuge of the scoundrel."[136]

III. Patent Law.

A. Life Forms as Valid Subject Matter.

1. NAFTA.

Each party must "make patents available for any invention, whether products or processes, in all fields of technology . . . ."[137] Patentability is conditioned on showing that the invention is new, results from an innovative step (synonymous with nonobvious), and capable of industrial application (synonymous with usefulness).[138] A nondiscrimination provision states that "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."[139]

Broad exclusions are allowed, however, if "necessary to protect the ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to nature or the environment . . . ."[140] But exclusions may not be applied solely because "the Party prohibits the commercial exploitation . . . of the subject matter of the

130. *See* Compagnie Générale des Établissements Michelin-Michelin & Cie v. CAW-Canada [1996] 71 C.P.R. (3d) 348, 381 (Fed. Ct. Trial Div.); Bishop, *supra* note 36, at 407–408 (exceptions to infringement should be narrowly interpreted).
131. *See* Michelin, *supra* note 130, at 354.
132. *Id.* at 379 (comparing the present holding to the U.S. Supreme Court's holding in *Campbell*).
133. *Id.* at 381.
134. *Id.* at 382.
135. *Id.* at 383. The Court rejected as a circular, the argument that parody does not require mention of the source because the source is implicitly mentioned. *Id.* at 382.
136. *Id.* at 384. The court, defining fair as "free from discrimination, dishonesty, etc. just; impartial," ruled that portraying the "Bibendum" as the "boss's henchman" was not fair. *Id.*
137. NAFTA, *supra* note 5, art. 1709(1).
138. *Id.*
139. *Id.* art. 1709(7).
140. *Id.* art. 1709(2).

patent."[141] Several discretionary specific exclusions are enumerated, including therapeutic methods, higher life forms, and biological processes for producing plants and animals.[142]

These exclusions are contrary to the United States' desire to broaden the scope of patentability to protect its biotechnology industry.[143] Because "ordre public" and "morality" are left undefined, they are open to a broad interpretation by each party.[144] For example, Canada and Mexico have the discretion to interpret their patent laws to exclude the patenting of higher life forms on moral grounds and still be in compliance with NAFTA.[145]

2. TRIPS.

TRIPS extends the same broad scope of patentability as NAFTA with nearly identical language.[146] Similar to NAFTA, a nondiscrimination provision is included.[147] But the same discretionary subject matter exclusions as in NAFTA are also offered to Members to protect "ordre public or morality," so long as the Member's "exclusion is not made merely because the exploitation is prohibited by their law."[148] Diagnostic, therapeutic, and surgical methods for treating humans and animals, higher life forms themselves, and biological processes for producing higher life forms are specifically mentioned as excludable at the Member's discretion.[149]

3. United States.

a. Statutory Law.

No changes were made in the definition of patentable subject matter following the NAFTA or TRIPS agreements. A patentable invention is "any . . . process, machine, manufacture, . . . composition of matter, or . . . improvement thereof . . . ."[150]

b. Judicial Interpretations.

In *Diamond v. Chakrabarty*, by a five to four margin, the U.S. Supreme Court affirmed the patentability of a transgenic bacterium containing genes inserted from other species of bacteria.[151] The genes result in the expression of enzymes that degrade components of crude oil. The Court interpreted the language of Section 101 to mean that

141. *Id.* art. 1709(2).
142. *Id.* art. 1709(3).
143. *See* Kevin W. McCabe, Comment, *The January 1999 Review of Article 27 of the TRIPS Agreement: Diverging Views of Developed and Developing Countries Toward the Patentability of Biotechnology*, 6 J. INTELL. PROP. L. 41, 43 (1998).
144. *See* Goolsby, *supra* note 12, at 37.
145. *See* McMahon, *supra* note 7, at 34–35.
146. *See* TRIPS, *supra* note 9, art. 27(1). There is explicit agreement that "innovative step" and "capable of industrial application" are synonymous with nonobvious and usefulness, respectively, as used in the United States. *Id.*
147. *Id.*
148. *Id.* art. 27(2).
149. *Id.* art. 27(3).
150. 35 U.S.C. § 101 (1994) [hereinafter Patent Act].
151. 447 U.S. 303, 318 (1980).

Congress intended a broad scope of patentable subject matter—including unanticipated subject matter like living organisms.[152] In contrast, the dissent believed that Congress's passage of the Plant Patenting Act and the Plant Variety Protection Act showed no broad mandate allowing the patenting of life forms.[153]

For the majority, the key to patentability was human intervention to produce a new microorganism "with markedly different characteristics from any found in nature and ... the potential for significant utility."[154] The majority rejected arguments that potential hazards should be considered as part of the decision as to whether an invention should be patented.[155] Rather, the Court's task was merely to determine what Congress meant by the words it used in section 101.[156]

Consistent with the holding in *Chakrabarty*, in *Ex parte Allen*, the Board of Patent Appeals and Interferences held that multicellular organisms such as oysters could be patented as new manufactures or compositions under Section 101, so long as they were not naturally occurring.[157] The U.S. Patent and Trademark Office (PTO) broadened its view on the scope of patentable subject matter to include nonhuman, multicellular organisms, including animals and human tissues modified by man.[158] *Chakrabarty* and *Allen* set the stage for allowing the patenting of genetically engineered mammals in the United States. The onco-mouse and all its progeny were granted patent protection in 1988 by the PTO.[159]

4. Canada.

a. Statutory Law.

Canada also made no changes in the definition of patentable subject matter following NAFTA or TRIPS. An invention is "any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter."[160]

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152. *Id.* at 308–10.

153. *Id.* at 320. The Majority rejected this, arguing that both the 1930 and 1970 Acts were simply intended to circumvent written description statutory bars to the patenting of artificially bred plants. *Id.* at 312–13.

154. *Id.* at 310.

155. *Id.* at 316–17.

156. *Id.* at 307.

157. *See* Ex Parte Allen, 2 U.S.P.Q.2d 1427 (1987).

158. *See* Eileen Morin, Comment, *Of Mice and Men: The Ethics of Patenting Animals*, 5 HEALTH L.J. 147, 157 & 157 n.62 (1997) (citing the Interpretive Statement of the U.S. Commissioner of Patents, 1077 Official Gazette Pat. Office 24 (April 21, 1987)).

159. Filed June 1984—date of patent Apr. 12, 1988. *See* U.S. Patent No. 4,736,866. The Harvard onco-mouse is a useful animal model for cancer research because the mouse and its progeny carry inserted recombinant onco-genes that result in an increased susceptibility to cancer. *Id.* The uncontested patenting of the onco-mouse in the United States contrasts with a long course of deliberations for the same application at the European Patent Office. *See generally* Darrell G. Dotson, Comment, *The European Controversy over Genetic-Engineering Patents*, 19 HOUS. J. INT'L L. 919, 927–33 (1997) (reviewing the first seven years of European Patent Office rulings concerning the onco-mouse patent application).

160. Patent Act, R.S.C., ch. P-4, § 2 (1985) (Can.) [hereinafter Canadian Patent Act] (visited Jan. 11, 2000), http://canada.justice.gc.ca/STABLE/EN/Laws/Chap/P/P-4.html.

b. Judicial Interpretations.

Similar to the United States, decisions from the 1980s suggested that life forms were not barred from patentability *per se*. In *Re Application of Abitibi Co.*, the Patent Appeal Board held that a yeast culture was patentable because it possessed uniform properties that were readily reproducible.[161] In dicta, the Board stated that there was no statutory bar to patenting complex life forms if they comprised an invention that was new, nonobvious, useful, and reproducible.[162] But, in *Pioneer Hi-Bred v. Canada*, the Supreme Court of Canada ruled that a new soybean variety produced from artificial crossbreeding was not patentable on the grounds of inadequate disclosure.[163] Although the inventor had described several crossbreeding procedures to improve the yield of the target variety, "someone skilled in the science of the invention could not arrive at the same result ... without further explanation."[164] The court accepted without comment the appellate court's opinion that the Canadian Patent Act does not exclude the patentability of living organisms.[165]

Nevertheless, the onco-mouse patent application was denied by the Commissioner of Patents in 1995, on the grounds that the onco-mouse was primarily a product of nature.[166] The trial court affirmed the Commissioner's holding that nonhuman mammals did not constitute an invention for the purposes of the Canadian Patent Act.[167] Key to the holding was the court's interpretation of what constitutes an invention.[168]

The court set forth four elements to guide decisions concerning a patentable invention. First, it is not necessary for the inventor to have control over all characteristics of the invention, although some element of control is necessary.[169] Second, the court would distinguish between human intervention and laws of nature when determining the scope of patentable subject matter.[170] Third, the invention must be reproducible.[171] Finally, in the absence of direction from the legislature, the court would not distinguish between higher and lower life forms with respect to patentability.[172] The onco-mouse patent failed in the second and third elements.

The court distinguished between the process of creating the plasmid containing onco-genes and introducing it into an oocyte, versus the subsequent effects of this process—breeding a mouse implanted with eggs containing the onco-gene with a normal mouse.[173] The court found the latter was analogos to the crossbreeding process in

161. *See* Re Application of Abitibi Co. [1982] 62 C.P.R. (2d) 81, 91 (P.A.B.).
162. *Id.* at 90.
163. [1989] 25 C.P.R. (3d) 257, 272 (S.C.C.).
164. *Id.* at 270.
165. *Id.* at 260.
166. *See* Morin, *supra* note 158, at 147 n.3 (citing the unpublished decision discussed in J. Rudolph, C. Collard & C. Ledgley, *Reporting of the Biotechnology Legislation Committee*, 13 CAN. INTELL. PROP. REV. 55, 60 (1996)).
167. *See* Harvard College v. Canada [1998] 79 C.P.R. (3d) 98, 115 (F.C.T.D.).
168. *Id.* at 106. The court accepted that the invention was new, useful, and nonobvious. *Id.*
169. *Id.* at 110.
170. *Id.* at 111.
171. *Id.* at 113.
172. *Id.* at 114.
173. *Id.* at 112.

Pioneer Hi-Bred, which was non-patentable.[174] In particular, all the characteristics of the resulting mouse were uncontrolled except for the onco-gene. Further, the presence, location, and quality of the onco-gene's expression in any one mouse was left to chance.[175] For these reasons, the court held that patentability should be limited to the creation of the plasmid and the process of introducing it into the mouse oocyte—not the mouse and its progeny.[176] Harvard has appealed the trial court's decision.[177]

B. Compulsory Licensing of Patented Drugs.

1. NAFTA.

Parties "may provide limited exceptions to the exclusive rights conferred by a patent," so long as two conditions are met.[178] First, the exceptions "do not unreasonably conflict with a normal exploitation of the patent."[179] Second, the patent holder's legitimate interests are not unreasonably prejudiced, "taking into account the legitimate interest of other persons."[180] Terms like "normal exploitation," "not unreasonably prejudiced," and "legitimate interests" are not defined.[181] Consequently, parties have almost unlimited discretion to interpret the scope of allowable exceptions as they see fit. For example, it has been speculated that provincial governments in Canada, seeking to reduce their health care costs, would seek a compulsory license for certain patented medicines and then import those medicines.[182]

Preventing this kind of behavior are twelve provisions that a proposed user (including the government) must respect before a party can allow licensed use without authorization by the patent holder.[183] Among the provisions is the requirement that the "proposed user [makes an] effort to obtain authorization from the right holder on reasonably commercial terms . . . within a reasonable period of time."[184] Waiver is allowed in cases of national emergency or public non-commercial use.[185] In addition, the right

174. *Id.* at 114.
175. *Id.* at 113.
176. *Id.* at 115. Although not used as a basis for rejecting the patent applicable, J. Nadon agreed with the minority in *Charkrabarty* that like the U.S. Patent Act, the Canadian Patent Act excluded complex life forms. *Id.* at 114. *But see* Franco E. Rossetto, *Patentability of Higher Life Forms Debate Far From Over*, 18 Lawyers Wkly. (Sept. 25, 1998) (technological advances in genetic engineering since the onco-mouse patent application was submitted in 1984 have rendered the Court's basis for rejecting the patent as moot).
177. *See* Harvard College, 79 C.P.R. at 115; Jean Christie, *Should Canada Allow Patents on New Plants and Animals?* London Free Press, Jan. 3, 2000, at A11, *available at* 2000 WL 2114891.
178. NAFTA, *supra* note 5, art. 1709(6).
179. *Id.*
180. *Id.*
181. *See* Goolsby, *supra* note 12, at 36.
182. *See* McMahon, *supra* note 7, at 36.
183. *See* NAFTA, *supra* note 5, art. 1709(10)(a).
184. *Id.* art. 1709(10)(b).
185. *Id.*

holder must be paid adequate remuneration,[186] the use must be nonexclusive,[187] non-assignable,[188] and subject to judicial or other independent review.[189]

2. TRIPS.

TRIPS permits Members to exempt exclusive rights to patents, subject to the same two conditions as in NAFTA.[190] Similar to NAFTA, compulsory licensing is granted only after the user attempts to obtain a voluntary license with reasonable terms and conditions, the patentee is paid adequate remuneration, and the reasonable value of the invention has been taken into account.[191] In addition, the patentee has the right to make the compulsory license subject to judicial or other independent review.[192]

3. United States.

a. Statutory Law.

Superficially, compulsory licensing is inconsistent with the U.S. Patent Act, which imposes no duty on a patent holder "to license or use any rights to the patent . . . ."[193] But long before the NAFTA or TRIPS agreements, Congress enacted Section 271(e) and Section 156 as part of the Drug Price Competition Act and Patent Term Restoration Act of 1984 (Waxman-Hatch Act).[194] The Waxman-Hatch Act strikes a compromise between the interests of innovative drug makers, the desire of generic drug makers to avoid unnecessary testing, and the public's need for safe and inexpensive drugs.[195] This compromise was addressed by fixing two perceived problems associated with the patenting of pharmaceuticals.

186. *Id.* art. 1709(10)(h).
187. *Id.* art. 1709(10)(d).
188. *Id.* art. 1709(10)(e).
189. *Id.* art. 1709(10)(i-j).
190. *See* TRIPS, *supra* note 9, art. 30.
191. *Id.* art. 31. McCabe has interpreted these provisions as allowing compulsory licensing but with severe conditions. *See* McCabe, *supra* note 143, at 59. *But see* Goolsby, *supra* note 12, at 40 (interpreting nearly identical language in NAFTA and concluding that "[t]he impact of the mandatory provisions on actual compulsory licensing systems remains to be seen.").
192. *See* TRIPS, *supra* note 9, art. 31(i). NAFTA has substantially the same provisions. *See* NAFTA, *supra* note 5, art. 1709(10)(k).
193. Patent Act, *supra* note 150, § 271(d)(4) (1994). U.S. courts have rarely imposed this obligation, limiting this as a remedy where a patent was wrongfully obtained or used in association with monopolistic behavior. *See* James B. Kobak, Antitrust Treatment of Refusal to License Intellectual Property, 566 PLI/P, at 517, 531–35 (1999) (reviewing exceptions to the general rule that an intellectual property owner has no duty to license).
194. *See* David J. Bloch, *If It's Regulated Like a Duck . . . Uncertainties in Implementing the Patent Exceptions of the Drug Price Competition and Patent Term Restoration Act*, 54 FOOD DRUG L.J. 111, 112 (1999).
195. *See* Tri-Bio Laboratories, Inc. v. Food and Drug Admin., 836 F.2d 135, 139 (3d Cir. 1987), *cert. denied*, 488 U.S. 818 (1988) (reviewing the formation and goals of the DPCA and noting that the Act only applies to drugs for human use—generic drug makers for animals are still required to generate and provide test data).

First, Section 156 allowed a five-year patent extension to compensate for "front-end distortion," resulting in shortened patent protection due to the long delay between patenting and Food and Drug Administration (FDA) approval for marketing.[196] Second, Section 271(e) compensates for "back-end distortion," resulting in lengthened patent protection because generic drug makers were considered to infringe if they conducted tests on a patented drug for the purposes of gathering information for FDA approval.[197] Section 271(e) allows an exception to patent infringement "for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products."[198] While increasing the period of market protection and decreasing the entry time of generic drugs, the merits of continuing the Waxman-Hatch Act have been questioned.[199]

b. Judicial Interpretations.

The degree of exception allowed under Section 271(e) has varied widely.[200] The debate centers on the meaning of the phrase "solely for uses reasonably related."[201] A minority of courts interpret Section 271(e)(1) to allow a narrow exception for performing tests on a patented drug necessary to get FDA approval for a generic version of the drug after the patent expired.[202] The majority of courts, however, have concluded that

196. *See* Patent Act, *supra* note 150, § 156 (1994).
197. *Id.* § 271(e)(1) (1994).
198. *Id.*
199. Data showing an increased period of market protection (2.4 years) and shorter entry periods for generic drugs (decreasing from three to four years, to one to three months) led the Congressional Budget Office to conclude that the FDCA successfully increased the market share for less expensive generic drugs while not detracting from the incentive for innovative drug companies. *See* Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, July 1998, Chapter Four, Table 7 (visited Oct. 24, 1999), http://www.cbo.gov/showdoc.cfm?index=655&sequence=0&from=1#anchor; *but see* Alfred B. Engelberg, *Special Patent Provisions for Pharmaceutics: Have They Outlived Their Usefulness?*, 39 IDEA 389, 392 (1999) (the FDCA promotes abusive use of the Act by both generic and innovative drug makers, imparts no benefit to the public, and causes the migration of drug manufacturing out of the United States); Joseph P. Reid, Note, *A Generic Drug Price Scandal: Too Bitter a Pill for the Drug Price Competition and Patent Term Restoration Act to Swallow?*, 75 NOTRE DAME L. REV. 309, 338–39 (1999) (the FDCA failed to contain drug costs and imposes hardships on innovative drug makers).
200. *See generally* Bloch, *supra* note 194, at 120–26; Courtenay C. Brinkerhoff, Comment, *Can the Safe Harbor of 35 U.S.C. § 271(e)(1) Shelter the Pioneer Drug Manufacturer?*, 53 FOOD DRUG L.J. 643, 648–54 (1998).
201. *See* Patent Act, *supra* note 150, § 271(e)(1).
202. *See* Scripps Clinic & Research Found. v. Genentech Inc., 666 F. Supp. 1379, 1396 (N.D. Cal. 1987) (Genentech's entering into a contract to develop a method for commercial manufacturing or to obtain bioequivalence data required by the FDA, and filing a European Patent application, were uses that served additional functions besides obtaining FDA approval, and therefore were infringing on Scripp's patent); Biogen, Inc. v. Schering AG, 954 F. Supp. 391, 396 (D. Mass 1996) (larger scale production and market production are not exceptions under § 271(e)(1)); Brinkerhoff, *supra* note 200, at 651–52 (legislative history suggests that Congress

activities having additional uses beyond getting FDA approval are within the scope of exceptions to infringement allowed under Section 271(e)(1).[203]

In *Eli Lilly & Co. v. Medtronic, Inc.*, the U.S. Supreme Court held that Section 271(e)(1) also applies to medical devices, because the phrase "a Federal law," historically refers to the entire subject matter of the statute, not just drugs or veterinary products.[204] The Court found support for this view from the language of the Waxman-Hatch Act, indicating that the scopes of Section 156 and Section 271(e)(1) were complementary.[205] Therefore, all products (i.e., drugs and medical devices) subject to a patent extension under Section 156 should be subject to Section 271(e)(1) infringement exceptions.[206] The Court concluded that this broad construction better served Congress's goals of correcting patent term distortion and making generic versions available as soon as possible after the expiration of the patented drug.[207]

4. *Canada.*

a. Statutory Law.

Before 1987, all prescription pharmaceuticals were subject to compulsory licensing.[208] Canadian generic drug manufacturing companies paid a minimal royalty payment for the right to market generic copies of patented pharmaceuticals.[209] Generic drug makers flourished because they could sell drugs at a lower cost than innovative drug makers, having minimal research and development expenses to recover. Compulsory licensing also directly reduced government spending, because the federal and provincial governments are major drug purchasers in Canada's government-administered health care system.[210] Although keeping the price of prescription drugs low, this system provided little

intended the § 271(e) infringement exception to narrowly apply to experimentation with a patented drug in preparation for commercial activity after expiration of the patent).

203. *See* Telectronics Pacing Sys., Inc. v. Ventritex Inc., 982 F.2d 1520, 1525 (Fed. Cir. 1992) (it is not infringing to demonstrate a product at a conference or show data to investors for business purposes); Intermedics, Inc. v. Ventritex, Inc., 775 F. Supp. 1269, 1280 (N.D. Cal. 1991) *aff'd* 991 F.2d 808 (Fed. Cir. 1993) (nonprecedential) (the key question is whether the activities result in information that reasonably could contribute to FDA approval); Abtox, Inc. v. Exitron Corp., 122 F.3d 1019, 1030 (Fed. Cir. 1997) (informing customers that a product will be commercially available or planning to introduce a rival product before the patent expires is not infringing); Amgen, Inc. v. Hoechst Marion Roussel, Inc., 3 F. Supp. 2d 104, 110 (D. Mass. 1998) (it is not an infringement to make and export a patented compound for use as a standard reference to evaluate alternative manufacturing process or for safety tests meeting European regulatory standards).
204. *See* 496 U.S. 661, 666 (1990).
205. *Id.* at 673.
206. *Id.* at 671–72.
207. *Id.* at 669–70.
208. *See* Michael B. Moore, Comment, *"Open Wide" (Your Pocket Book That Is!)—A Call for the Establishment in the United States of a Prescription Drug Price Regulatory Agency*, 1 S.W. J.L. & TRADE AM. 149, 162 (1994) (reviewing Canada's Patented Medicine Prices Review Board).
209. *See* Novopharm Ltd. v. Janssen Pharm. N.V. [1992] 41 C.P.R.(3d) 384, 389 (court refusing to require more than a four percent royalty to be paid to the patent holder).
210. *See* Moore, *supra* note 208, at 162.

incentive for innovative drug companies to invest in research and development programs inside Canada.

In 1987, the Canadian Patent Act was amended to give innovative drug makers an exclusivity period for seven years against production and for ten years against importation.[211] The price of drugs, however, was still regulated during this exclusivity period by the Patented Medicine Prices Review Board.[212] At the end of the exclusivity period, compulsory licensing was allowed.[213] The Board set guidelines for the price that innovative drug makers could sell to wholesalers, and the Board could revoke the manufacturer's patent for noncompliance.[214]

In 1997, several changes were made in compliance with TRIPS and NAFTA.[215] Patent protection was extended to twenty years for *all* technologies, including pharmaceuticals, and compulsory licensing was eliminated.[216] The Board's power to revoke patents was removed.[217] But the Board's capacity to impose fines and imprisonment for noncompliance with their price guidelines was expanded.[218] Existing compulsory licenses granted before December 20, 1991 remained in force.[219] Similar to 35 U.S.C § 271(e), it is not an infringement "to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada . . . ."[220]

The Board's monitoring and enforcement activities may explain why drug prices are nearly half as expensive for consumers in Canada compared to America.[221] Alternatively, the impact of Canada's changes in its patent laws only now may be felt as new drugs are developed and marketed without a generic equivalent.[222] So far, the U.S. Congress

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211. *Id.*; *see* Patricia Carter, *Federal Regulation in the United States and Canada*, 21 LOY. L.A. INT'L COMP. L.J. 215, 242 n.221 (citing Joel Lexchin's suggestion that the elimination of Canada's compulsory licensing was a condition for U.S. approval of the FTA. *See* Joel Lexchin, *Pharmaceuticals, Patents & Politics: Canada & Bill C-22* (Feb. 1992) (paper prepared for The Canadian Centre for Policy Alternatives)).
212. *See* Moore, *supra* note 208, at 163.
213. *See* Carter, *supra* note 211, at 242–43.
214. *See* Moore, *supra* note 208, at 164.
215. *See* Carter, *supra* note 211, at 244–45; NAFTA, *supra* note 5, art. 1709(12).
216. *See* Carter, *supra* note 211, at 243. The United States also increased the term of patent protection from seventeen to twenty years, as required by TRIPS. *See* TRIPS, *supra* note 9, art. 33.
217. *See* Moore, *supra* note 208, at 164.
218. *Id.* at 164 n.85.
219. *See* G. Alexander Macklin & Emma A. Grell, *Canada Doctors Its Pharmaceutical Patents*, IP World Wide (January/February 1996) (visited Aug. 31, 1999), http://www.ipww.com/january96/p13Canada.html.
220. Canadian Patent Act, *supra* note 160, § 55.2 (1).
221. *See* Bernie Sanders, *We Pay Too Much for Prescribed Drugs*, USA TODAY, Aug. 18, 1999, at 13A (citing a 1998 study by the House Democrats and an international study by the PRIME Institute); Moore, *supra* note 208, at 165.
222. Drug costs to patients increased by 12.7 percent in 1998, and for the first time in ten years, the growth in brand name drugs sales outpaced generic drugs. *See Impact of Bill C-91 and Additional Patent Protection Only Now Being Felt, Says Canadian Drug Manufacturers Association*, Canada News Wire Ltd., Apr. 12, 1999, *available in* LEXIS, Canadian Publications File (citing a survey by IMS Health (Canada)).

has declined to adopt a price review board, fearing that price guidelines might decrease expenditures on research and development by the pharmaceutical industry in the United States.[223]

b. Judicial Interpretations.

Canada's long history of allowing compulsory licensing has created a powerful generic drug industry. Generic drug makers have mounted a vigorous legal campaign to resist the most recent changes to Canada's patent laws.[224] In turn, innovative drug makers have challenged the jurisdiction of the Patented Medicines Price Review Board.[225] The Supreme Court's willingness to consider three cases involving litigation between generic and innovative drug companies illustrates the importance of drug pricing and patent regulation.[226]

All three cases involved Canada's two largest generic drug companies, Apotex and Novopharm. In 1993, anticipating that compulsory licensing laws were about to be repealed, the two companies entered into a mutual "supply agreement," where the companies would share their existing licenses for each other's benefit.[227] When Apotex attempted to obtain a notice of compliance for patented drugs for which Novopharm had obtained a license, the innovative drug companies Eli Lilly and Merck applied for a court order to halt Ministerial approval.[228] Eli Lilly and Merck argued that Novapharm's agreement with Apotex amounted to a sublicense, in violation of its compulsory license agreement with Lilly and Merck.[229] Three trial division courts found that there was no sublicense—three appellate courts reversed, finding that there was a sublicense.[230] The appellate court ruling spelled serious economic hardship for the generic drug companies because violating a compulsory licensing agreement meant revocation of the license.[231]

223. *See* Carter, *supra* note 211, at 248–49.
224. Nearly 150 patent infringement cases between generic and innovative drug makers are pending. *See* John Greenwood, *Generic Drug Makers Get Shot in Arm from Supreme Court*, FINANCIAL POST, July 14, 1998, *available in* LEXIS, Canadian Publications file.
225. For example, in ICN Pharmaceuticals, the court held that the Board had broad jurisdiction to review prices and take remedial action for excessive prices so long as there was "the merest slender thread" of rational connection between the inventor's patent and the medicine being sold. This follows from the fact that the Board was created to replace the price controls that previously provided by compulsory licensing. *See* ICN Pharmaceuticals, Inc. v. Patented Med. Prices Review Bd. (1996), 138 D.L.R. (4th) 71, 89–91.
226. *See generally* Sheldon Burshtein, *Sublicense or Supply Agreement? Supreme Court of Canada Interpretation Benefits Generic Pharmaceutical Industry*, 54 FOOD DRUG L.J. 73 (reviewing the holding in all three cases at the trial, appellate and supreme court level: *Eli Lilly & Co. v. Novopharm, Ltd.*, and *Eli Lilly & Co. v. Apotex, Inc.* (1998), 80 C.P.R. (3d) 321; *Merck Frosst Canada Inc. v. Canada* (1998), 80 C.P.R. (3d) 368).
227. *See* Burshtein, *supra* note 226, at 77.
228. *Id.* at 79.
229. *Id.* at 79–83.
230. *Id.*
231. *Id.* at 73. This would also mean serious cost over runs for provincial government health plans dependent on the purchase of lower costing generic drugs. *Id.*

The Supreme Court of Canada reversed all three appellate court holdings, ruling that there was no sublicense agreement between Novapharm and Apotex.[232] The court reasoned that there was no sublicense because Apotex was unable to obtain the patented medicines independent of Novopharm.[233] Therefore, Novopharm had not violated the terms of its compulsory license with Eli Lilly and Merck, and Apotex had not infringed the patents.[234] The court also ruled that it is not an infringement for a licensee to reformulate a drug's final dosage into a commercial usable form.[235] The later rulings in part may have been motivated by the desire to curtail litigation involving the "evergreening" of drugs, a tactic where innovative drug makers try to patent each new formulation of a drug, and thereby narrow the scope of what generic drug makers can produce without infringing existing licenses.[236]

IV. Trade Secret Law.

A. Pharmaceutical Testing Data Submitted to Government Agencies.

1. NAFTA.

NAFTA requires legal means to prevent trade secrets from being disclosed, acquired, or used by others "in a manner contrary to honest commercial practices."[237] A non-inclusive list of examples shows what minimally is contrary to honest commercial practice.[238] Three elements are required to establish trade secret protection.[239] First, the information, "as a body or in the precise configuration and assembly of its components," is not "generally known among or readily accessible to" persons that normally deal with this kind of information.[240] Second, the information "has actual or potential commercial value because it is secret."[241] Third, the person in lawful control of the information "has taken reasonable steps . . . to keep it secret."[242]

NAFTA also requires that trade secrets be protected against unfair commercial use when undisclosed tests or other data are submitted to government agencies as a condition for approval to market drugs or agricultural chemical products.[243] If an applicant relies

232. *Id.* at 86–87.
233. *Id.*
234. *Id.*
235. *Id.*
236. *See Novopharm Vindicated in Seven Year Patent Dispute with Glaxo*, Canada News Wire Ltd., Aug. 6, 1998, *available in* LEXIS, Canadian Publications File.
237. NAFTA, *supra* note 5, art. 1711(1).
238. "Breach of contract, breach of confidence[,] . . . inducement to breach, and . . . the acquisition of undisclosed information by other persons who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition." *Id.* art. 1721(2).
239. *Id.* art. 1711(1)(a–c).
240. *Id.* art. 1711(1)(a).
241. *Id.* art. 1711(1)(b).
242. *Id.* art. 1711(1)(c).
243. *Id.* art. 1711(5). The only exception is where "disclosure is necessary to protect the public" or "steps are taken to ensure . . . unfair commercial use." *Id.* These exceptions are vague

on test data from a competitor's prior application, then the party must hold approval, "normally . . . not less than five years from the date on which the Party granted approval to the person that produced the data . . . ."[244] This provision was designed to prevent generic drug makers from using the test data of innovative drug makers to support their own product's approval.[245]

2. TRIPS.

TRIPS requires Members to ensure a legal means to prevent the use, acquisition, or disclosure by others, contrary to honest commercial practice. Similar to NAFTA, to qualify for protection the owner must prove they have commercially valuable information, which is not publicly known, and that they have taken reasonable steps to maintain the information as secret.[246] Whereas NAFTA allows a showing of actual or potential commercial value, TRIPS is slightly more stringent in requiring that the information "has commercial value because it is a secret."[247] TRIPS also requires protecting data submitted to Members as a condition for approval to market pharmaceutical or agricultural products, although no minimum holding period is specified.[248]

3. United States.

a. Statutory Law.

Trade secret protection derives from the statutory and common law of individual states.[249] The Uniform Trade Secrets Act (UTSA), used as a model statute by the majority of states, defines a trade secret as information with "independent economic value, actual or potential . . . ," that is not "generally known to, and not . . . readily ascertainable by proper means . . . " and subject to reasonable efforts to maintain it secret.[250] To establish a cause of action, the plaintiff must prove they have qualified subject matter, the defendant misappropriated their trade secret, and the plaintiff took reasonable precautions to prevent disclosure.[251] Misappropriation occurs when one acquires the trade secret by improper means or breaches a confidential relationship.[252] The wording of NAFTA and

and subject to Party discretion, and therefore may render article 1711(5) meaningless. *See* Goolsby, *supra* note 12, at 47.

244. NAFTA, *supra* note 5, art. 1711(6). Subject to this provision, abbreviated approval procedures based on bioequivalence and bioavailability are allowed. *Id.*

245. *See* Lars Noah, *NAFTA's Impact on the Trade in Pharmaceuticals*, 33 HOUS. L. REV. 1293, 1298–1300 (1997).

246. *See* TRIPS, *supra* note 9, art. 39(2)(a–c).

247. *Id.* art. 39(2).

248. *Id.* art. 39(3). Similar to NAFTA, an exception is allowed "where necessary to protect the public" or "steps as taken to ensure . . . against unfair commercial use." *Id.*

249. *See generally* Merges, *supra* note 30, at 29–32 (history of trade secret protection in the U.S.).

250. Uniform Trade Secrets Act § 1 (4)(i-ii) (1985) [hereinafter UTSA]. Forty states and the District of Columbia have enacted the UTSA. *See* Merges, *supra* note 30, at 32.

251. *See* Merges, *supra* note 30, at 33–34.

252. *See* UTSA, *supra* note 250, §§ 1(2)(i–ii).

TRIPS closely follows the UTSA and, consequently, no specific changes were made as a result of these agreements.[253]

The FDA has the duty to ensure that all new drugs are safe and effective in use.[254] In the United States, the public interest in having rapid approval of lower costing generic drugs is balanced against the innovative drug maker's interest to not lose its patent protection or trade secrets disclosed as part of the approval process. The FDA imposes several restrictions on the approval of drugs when the applicants did not do the testing themselves. Typically, a generic drug maker files an accelerated new drug application (ANDA) by showing bioequivalence to an already approved drug, instead of submitting new animal and human studies showing safety and effectiveness.[255] The applicant must certify that a patented drug "will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . . ."[256] Alternatively, the applicant may certify that the patent is invalid or has expired and, therefore, will not be infringed.[257] If either of the latter two certifications is made, then the generic drug maker must notify the patentee.[258] The patentee has forty-five days from notification to sue the applicant for patent infringement under 21 U.S.C. § 271(e)(2).[259] If the patentee sues, then the commercial manufacture or sale of the drug by the applicant is put on hold for five years, or until the patent is determined by a court to be invalid or not infringed.[260]

Several additional statutory restrictions ensure that trade secrets disclosed as part of gaining agency approval or complying with agency regulations are kept confidential. Any employee or officer of the United States who discloses information gained in the course of their employment or official duties is subject to removal from office and fines or imprisonment, or both, under the Trade Secrets Act.[261] Trade secrets required to be submitted to a public agency are exempt from the Freedom of Information Act (FOIA).[262] Trade secrets revealed to the FDA are entitled to protection by the agencies, officers, and employees.[263]

253. *See* Goolsby, *supra* note 12, at 57.
254. *See* Federal Food, Drug and Cosmetic Act 21 U.S.C.S. § 355(b)(1) (1999) [hereinafter FDCA].
255. *Id.* § 355(j)(2)(A)(iv). For bioequivalence, the rate and extent of absorption must not be significantly different from the approved drug. *See id.* § 355(j)(8)(B)(i); Schering Corp. v FDA, 51 F.3d 390, 398 (3d Cir. 1995), *cert. denied*, 116 S. Ct. 274 (1995) (holding that the statute's definition of absorption was ambiguous, but the FDA's interpretation of "available at the site of drug action" was a permissible construction). A drug maker may also file a new drug application by using published studies done by others to show safety and effectiveness. *See* FDCA, *supra* note 254, § 355(b)(2).
256. *Id.* § 355(j)(2)(A)(vii)(IV).
257. *Id.*
258. *Id.* § 355(j)(2)(B)(i).
259. *Id.* § 355(j)(5)(B)(iii).
260. *Id.* A similar process exists for a new drug application. *Id.* § 355(c).
261. *See* 18 U.S.C.S. § 1905 (1999).
262. *See* 5 U.S.C.S. § 552(b)(4) (1999).
263. *See* 21 U.S.C.S. § 331(j) (1999).

b. Judicial Interpretations.

The scope of exception for trade secrets under the FOIA has added importance in light of increased litigation between generic and innovative drug makers and mutual recognition agreement between the United States and the European Union to share confidential information submitted to the FDA or its foreign equivalent.[264] The extent to which the public should have access to safety and effectiveness data for new drugs submitted for approval to the FDA has long been debated.[265] Disclosure may increase an agency's effectiveness by allowing outside open scientific comment and inquiry about the adequacy of the safety and effectiveness data.[266] The public would have more information to evaluate the risks and rewards of a particular drug.[267] The need for duplicative testing by a second company would be reduced.[268] Innovations in drug discovery could be aided.[269] The argument against disclosure is that it erodes the benefit a company gains from performing health and safety testing and therefore decreases the motive for innovation and discovery.[270] This would be especially harmful for drugs not protected under a patent.[271]

In *Chrysler Corp. v. Brown*, the U.S. Supreme Court held that a court shall "hold unlawful and set aside agency action . . . not in accordance with law," and that "any disclosure that violates § 1905 [Trade Secrets Act] is 'not in accordance with law' within the meaning of § 706(2)(A) [Administrative Procedures Act]."[272] Information submitted to a government agency is confidential if disclosure "(1) impair[s] the Government's ability to obtain necessary information in the future" or "(2) cause[s] substantial harm to the competitive position of the person from whom the information was obtained."[273] Nevertheless, the FDA has been accused of adopting a pro-disclosure approach.[274] In response, innovative drug makers may sue the FDA under *Chrysler*, claiming that disclosure of their trade secrets would be arbitrary and capricious.[275]

Conversely, public citizen groups have sued the FDA for failing to disclose test data under the FOIA. For example, Public Citizen Health Research Group (Public Citizen)

264. *See* James T. O'Reilly, *Implications of International Drug Approval Systems on Confidentiality of Business Secrets in the U.S. Pharmaceutical Industry*, 53 FOOD DRUG L.J. 123, 124 (1998) (discussing the FDA's willingness to disclose privately generated research data).

265. *See* Thomas O. McGarity & Sidney A. Shapiro, *The Trade Secret Status of Health and Safety Testing Information: Reforming Agency Disclosure Polices*, 93 HARV. L. REV. 837 (1980).

266. *Id.* at 842.

267. *Id.* at 844.

268. *Id.* at 845.

269. *Id.* at 848.

270. *Id.* at 849.

271. *Id.* at 850–51.

272. 441 U.S. 281, 318 (1979). *See also* McGarity & Shapiro, *supra* note 265, at 858–59 (reviewing the Chrysler holding).

273. National Parks & Conservation Ass'n v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974) (interpreting the scope of protects offered by 5 U.S.C. § 552).

274. *See* O'Reilly, *supra* note 264, at 129 & 129 nn.34–39 (reviewing policy statements and arguments presented by the FDA in court cases favoring disclosure).

275. *Id.* at 129 & 129 n.45; *see* Schering, 51 F.3d at 396 (innovative drug makers have standing to challenge the FDA concerning the implementation of its regulations on the approval of a generic drug through the ANDA process).

sued the FDA when it refused to disclose the protocol of a FDA-required, post-market survey conducted by Bristol-Myers Squibb concerning the efficacy and side effects of an antihyperglycemic drug.[276] The court rejected as speculative, innovator-defendant Squibb's argument that disclosure would allow competitors to raise safety concerns about the drug.[277] The court ruled that to qualify for protection against disclosure there must be proof of competitive injury resulting from disclosure of the protocol.[278] Public Citizen also challenged the FDA's refusal to release safety and effectiveness data submitted as an investigational new drug application (INDA) to the FDA by Schering Corporation.[279] The district court granted Public Citizen's motion for summary judgment and ordered the release of the information on the grounds that 21 U.S.C. § 355(l) mandates disclosure, absent extraordinary circumstances. The appellate court reversed, however, holding the FOIA was not applicable to INDAs and does not support the disclosure of information to prevent other drug companies from repeating past mistakes from human testing.[280] Courts have also upheld the FDA's right to withhold confidential information requested as a result of litigation between drug companies, and between drug companies and private citizens.[281]

4. Canada.

a. Statutory Law.

Like the United States, trade secret protection in Canada derives from local and common-law principles.[282] The Supreme Court of Canada applies a three-element test to determine a breach of confidence: (1) the information is confidential; (2) the information is conveyed under conditions creating an obligation of confidence; and (3) the information is misused, to the detriment of the owner of the information.[283] An exception to the disclosure of information submitted to government institutions is allowed if the information contains trade secrets treated as confidential, and which could change the financial position, prejudice the competitive position, or interfere with contractual

276. *See* Public Citizen Health Research Group v. FDA, 964 F. Supp. 413, 414 (1997).

277. *Id.* at 415. The court suggested that even a legitimate concern about "alarmism" would not qualify for an exemption from the FOIA under § 552(b)(4). *Id.* at 415 n.2.

278. *Id.* at 416.

279. *See* Public Citizen Health Research Group v. FDA, 185 F.3d 898, 901 (D.C. Cir. 1999). Before submitting a new drug application, the FDA requires the submission of an INDA, describing the drug, laboratory, and preclinical testing, and proposed clinical testing. *Id.*

280. *Id.* at 903–04. Rather, the FOIA is intended to allow the public to learn about the workings of the government. *Id.*

281. *See* Serono Lab., Inc. v. Shalala, 35 F. Supp. 2d 1, 4 (D.C. 1999) (holding that the FDA must remove the defendant drug company's trade secrets from its administrative record before making the record available to plaintiff drug company); Eli Lilly & Co. v. Marshall, 850 S.W.2d 155, 160 (Tex. 1993) (the FDA has a compelling public interest to redact patient and reporter names and addresses from adverse reaction reports requested by a private citizen as part of litigation against a drug company).

282. *See* Goolsby, *supra* note 12, at 44.

283. *See* Lac Minerals Ltd. v. International Corona Resources [1989] 61 D.L.R. (4th) 14, 79-70 (S.C.C.).

or negotiations of a third party not requesting the disclosure.[284] Similar to the United States, the burden of proof lies with the plaintiff to show the confidential information, "has the necessary quality . . . namely, it must not be something which is public property and public knowledge."[285]

The Ministry of National Health and Welfare has broad power to make regulations "prescribing standards . . . or other property of any article of food, drug, cosmetic or device"[286] or to prohibit drug imports as "necessary for the protection of the public in relation to the safety and quality of any such drug."[287] To comply with the trade secret provisions in NAFTA and TRIPS, the Minister was given authority to issue regulations limiting a generic drug applicant's right to cross-reference previously submitted safety and effectiveness data.[288] Canada's obligations to protect trade secrets submitted to the Ministry are embodied in Food and Drug Regulation C.08.004.1.[289] A holding period is triggered if the Minister examines and relies on data previously filed by an innovative drug maker, in support of a generic drug maker's application for a notice of compliance.[290] In these cases, the generic drug maker's notice of compliance will not be issued until five years after the innovative drug maker's notice of compliance was issued.[291] Before the NAFTA and TRIPS agreements, generic drug makers were granted access to the safety and effectiveness data submitted by innovative drug makers.[292]

Similar to the protections afforded by the Federal Food, Drug, and Cosmetic Act (FDCA), the rights of innovative drug makers are protected by formally linking the regulatory approval of generic drugs to previously patented drugs. The patentee may submit a "patent list" of all patents that contain a claim to the medicine itself or the use of the medicine.[293] Generic drug makers wishing to market a new drug must declare they accept that a Notice of Compliance will not issue until the patents on the list expire,

284. *See* Access to Information Act, R.S.C., ch. A-1, § 20(1)(a–d) (1983) (Can.) (visited Jan. 10, 2000), http://canada.justice.gc.ca/STABLE/EN/Laws/Chap/A/A-1.txt.

285. Lac Minerals Ltd, 61 D.L.R. at 20 (citing *Saltman Engineering Co. Ltd. v. Campbell Engineering Co. Ltd.* [1948] 65 R.P.C. 203, 215 (Eng. C.A.)).

286. Canadian Food and Drug Act, R.S.C., ch. F-27, § 30(1) (1985) (Can.) (visited Jan. 11, 2000), http://canada.justice.gc.ca/STABLE/EN/Laws/Chap/F/F-27.txt.

287. *Id.* § 30(2).

288. "[T]he Governor in Council may make such regulations as the Governor . . . deems necessary for the purpose of implementing, in relation to drugs, Article 1711 of the [NAFTA] or [Art. 39(3)] of the [TRIPS] [a]greement . . . ." *Id.* § 30(3).

289. *See* Food and Drug Regulations, C.R.C., c. 870, §C.08.004.1 (1995) (Can.), *available in* LEXIS, Consolidated Regulations of Canada File.

290. *Id.* §C.08.004.1(1).

291. *Id.* The holding period, however, only applies to data filed by the innovative drug maker on or before Jan. 1, 1994. *Id.* §C.08.004.1(3).

292. *See, e.g.*, Cyanamid Canada Inc. v. Minister of Nat'l Health & Welfare [1992] 45 C.P.R. (3d) 390, 393-94 & 404 (F.C.A.); Glaxo Canada, Inc. v. Ministry of Nat'l Health & Welfare [1992] 41 C.P.R. (3d) 179, 185–186 (F.C.T.D.).

293. *See* Patented Medicines (Notice of Compliance) Regulations, SOR/93-133 §§ 4(1–2) (1993) (Can.) (visited Mar. 4, 2000), http://canada.justice.gc.ca/FTP/EN/Regs/Chap/P/P-4/SOR93-133.txt [hereinafter Patented Medicines]. A medicine is defined as "a substance intended or capable of being used for the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or the symptoms thereof." *Id.* § 2.

or alternatively, allege that the patents are not infringed or are not valid.[294] A patentee disputing the allegation has forty-five days to apply for a court order to prohibit the Minister from issuing a Notice of Compliance.[295] Giving the Minister notice that an application for a court order has been filed starts a twenty-four-month hold on the issuance of a Notice of Compliance to the generic drug maker, unless the court dismisses the application, the application is withdrawn, the patent expires or is proven invalid, or no claim of the medicine or its use would be infringed.[296] Innovative drug makers always dispute an allegation because of the value in delaying the market appearance of a competitive generic drug by at least two years.[297]

b. Judicial Interpretations.

An important issue is under what conditions the Minister of Health may invoke the five-year holding period to protect an innovative drug maker. As noted above, invoking the holding period largely depends on whether the Minister decides to examine and rely on prior information presented by innovative drug makers in support of a generic drug maker's application for a Notice of Compliance. The scope of the Minister's discretion is clarified in *Bayer*, where the innovative drug maker argued that the trial court interpreted a subsection of the Food and Drug Regulations in violation of the trade secret protections agreed to under Article 1711 of NAFTA.[298] Bayer asserted that Article 1711(6) entitled innovative drug makers to five years of protection whenever a generic drug manufacturer filed an abbreviated new drug submission under subsection C.08.004.1. Bayer reasoned that the Minister of Health "must implicitly be examining and relying upon the confidential information filed by the [innovator's New Drug Submission]. . . ."[299]

The court of appeals, however, rejected Bayer's argument, ruling that nothing in Article 1711 of NAFTA prohibits a generic manufacturer from demonstrating safety and effectiveness by showing that the product is the pharmaceutical and bioequivalent of the innovator's product. "If the generic manufacturer is able to do so solely by comparing its product with the innovator's product which is being publicly marketed, the Minister will not have to examine or rely upon confidential information filed as part of the innovator's [New Drug Submission]."[300] The five-year market protection for the innovator applies only if the Minister chooses to examine and rely on the information filed by the innovator.

294. *Id.* § 5(1); Canadian Patent Act, *supra* note 160, § 55.2(4) (giving the Governor in Council the right to make regulations to prevent infringement of a patent).
295. *See* Patented Medicines, *supra* note 293, § 6(1).
296. *Id.* § 7(1)(e). In 1998, the holding period was reduced from thirty months amid calls by opposition parties and provincial governments to repeal the entire regulation. *See CDMA Calls on Prime Minister to Fire Industry Minister John Manley; Actions on Patented Medicines Regulations Show Minister Is Putting Interests of Foreign Drug Lobby Before Those of Canadians*, CANADA NEWS WIRE LTD., Mar. 16, 1998, *available in* LEXIS, Canadian Publications File.
297. *See* McMahon, *supra* note 7, at 45.
298. *See* Bayer Inc. v. Canada (1999), 87 C.P.R. (3d) 293, 297 (F.C.A.).
299. *Id.* at 295.
300. *Id.* at 296.

The court found that Bayer's interpretation would read out the option given to the Minister as to whether or not to examine and rely on the confidential information filed by the innovator. Critical to the court's interpretation was the Statements in the Regulatory Impact Analysis Statement accompanying C.08.004.1.[301] The court ruled that the government's policy was to give generic drug makers the option of supplying additional information so as to avoid having the Minister rely on confidential information supplied by the innovator and then imposing the holding period.[302] The court found this not at variance with NAFTA Article 1711 because safety and effectiveness could be established "on the basis of bioequivalence or bioavailability."[303]

It is questionable whether this interpretation of C.08.004.1 complies with NAFTA's overall objective of requiring "honest commercial practice" in the use of trade secrets submitted to government agencies. An innovative drug maker spends considerable time and money collecting pre-clinical and clinic safety and efficacy data to gain approval for a new drug.[304] As recognized in the United States by passing the Waxman-Hatch Act, this gives rise to "front-end distortion," reducing the effective term of patent protection due the delay between patenting a drug and its approval by the FDA.[305] According to *Bayer*, however, the day after the innovative drug maker gets approval, a generic drug maker may submit an accelerated new drug application and receive approval to market the same drug solely by showing bioequivalence. Judge Evans of the trial division suggested that C.08.004.1 may provide an innovative drug owner with additional market protection for a patented drug that is about to expire.[306] But it is totally within the Minister's discretion to rely on something other than bioequivalence data provided by the generic drug maker seeking to market a drug previously protected by patent, but not for an unpatented drug, as in *Bayer*. It is worth noting that the above-mentioned sections of NAFTA do not restrict the protective five-year holding period to patented inventions only.[307] Trade secret protection is thus solely within the discretion of the Minister of Health, and unlikely to provide innovative drug makers assurance of preventing "front-end distortion" of the period of protection for patented drugs, and no protection for unpatented drugs.

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301. "If the manufacturer wishes to supply the required [safety and efficacy] information directly . . . the manufacturer will avoid the application of this provision." *Id.* at 297.
302. *Id.*
303. *Id.* at 298. But the court seems to have ignored Article 1711(6)'s requirement that approval based on bioequivalence or bioavailability is subject to the provision that no one may rely on trade secret data in support of an application for five years after approval was granted to the person that produced the data.
304. The trial court noted that Bayer, as part of its new drug submission, provided "366 volumes of description, test data and other information, and includes the results of clinical tests conducted over 8 years and involving 2,200 patients." Bayer Inc. v. Canada (1998), 84 C.P.R. (3d) 129, 133 (F.C.T.D.)
305. *See* discussion, *supra* Part III.B.3.
306. *See* Bayer, *supra* note 304, 84 C.P.R. at 142.
307. This also raises doubts as to whether the Waxman-Hatch Act provides the protections agreed to in Article 1711 of NAFTA or Article 39 of the TRIPS agreement, since § 156 addresses patent term restoration, not trade secret protection. *See* Patent Act, *supra* note 150, § 156.

V. Trademark Law.

A. The Protection of Well-known Foreign Marks.

1. *NAFTA.*

Trademarks are broadly defined as "any sign . . . capable of distinguishing the goods or services of one person from those of another . . . ."[308] The scope of protection applies where there is a likelihood of confusion in the use of "identical or similar signs for goods or services . . . identical or similar to those goods or services" for which a trade-mark is registered.[309] NAFTA incorporates protections to well-known trademarks afforded by article 6*bis* of the Paris Convention, with the expansion of the Convention to cover services.[310] To determine whether a trademark is well-known "account shall be taken of the knowledge . . . in the relevant sector of the public, including knowledge . . . obtained as a result of promotion of the trademark."[311] The parties, however, may not "require that the reputation of the trademark extend beyond the scope of the public that normally deals with the relevant goods or services."[312]

2. *TRIPS.*

TRIPS has nearly identical language to NAFTA defining eligible trademark material.[313] Article 6*bis* of the Paris Convention is also incorporated into protections for well-known trademarks, with expanded protection to cover services.[314] A determination of well-known is assessed "in the relevant sector of the public, including knowledge . . . obtained as a result of the promotion of the trademark."[315] TRIPS, however, then goes beyond NAFTA by providing broader protections to well-known marks than NAFTA, subject to proof of a connection with the registered trademark and a likelihood of damage. Article 6*bis* is applied "to goods or services which are *not similar* to those in respect of which a trademark is registered . . . " (emphasis added).[316] Protection is provided so long as the use "would indicate a connection between those goods and services and the

308. NAFTA, *supra* note 5, art. 1708(1). There are doubts that this definition could serve as a unambiguous legal standard. *See* Goolsby, *supra* note 12, at 30.

309. NAFTA, *supra* note 5, art. 1708(2). Because NAFTA fails to define likelihood of confusion or the degree to which goods and marks must be identical, each Party has broad discretion to adopt their own definitions. *See* Goolsby, *supra* note 12, at 31.

310. *Id.* art. 1708(6). Article 6*bis* permits countries to "refuse or to cancel the registration, and to prohibit the use, of a trademark . . . considered . . . to be well known in that country as being already the mark . . . entitled to the benefits of this Convention and used for identical or similar goods." Paris Convention for the Protection of Industrial Property, July 14, 1967, 21 U.S.T. 1583, 823 U.N.T.S. 305 [hereinafter Paris Convention].

311. NAFTA, *supra* note 5, art. 1708(6).

312. *Id.*

313. "Any sign, or any combination of signs, capable of distinguishing the goods or services of one undertaking from those of other undertakings . . . ." TRIPS, *supra* note 9, art. 15(1).

314. *Id.* art. 16(2).

315. *Id.*

316. *Id.* art. 16(3) (emphasis added).

owner of the registered trademark . . . ."[317] Also, TRIPS requires that "the interests of the owner . . . are likely to be damaged by such use."[318]

3. United States.

a. Statutory Law.

Unlike patents and copyright law deriving from federal regulations, trademark law comes from the common-law torts of misappropriation and deception.[319] Federal trademark law is embodied in the Trademark Act of 1946 (Lanham Act).[320] The Lanham Act provides a federal cause of action for deceptive or misleading uses of a mark in commerce, protects against state interference or legislation, and serves to prevent unfair competition.[321] The mark owner has a civil action when a likelihood of confusion is created due to the use of an imitation or copy of a mark,[322] or a mark is used to falsely designate the origin or description of goods.[323]

The Lanham Act also "provide[s] rights and remedies stipulated by treaties and conventions respecting trademarks, trade names, and unfair competition entered into between the United States and foreign nations."[324] Any foreigner whose country has a treaty with the United States relating to the protection of trademarks or preventing unfair competition is entitled to protection under the Lanham Act, "to the extent necessary to give effect to any provision of such . . . treaty . . . ."[325] The subject matter of trademark protection extends to "any word, name, symbol, or device, or any combination thereof . . . used by a person, or . . . which a person has a bonafide intention to use in commerce . . . to identify and distinguish his or her goods . . . from those manufactured or sold by others and to indicate the source of the goods . . . ."[326] For goods, a mark is used in commerce when "it is placed . . . on the goods or their containers . . . and the goods are sold or transported in commerce . . . ."[327] For services, used in commerce means "used or displayed in the sale or advertising of services and the services are rendered in commerce, or . . . in more than one State or in the United States and a foreign country and the person rendering the services is engaged in commerce in connection with the services."[328]

317. *Id.*
318. *Id.* In comparison, NAFTA has no such requirement.
319. *See* Merges, *supra* note 30, at 525 (overview of trademark theory).
320. *See* 15 U.S.C §§ 1051–1127 (1994) [hereinafter Lanham Act].
321. *Id.* § 1127.
322. *Id.* § 1114(1).
323. *Id.* § 1125(a).
324. *Id.* § 1127.
325. *Id.* § 1126(b).
326. *Id.* § 1127.
327. *Id.*
328. *Id.*

The Federal Trademark Dilution Act (Dilution Act) was signed into federal law in 1996, adding dilution as a new basis for infringement.[329] Dilution is defined as "lessening of the capacity of a famous mark to identify and distinguish goods or services . . . ."[330] The Dilution Act prevents uses that may blur the distinctiveness or tarnish the image of a mark regardless of a likelihood of confusion or competition between the mark holder and infringer.[331] Among several factors to decide if a mark is famous are: "inherent or acquired distinctiveness," "duration and extent of use" and "degree of recognition . . . in the trading areas and channels of trade used" by the owner and the infringer.[332] Congress intended the Dilution Act to make the Lanham Act consistent with the United States' obligation under the TRIPS agreement by providing a cause of action for the dilution of famous marks.[333] The Committee on the Judiciary recommended that the Lanham Act be further amended to clarify that dilution provides a basis for the opposition or cancellation of marks.[334]

b. Judicial Interpretations.

Courts have long struggled with trying to decide the extent to which the Lanham Act incorporates provisions from foreign treaties and agreements.[335] The Second Circuit in *Vanity Fair Mills, Inc. v. T. Eaton Co.* held that a U.S. company could not sue a Canadian company for unfair competition when the latter sold feminine underwear bearing the plaintiff's mark.[336] The court reasoned that Section 1126(b) of the Lanham Act and the Paris Convention only provides national treatment and, therefore, a U.S. company could not hold a foreign company liable for a U.S. trademark violation occurring in a foreign country.[337] In contrast, on reviewing *Vanity Fair Mills*, subsequent cases, and legislative history, the court in *General Motors* decided that the Lanham Act incorporated the substantive provisions of the Paris Convention governing trademarks.[338] Because the Paris Convention provides a broad prohibition against unfair competition, the court held

329. *Id.* § 1125(c) (first introduced as Pub. L. No. 104-98, 190 Stat. 985 (1995)) [hereinafter Dilution Act].
330. *Id.* § 1127.
331. *Id.*; *see* Susan L. Serad, Comment, *One Year After Dilution's Entry into Federal Trademark Law*, 32 WAKE FOREST L. REV. 215, 221 (1997) (legislative history of the Dilution Act).
332. Lanham Act, *supra* note 320, § 1125(c)(1).
333. *See* H.R. REP. No. 104-374, at 3 (1995), *reprinted in* 1995 U.S.C.C.A.N. 1029 (report from the Committee on the Judiciary).
334. *See* H.R. REP. No. 106-250, at 1-2 (1999), *available at* 1999 WL 528534.
335. *See* General Motors Corp. v. Lopez, 948 F. Supp. 656, 687–89 (E.D. Mich. 1996) (summarizing cases and legislative history interpreting international obligations incorporated into the Lanham Act).
336. *See* 234 F.2d 633, 644 (2d Cir. 1956).
337. *Id.* The court distinguished the United States Supreme Court's holding in Steele, that the Lanham Act applied to prevent the extraterritorial activities of a U.S. citizen who obtained the Mexican registration of the Bulova mark and then sold goods bearing the mark in the U.S. *Id.* (commenting on *Steele v. Bulova Watch Co.*, 344 U.S. 280, 285 (1952)). Unlike *Steele*, the court in *Vanity Fair* found no substantial effect on foreign or interstate commerce in the United States. *Id.*; *see* 234 F.2d, *supra* note 336, at 642.
338. *See* General Motors, 948 F. Supp. at 689.

that General Motors had established a valid claim for the theft of their trade secrets and their use by Volkswagen outside of the United States.[339]

Courts have been reluctant to prevent domestic citizens from trading on the goodwill of a well-known foreign trademark, despite the provisions in NAFTA and TRIPS incorporating article 6*bis* of the Paris Convention. For example, in *Buti*, the domestic plaintiffs sought to clarify their right to open a restaurant in the United States under the mark "Fashion Café."[340] The district court rejected the defendant's argument that, although they were operating a restaurant using this mark in Italy, their advertising in the United States was enough to constitute use of a mark in a service as defined in section 1127 of the Lanham Act.[341] The Second Circuit affirmed, noting that this case presented the mirror image of the situation in *Vanity Fair*.[342] As in *Vanity Fair*, a key issue was whether the defendant had conducted the affairs of their restaurant to substantially affect either interstate or foreign commerce.[343] The court noted that the defendant's restaurant services in Italy involved no trade between the United States and Italy, there was no constitutional authority for the United States to regulate the restaurant, and its advertising was insufficient to constitute use in commerce.[344]

Two decisions by the Trademark Trial and Appeal Board (TTAB) are especially germane to defining the extent of protection afforded to Canadian-registered trademarks. In *Mother's Restaurants Inc. v. Mother's Other Kitchen Inc.*, the owner of several restaurants operating in Canada under the mark "Mother's Pizza Parlour," opposed the registration of "Mother's Other Kitchen" as a mark in the United States.[345] Mother's Restaurants argued that they had created goodwill in the United States by radio advertisements reaching parts of the United States, and by distributing promotional materials along tourist routes frequented by Americans visiting Canada.[346] The TTAB rejected the argument, holding that priority in a mark is not created through "prior use and advertising of a mark in connection with goods or services marketed in a foreign country (whether said advertising occurs inside or outside the United States) ... against one who, in good faith, has adopted the same or similar mark ... in the United States prior to the foreigner's first use of the mark ... in the United States."[347] The TTAB acknowledged

339. Article 10*bis* of the Paris Convention prohibits "[a]ny act of competition contrary to honest practices" in particular acts like to create confusion, false allegations, or misleading allegations. Paris Convention, *supra* note 310. In addition, the court stated that "Congress has the power to regulate even entirely foreign commerce where it has a substantial effect on commerce between the states or between the United States and foreign countries." General Motors, 948 F. Supp. at 690.
340. *See* Buti v. Impressa Perosa S.R.L., 139 F.3d 98, 99 (2d Cir. 1998).
341. *Id.* at 101. Although the defendant Impressa Perosa filed several counterclaims, dilution of a famous mark under § 1125(c) of the Lanham Act was not among them. *Id.*
342. *Id.* at 102.
343. *Id.* at 103.
344. *Id.* at 103.
345. *See* 218 U.S.P.Q. (BNA) 1046 (T.T.A.B. 1983), *available in* 1983 TTAB LEXIS 117.
346. *Id.* at 1047–48.
347. *Id.* at 1048.

that an exception maybe allowed for a foreign famous mark as done in *Vaudable v. Montmartre, Inc.*[348] although that was not the situation in the present case.[349]

More recently, in *Linville v. Rivard*, the TTAB found that Rivard's radio, television, and newspaper ads reaching the United States, and promotional material distributed inside the United States, did not constitute use sufficient to allow a Canadian hair salon to prevent cancellation of "ULTRACUTS" as a registered mark in the United States.[350] The Federal Circuit Court of Appeals found no error in the Board's decision, noting that Rivard's trips to the United States to investigate establishing hair dressing and beauty salons in the United States was insufficient to show an intent to use the mark in commerce in the United States, and therefore refute a finding of abandonment of the mark.[351]

4. Canada.

a. Statutory Law.

The Federal rights are grounded in the Trademark Act.[352] A trademark "is used by a person for ... distinguishing ... wares or services manufactured, sold, leased, hired or performed by him from those manufactured, sold, leased, hired or performed by others. ..."[353] Infringement occurs if a "person not entitled to [the mark's] use ... sells, distributes or advertises wares or services in association with a confusing trademark. ..."[354] There could be confusion between trademarks, even if the infringing mark is associated with wares or services not of the same general class.[355] The Canadian Trademark Act also provides a federal cause of action against unfair competition, including the common law of passing off: "direct[ing] public attention to his wares, services or business in such a way as to cause or be likely to cause confusion ...."[356] A mark is deemed to be adopted by its owner when used or made known in Canada, or when a registration is filed.[357] Use in association with goods occurs when wares

348. 193 N.Y.S. 2d 332 (N.Y. Sup. Ct. 1959).

349. *Id.* In *Vaudable*, the owner of Maxim's restaurant in Paris was granted a permanent injunction against using their mark as the name of restaurant in New York. *See* Vaudable, *supra* note 348, at 334. In finding Maxim's to be a famous mark in the United States, the court pointed to the mark's renown by a particular class of up-scale restaurant goers in New York, the registration of "Maxim's" as a mark in the United States, and the actual sale of goods and services bearing the mark in the United States. *Id.* The court cited both the prevention of confusion and dilution of the mark as grounds for granting relief to the plaintiff. *Id.* at 335.

350. *See* 41 U.S.P.Q.2d (BNA) 1731, 1735–1737 (TTAB 1997), *available in* 1996 TTAB LEXIS 32.

351. *See* Rivard v. Linville, 133 F.3d 1446, 1449 (Fed. Cir. 1998).

352. *See* Trademark Act, R.S.C., ch. T-13, § 1 (1985) (Can.) (as amended) [hereinafter Canadian Trademark Act] (visited Jan. 11, 2000), http://canada.justice.gc.ca/STABLE/EN/Laws/Chap/T/T-13.html.

353. *Id.* § 2.

354. *Id.* § 20.

355. *Id.* §§ 6(1–4).

356. *Id.* § 7(b). Unfair competition may also arise from: "false or misleading statement[s] ...; pass[ing] off other wares or services as and for those ordered or requested ...; make use ... of any description that is false ...; or ... any other practice contrary to honest industrial or commercial [use]." *Id.* §§ 7(a, c–e).

357. *Id.* § 3.

or packaging are marked such that the person possessing the goods has notice of the association.[358] For services, a mark is used when "used or displayed in the performance or advertising of those services."[359]

The evidence necessary to establish a famous foreign mark is addressed within the definition of "made known in Canada." A mark is made known if used by a person "in a country of the Union, other than Canada, in association with wares or services, and ... distributed in ... or advertised in ... any printed publication circulated in Canada ... or radio broadcasts ordinarily received in Canada ... and it has become well-known in Canada by reason of the distribution or advertising."[360] A "country of the union" refers to "any country that is a member of the Union for the protection of Industrial Property constituted under the [Paris] Convention, or any WTO member."[361] Thus, a foreign mark not in distribution in Canada may be still given protection if it has become well-known through advertising. The meaning of "well-known," however, is not defined in the Canadian Trademark Act.[362] This has important consequences, because the extent to which a trademark has become known is a factor in deciding if two trademarks are confusing.[363] Analogous to dilution in the United States, a registered trademark may not be used by another person in a manner likely to depreciate the value of goodwill associated with the mark.[364]

b. Judicial Interpretations.

Traditionally, courts and the trademark board required a foreign mark to be known in every part or a substantial part of Canada before being allowed registration or to bring an opposition.[365] This may violate NAFTA and TRIPS, which require protection of a trademark so long as there is notoriety within the relevant sector of the public.[366] Broader protection has been afforded, however, to foreign marks in a passing off cause of action.

358. *Id.* § 4(1).
359. *Id.* § 4(2).
360. *Id.* §§ 5(a–b).
361. *Id.* § 2.
362. *See* Hugues G. Richard, *Protecting Intellectual Property in a World Getting Smaller: The Treatment of Well-Known Trade-Marks in Canada* (visited Sept. 16, 1999), http://www.robic.ca.publications.236.html.
363. *Id.*; *see* Canadian Trademark Act, *supra* note 352, § 6(5).
364. *See* Canadian Trademark Act, *supra* note 352, § 22(1).
365. *See* Wian Enter. Inc. v. Mady [1965] 46 C.P.R. 147, 169–70 (E.C.C.) (a foreign trade mark cannot be regarded as well known in Canada if knowledge of it is restricted to only a local area); E & J Gallo Winery v. Andres Wines Ltd. [1974] 14 C.P.R.2d 204, 212–13 (F.C.T.D) (adopting and interpreting Wian to mean that a mark must be well known across Canada among potential users or dealers in or users of the goods); Valle's Steak House v. Tessier [1980] 49 C.P.R.2d 218, 226 (F.C.T.D.) (interpreting Wian to mean that to be well known, a mark must be known in "a substantial part" of the country); Redsand Inc. v. Dylex Ltd. [1997], 74 C.P.R.3d 373, 385 (F.C.T.D.) (following Wian, and holding that to be well known through advertising the foreign mark must be "substantial enough to have a noticeable impact in the Canadian market" and be "well known" over a substantial area of Canada).
366. *See* discussion, *supra* Parts V.A.1-2.

For example, Orkin brought a common-law passing off action against Pestco, who listed itself in the business and yellow pages under the name of Orkin, and used a likeness of the Orkin logo.[367] Orkin was granted an injunction even though it did no business in Canada.[368] The court rejected Pestco's argument that Orkin did not have any goodwill in Canada, noting that Orkin had established a base of Canadian customers owning property in the United States, and intended to extend its business into Canada.[369] Pestco's bad faith in the appropriation of Orkin's mark also acted in Orkin's favor. Justice Morden wrote, "[t]he specter of Orkin having a monopoly in Ontario . . . even though now it is not now carrying on business here, is considerably less troubling than the deceptive use of its name and symbol by another."[370]

More recently, a court rejected the argument that a foreign company not doing business in Canada has to be well known across Canada before they have a federal passing off cause of action against a Canadian company.[371] In an effort to obstruct the entry of the U.S. company, Enterprise Rent-a-Car Company (Enterprise), the owner of a Canadian car rental company (Singer), changed the company's name to "Enterprise Car and Truck Rentals Ltd.," one year before Enterprise opened a branch in Canada.[372] Singer argued that under section 5 of the Canadian Trademark Act, Enterprise had to show that they were well known in Canada before they could bring a passing-off action.[373] The trial court held that "compliance with [§]5 is not a prerequisite to a passing-off action under [§]7(b)."[374] In the court's view, the key issue in a passing off claim was that the mark owner had created sufficient local goodwill in the country to be protected by the law.[375] Similar to *Orkin*, the court found that Enterprise, while not necessarily famous, had established goodwill by showing the existence of Canadian customers across the country, maintaining a 1-800 phone number accessible to Canadians, using Canadian travel agents to make reservations, and showing an intent to open its business in Canada.[376]

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367. *See* Orkin Exterminating Co., Inc. v. Pestco of Canada Ltd. [1985] 5 C.P.R.3d 433, 438–439 (Ont. C.A.).
368. *Id.* at 454 (affirming the trial judge's awarding of an injunction to prevent Pestco's further misappropriation of the Orkin's mark).
369. *Id.* at 444.
370. *Id.* at 448.
371. *See* Enterprise Rent-A-Car Co. v. Singer [1996], 66 C.P.R.3d 453, 458 (F.C.T.D.), *aff'd* [1998] 79 C.P.R.3d 45 (F.C.A.).
372. *See id.* at 454.
373. *Id.* at 478.
374. *Id.* at 480. In affirming the trial court's holding, the appellate court noted that as deeming clauses, "[s]ections 3, 4, and 5 . . . did not prescribe substantive rules governing the acquisition and use of trademarks[,]" and are only applied to "sections of the Act where those phrases [are] used." 79 C.P.R.3d at 45–46.
375. *See supra* note 379, at 479. The three elements to establish the prima facie case for passing off are: the plaintiff established goodwill in the mind public; the defendant misrepresented the public; and the plaintiff had or is likely to have damages as result of the misrepresentation. *Id.* at 474.
376. *Id.* at 476–77.

There may be less protection, however, where there is confusion related to wares or services from different classes.[377] For example, the Registrar of Trademarks rejected United Artist's opposition and allowed Pink Panther Beauty Corp. to register "Pink Panther."[378] The Registrar found that although United Artists had a registered mark in the words "Pink Panther," it was not a well-known mark in Canada and because the mark was used on dissimilar products, there was no likelihood of confusion.[379] Based on additional evidence presented by United Artists, the trial court overturned the Registrar, holding that "Pink Panther" was widely known in Canada, and there was a likelihood of confusion in the mind of Canadian consumers.[380]

The court of appeals reversed, holding that although famous and distinctive, there was no likelihood of confusion between the marks because of the different nature of the products sold by the two companies (i.e., beauty supplies versus movies), and the location of sales (beauty parlors versus theaters or video stores).[381] Previous case law supported the court's holding that a mark's fame was not so important as to outweigh the large difference in the nature of the wares or trade sold.[382] To find otherwise, in the majority's view, would extend "protection to every field of endeavor imaginable. There would be no area that Hollywood's marketing machine would not control. Just because they are well-known, the whole world is not barred forever from using words found in the title of a Hollywood film to market unrelated goods."[383]

The dissent noted that the beauty salon choose "Pink Panther" as its mark precisely because it was well known in Canada.[384] The dissent asserted that there was case law supporting the view that trademarks should be protected in spite of dissimilar settings.[385] In addition, the majority's holding may conflict with Article 16(3) of TRIPS, which requires protecting marks beyond the class of goods the trademark is associated with, so long as use would indicate a connection with the mark owner's goods or services, and there is a likelihood of damages. This potential conflict with TRIPS is now unlikely to be addressed by Canada's Supreme Court.[386]

377. *See* United Artists Corp. v. Pink Panther Beauty Corp. [1990] 34 C.P.R.3d 135 (T.M.O.B.), *rev'd* [1996] 67 C.P.R.3d 216 (F.C.T.D.); *rev'd* [1998] 80 C.P.R.3d 247, leave to appeal to Supreme Court of Canada granted, [1999] 82 C.P.R.3d vi (S.C.C.).
378. *See* 34 C.P.R.3d at 139–140.
379. The only acceptable evidence offered by United Artists was distribution revenues of the movie *The Pink Panther* from the mid-60s. The Registrar found this insufficient to establish nonabandonment of the mark or of the mark being well known to a significant extent in Canada. *See* 34 C.P.R.3d at 139.
380. *See* 67 C.P.R.3d at 226.
381. *See* 80 C.P.R.3d at 269.
382. *Id.* at 265–67.
383. *Id.* at 270.
384. *Id.* at 271.
385. *Id.* at 274.
386. *See* Ed Hore, *Intellectual Property S.C.C. to Hear 2 Patent Cases*, THE LAWYERS WEEKLY, Aug. 13, 1999 (although the Supreme Court of Canada granted leave to hear United Artists, the parties are now likely to settle).

VI. Summary, Analysis, and Conclusions.

A. Disparities between Canadian and U.S. Intellectual Property Protection and the Harmonizing Effect of NAFTA or TRIPS.

1. Copyright Law.

Canada's revision of its laws regarding database protection provides a good example of how international agreements like NAFTA can harmonize the laws between two parties. In *Tele-Direct*, the Supreme Court of Canada was strongly influenced by the wording of Article 1705(1) in NAFTA and the U.S. Supreme Court's interpretation of Section 103 of the Copyright Act in *Feist*. This influence proceeded from the fact that Canada amended its copyright law to include database compilations specifically for the purpose of implementing NAFTA. Consequently, the "sweat of the brow" rationale for database protection was rejected in favor of a creativity requirement.

NAFTA's influence on Canada's database protection also illustrates the inability of international agreements to anticipate changing intellectual protections necessitated by technological advances. Since the NAFTA agreement was negotiated in the early 1990s, advances in computer and telecommunication technology have increased the value of databases and the need to prevent its piracy. Although the United States may enact laws to increase the protection given to American database owners, NAFTA or TRIPS provides no obligation for Canada to do the same. Rejecting the "sweat of the brow" rationale has left Canadian courts with less discretion to protect database owners against piracy under the Canadian Copyright Act. As a developed country, the Canadian government will likely face a strong enough domestic lobby to prompt strengthening its copyright laws in this regard. But less developed nations maybe less inclined to provide more protection than that agreed to under NAFTA or TRIPS.

Canada's levy and royalty system for sound recordings shows how the "cultural industries exception" and reciprocity principles allowed under NAFTA can produce disparate treatments of intellectual property owners from different parties. Only Canadian artists benefit from the levy placed on recording media that undoubtedly is also used for copying sound recordings created and produced by U.S. artists. In addition, because the United States does not charge a levy for analog recording media and limits the scope of covered digital media, Canada can point to the national reciprocity provision for sound recordings allowed under both NAFTA and TRIPS as grounds for disparate treatment. Canada's disparate treatment on the grounds of promoting a culture industry is weakened, however, by its signing of TRIPS, which does not allow a cultural industries exception.

Similarly, NAFTA and TRIPS exempt parties from following the provisions of article 6*bis* of the Berne Convention and, consequently, an artist's moral rights are significantly different in Canada and America. In the United States, moral rights are strictly limited to visual art, and even then the artist's rights are exceedingly difficult to enforce. In contrast, moral rights are broadly accepted by Canadian courts, and provides important grounds for damage remedies, especially when there is no commercial loss associated with copyright infringement.

The failure of NAFTA or TRIPS to consider defenses to copyright infringement also produces disparate intellectual property protection in the two countries. In the United States, fair use as an exception to copyright infringement is given broad latitude. Consequently, actions such as parody are allowed, even though parody is not explicitly

listed in the Copyright Act as fair use. In contrast, in Canada, fair dealing as an exception to infringement is limited to only those actions listed in the Canadian Copyright Act. As a result, because it is not listed, parody is not allowed as a fair dealing exception to copyright infringement in Canada.

2. Patent Law.

Although the definitions of a patentable invention are very similar in both countries, Canada refused to allow the patenting of higher life forms, like the onco-mouse, while the United States treats life forms as any other patentable invention. But the United States' and Canada's different treatment of life forms as patentable subject matter illustrates more the unpredictable nature of courts in interpreting intellectual property laws, than the inability of NAFTA and TRIPS to harmonize patent laws. It is true that NAFTA and TRIPS allow a broad gamut of exclusions on moral grounds. However, these were not the basis used by a Canadian court to reject the onco-mouse as a patentable invention. Rather, the court cited the failure to distinguish between human intervention and laws of nature, and the lack of reproducibility of the onco-gene's expression, as grounds for rejecting the patent. Subsequent advances in genetic engineering, however, may obviate these as valid grounds for rejecting life forms as patentable inventions, forcing the Canadian judiciary to revisit this issue in the near future.

Just as disallowing the patentability of life forms has little effect on Canada's economy, compulsory licensing or the imposition of price guidelines does little to hamper a relatively small innovative drug industry in Canada. Maintaining low drug prices by these measures also reduces the cost of Canada's government-run health care programs and endears the current political party to the public. The NAFTA and TRIPS agreements did help ending compulsory licensing and extend the term of protection of patented drugs in Canada. It is questionable, however, whether "price guidelines" imposed and enforced by a government board do not unreasonably conflict with the normal exploitation of a patented drug and prejudice the patentee's legitimate interests, in violation of NAFTA and TRIPS.

In the United States, a more acceptable but less effective means to contain the costs of drugs is to allow the generic drug industry a head start in preparing to compete against innovative drug makers. It remains to be seen how much leeway U.S. courts will give to the activities of generic drug makers on the grounds of being reasonably related to developing information for submission to the FDA. Canadian courts have expressed great willingness to give generic drug makers opportunities beyond preparing to compete, such as entering supply agreements and reformulating drug doses.

3. Trade Secret Law.

To assure honest commercial practices, both NAFTA and TRIPS require the protection of innovative drug makers against generic drug makers who submit an abbreviated new drug submission, where the confidential test data of the innovative drug maker is relied on. Unfortunately, neither agreement defines the scope of "reliance." In Canada, reliance is left totally to the discretion of the Minister of Health. The holding in *Bayer* suggests that the Minister will not be inclined to rely on the confidential data of innovative drug makers when generic drug makers submit an accelerated new drug application.

As a result, there is no guarantee of trade secret protections as required under NAFTA or TRIPS.

In the United States, the protections given to confidential pharmaceutical data submitted to the FDA also are questionable. The Waxman-Hatch Act does provide an additional term of protection for patented drugs when a generic drug maker submits an accelerated new drug application. The holding period required under NAFTA and TRIPS to protect trade secrets, however, is not restricted to patented drugs. Therefore, the scope of trade secret protections required under NAFTA and TRIPS are not fully addressed by the Waxman-Hatch Act.

Neither the NAFTA nor the TRIPS agreements address when confidential information may be released to the public, other than the two nebulous exceptions: where necessary to protect the public or where steps are taken to ensure unfair commercial use. The extent to which confidential information is released from agencies like the FDA, either on their own discretion or under the pressure of special interest groups, can be highly damaging to innovative drug makers. It remains up to innovative drug companies to curtail such activities by suing agencies that release confidential information. NAFTA and TRIPS do not clarify or harmonize the conditions under which a party's discloser of trade secrets does not violate these agreements.

4. Trademark Law.

Although NAFTA and TRIPS have motivated changes in both American and Canadian trademark law, disparities still exist between the protections offered by the two countries. A key issue is each country's interpretation of what article 6*bis* of the Paris Convention, incorporated into both NAFTA and TRIPS, requires. The language of article 6*bis* suggests a goal of preventing the use of marks considered well-known in a foreign country for similar or identical goods. The United States purports to comply with its obligations under TRIPS by passing the Dilution Act. Courts and the Trademark Board have required actual use of a well-known foreign mark in the United States before allowing protection of the mark—foreign use plus advertising in the United States not being enough to constitute use within the meaning of the Lanham Act. It remains to be seen whether passage of the Dilution Act will expand the U.S.'s protection of foreign marks.

In comparison, Canadian courts have allowed advertising as sufficient grounds to establish goodwill in Canada for the purpose of a foreign mark holder bringing a federal passing off cause of action against a domestic infringer. But registration or opposition requires a showing of fame over a substantial part of Canada. TRIPS has extended the protection of famous marks to uses not similar to those for which the mark is registered, so long as a connection would be indicated and the mark owners interests would be damaged. The *Pink Panther* holding suggests that Canadian courts still require proof of a likelihood of confusion, even for famous marks.

B. Implications for Future Intellectual Property Agreements.

The disparities between intellectual property protections between America and Canada exemplifies several areas of contention that developed (or more properly, intellectual property exporting) and developing (or more properly, intellectual property

importing) nations face when negotiating future agreements. Developed nations want protections explicit enough to assure businesses that their intellectual property rights are legally enforceable within each party's judicial system. Developing nations want built-in discretionary exceptions so they can ensure the preservation of their culture identity and control the costs of certain critical products, such as drugs. Provisions left undefined tend to work to the benefit of developing nations because the provision can then be interpreted in a manner that minimizes the intellectual rights that must be provided to foreign businesses.

Canada's adoption of the creativity requirement for database protection, ending compulsory licensing, and extending the period of patent protection for drugs are important rights benefiting intellectual property owners in the United States. But NAFTA's allowance of a cultural industry exception permits Canada to use the proceeds of a royalty and levy system to benefit Canadian artists, to the exclusion of American artists. Although compulsory licensing of patents has ended, Canada continues to control the price of drugs and create a regulatory climate favorable to generic drug makers. Canada's reluctance to protect famous foreign trademarks against dissimilar uses reflects a desire to restrain the onslaught of the American "marketing machine."

The United States is also not above restricting intellectual property rights, although usually this is done out of concerns that too large a scope of rights will deter domestic free enterprise. For example, the United States' restrictive acknowledgment of an artist's moral rights reflect the view that innovation will not be promoted by granting broad rights. This may also explain why fair use is given broad latitude, despite the likelihood that parody depreciates the value of the original work. Similarly, requiring that famous marks be in actual use in the United States before being protected benefits businesses wishing to use the same or a similar mark.

Despite their deficiencies, NAFTA and TRIPS have advanced the United States and Canada towards harmonizing their intellectual property rights. As trade becomes more global, intellectual property protections are an increasingly critical negotiating point in trade agreements. NAFTA and TRIPS provide important lessons for improving future agreements.