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# PATENT PROTECTION FOR PHARMACEUTICALS: A COMPARATIVE STUDY OF THE LAW IN THE UNITED STATES AND CANADA

Mary Atkinson

*Abstract:* A fundamental purpose of patent law is to encourage the development of new inventions by granting to the inventor exclusivity in the marketplace for a limited period of time. Patent law in the area of pharmaceuticals is complicated by the responsibility of governments not only to encourage research and development of new drugs, but also to assure that new drugs are widely available and affordable, as well as safe and effective. Governments, influenced by market and political philosophies, design patent laws and drug regulatory schemes to meet these responsibilities. The United States has a well-developed pharmaceutical industry and private-payer health care, and thus has very strong patent protection for pharmaceuticals. Canada, on the other hand, has a relatively small pharmaceutical industry and government-payer health care. Canada, therefore, weakened the patent rights of pioneer drug companies by instituting compulsory licensing and price controls on brand-name drugs. Despite these fundamental differences, the North American Free Trade Agreement and the General Agreement on Tariffs and Trade have brought near uniformity to the patent and regulatory schemes of both countries. Pioneer drugs have made great strides in increasing longevity and improving quality of life. The challenge is to make these new drugs affordable. Governments need to find creative solutions to this challenge while maintaining strong patent protection for pharmaceuticals so as to ensure the continued development of new medicines. Given the political and economic realities in both the United States and Canada, each government has fulfilled its obligation to the public to develop a reasonably balanced system of patent protection for pharmaceuticals.

## I. INTRODUCTION

Canada and the United States share a common border as well as a common-law legal heritage. However, their differing political systems and market philosophies have led to significant differences in patent protection for pharmaceuticals. The fundamental purpose of patent law is to encourage invention and new discoveries by granting to the inventor exclusivity in the market place for a limited period of time.<sup>1</sup> Patent protection for new inventions in the pharmaceutical industry is complicated by competing public interests. The public has an interest in encouraging research and development of new medicines to increase longevity and quality of life. However, the public also has an interest in keeping the price of new

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<sup>1</sup> *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480 (1974). See also U.S. CONST. art. I, § 8, cl. 8 ("The Congress shall have Power . . . To promote the Progress of Science . . . by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries.").

medicines low to maximize the number of persons who have access to the drugs. Furthermore, the public has an interest in ensuring that new medicines entering the market are both safe and effective.

These competing public interests create tension between the pharmaceutical industry and the generic drug industry. Pharmaceutical companies make large investments in research and development to bring new drugs<sup>2</sup> that are safe and effective to market.<sup>3</sup> New drugs are priced to recoup these investments.<sup>4</sup> In contrast, the generic industry does not invest in original research and development, but instead makes copies of brand-name drugs that are already in the market place and have been approved by a governmental regulatory body as safe and effective.<sup>5</sup> The price of a generic drug is thus lower than the price of the equivalent brand-name drug.<sup>6</sup>

Government policy in the area of pharmaceuticals thus has three objectives: (1) to protect the intellectual property rights of brand-name pharmaceutical companies in an effort to encourage research and development; (2) to foster a strong generic drug industry to contain the costs of new drugs; and (3) to design a regulatory scheme that balances the interests of the pharmaceutical companies and the generic drug companies, while ensuring the safety and efficacy of drugs in the market place.

This Comment examines how the Canadian and United States governments have designed their patent laws and regulatory processes to fulfill their obligations to the public in the area of pharmaceuticals. Part II of this Comment examines how the United States, while maintaining its free market system, has moved to reduce the price of drugs by allowing generic drug companies to engage in some activities during the regulatory process that otherwise would infringe on the exclusive rights of the patent holder. Part III examines how Canada, with its system of socialized medicine and a lesser commitment to free markets, adopted a system of compulsory licensing and price controls to reduce the cost of drugs. Part IV examines how international trade agreements have resulted in near uniformity of patent protection for pharmaceuticals in both countries. Finally, Part V concludes that, given the political and economic realities in both countries,

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<sup>2</sup> Sometimes referred to as "brand-name" or "pioneer drugs."

<sup>3</sup> *Drug Development—A Long and Risky Process*, in PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, PHARMACEUTICAL INDUSTRY PROFILE 2000, at <http://www.phrma.org/publications/publications/profile00/execsum.phtml>.

<sup>4</sup> *Understanding Brand-Name and Generic Drugs, What You Need to Know*, in THE CANADIAN DRUG MANUFACTURERS ASSOCIATION, EDUCATION & COMMUNICATIONS MATERIAL FOR EMPLOYER DRUG PLANS, at [http://www.cdma-acfpp.org/resourcecentre/drgpln\\_qa.shtml](http://www.cdma-acfpp.org/resourcecentre/drgpln_qa.shtml) (last visited Oct. 26, 2001).

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

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

each government has fulfilled its obligation to the public to develop a reasonably balanced system of patent protection for pharmaceuticals.

## II. THE LAW IN THE UNITED STATES

The United States has a very strong domestic pharmaceutical industry.<sup>7</sup> Pharmaceutical companies in the United States make the largest investment in research and development (“R&D”) of new drugs worldwide, conducting 36% of global R&D.<sup>8</sup> While the United States government has an interest in maintaining a healthy pharmaceutical industry, the government is also concerned with providing the public with affordable drugs. The United States has at its core a free market economy.<sup>9</sup> Although the United States has used price controls in the past,<sup>10</sup> Congress has chosen to control the price of prescription drugs by encouraging price competition through a statutory and regulatory scheme that facilitates the entry of generic drugs into the market.<sup>11</sup>

### A. Patent Protection for Pharmaceuticals—The Patent Act<sup>12</sup>

The Patent Act governs the granting of patents in the United States:

Every patent shall . . . grant to the patentee . . . the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States. . . .<sup>13</sup>

[W]hoever, without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefore, infringes the patent.<sup>14</sup>

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<sup>7</sup> Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness? A Political, Legislative and Legal History of U.S. Law and Observations for the Future*, 39 J.L. & TECH. 389, 390 (1999).

<sup>8</sup> *U.S. Leadership In Drug Innovation Due To R&D, Free Market*, in PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, *supra* note 3.

<sup>9</sup> BRADLEY R. SCHILLER, *THE ECONOMY TODAY* 30 (4<sup>th</sup> ed. 1989).

<sup>10</sup> *Id.* at 343-45.

<sup>11</sup> Henry Grabowski & John Vernon, *Longer Patents for Increased Generic Competition in the US: The Waxman-Hatch Act after One Decade*, 10 PHARMACOECONOMICS, 110, 121 (Supp. 1996).

<sup>12</sup> 35 U.S.C.S. §§ 1-376 (2001).

<sup>13</sup> 35 U.S.C.S. § 154(a)(1).

<sup>14</sup> Patent Act, 35 U.S.C.S. § 271(a) (2000).

B. *Regulation of Safety and Efficacy of Pharmaceuticals Prior to 1984*

Patent protection for pharmaceuticals is complicated by requirements imposed under the federal regulatory process to ensure the safety and efficacy of drugs.

1. *The Federal Food, Drug, and Cosmetic Act*<sup>15</sup>

In 1962, Congress enacted major changes to the Federal Food, Drug, and Cosmetic Act, requiring drug manufacturers to submit "substantial evidence" that their drugs were both safe and effective.<sup>16</sup> To implement this requirement, the Food and Drug Administration ("FDA") set up a lengthy approval process for new drugs, including clinical trials.<sup>17</sup> These new regulations significantly shortened the effective patent term for pioneer drugs because the drugs are not in the commercial market during the regulatory process.<sup>18</sup>

2. *Infringement by Generic Companies during the Regulatory Process*

FDA regulations also required generic drug manufacturers to comply with its regulatory process without relying on data submitted by the pioneer drug manufacturer to prove safety and efficacy.<sup>19</sup> Generic manufacturers thus had to perform many of their own tests. Since it is an act of infringement to manufacture or use a patented product during the term of the patent,<sup>20</sup> generic manufacturers could not begin testing until after the patent term expired. As a result, the entry of generic drugs into the market was often delayed for several years after the brand-name drug's patent expired.<sup>21</sup> These regulations gave pioneer drugs a *de facto* patent term extension.

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<sup>15</sup> 21 U.S.C.S. §§ 301-95 (1997).

<sup>16</sup> Patricia I. Carter, *Federal Regulation of Pharmaceuticals in the United States and Canada*, 21 LOY. L.A. INT'L & COMP. L.J. 215, 220 (1999).

<sup>17</sup> *Id.* See also 21 U.S.C.S. § 355.

<sup>18</sup> Grabowski & Vernon, *supra* note 11, at 118. Drug manufacturers apply for patents before entering the FDA regulatory process because once information about the drug is in the public domain, the inventor only has one year to file for a patent. See 35 U.S.C. § 102(b). If the inventor does not file for patent protection within one year, the statute bars the issuance of a patent to the inventor. *Id.*

<sup>19</sup> Grabowski & Vernon, *supra* note 11, at 111.

<sup>20</sup> Patent Act, 35 U.S.C.S. § 271(a) (2000).

<sup>21</sup> Grabowski & Vernon, *supra* note 11, at 111 n.1.

In the landmark case, *Roche Products, Inc. v. Bolar Pharmaceutical Co.*,<sup>22</sup> the Court of Appeals for the Federal Circuit affirmed that a generic drug manufacturer commits infringement by using the active ingredient of a patented drug to perform pre-market entry tests mandated by the FDA before the patent term of the pioneer drug expires. In that case, generic manufacturer Bolar Pharmaceutical imported the active ingredient of a Roche Products drug and manufactured a generic version of the drug before the Roche patent had expired.<sup>23</sup> Bolar had begun the regulatory process during the patent term in preparation for market entry when Roche's patent expired.<sup>24</sup>

The court rejected Bolar's argument that its use fell under the experimental use defense,<sup>25</sup> ruling that although Bolar's use may have been experimental, its ultimate purpose was commercial and therefore infringed Roche's patent rights.<sup>26</sup> The court also refused Bolar's request to create a new exception to the use prohibition.<sup>27</sup> The court decided to leave it to Congress to resolve the conflicting policies between the Food, Drug, and Cosmetic Act and the Patent Act.<sup>28</sup>

### C. *The Drug Price Competition and Patent Term Restoration ("Waxman-Hatch") Act of 1984*<sup>29</sup>

In 1984, Congress attempted to resolve the conflict between the Patent Act and the Food, Drug, and Cosmetic Act with passage of the Drug Price Competition and Patent Term Restoration ("Waxman-Hatch") Act.<sup>30</sup> The Act was a compromise between the interest of generic manufacturers obtaining faster entry into the market, and the interest of brand-name

<sup>22</sup> 733 F.2d 858, 221 U.S.P.Q. (BNA) 937 (1984).

<sup>23</sup> *Id.* at 860.

<sup>24</sup> *Id.*

<sup>25</sup> *Id.* at 863. Experimental use defense is an affirmative defense to patent infringement, under which manufacture or use of a patented device for experimentation only, and not for sale or profit, does not constitute infringement. See, e.g., *Whittemore v. Cutter*, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813); *Bonsack Mach. Co. v. Underwood*, 73 F. 206, 211 (C.C.E.D.N.C. 1896).

<sup>26</sup> *Roche Products*, 733 F.2d at 863.

<sup>27</sup> *Id.* at 863-64. Bolar argued that the public should benefit from price competition as soon as a patent expires, and that a generic drug should not be delayed in coming to market because of conflicts between the Patent Act and the Food, Drug, and Cosmetic Act. *Id.*

<sup>28</sup> *Id.* at 865.

<sup>29</sup> Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355 (1997); 35 U.S.C. §§ 156, 271, 282 (2000)).

<sup>30</sup> *Grabowski & Vernon*, *supra* note 11, at 110.

pharmaceutical companies in regaining patent term lost during the regulatory process.<sup>31</sup>

Title I of the Act established an abbreviated new drug application ("ANDA") approval process for generic drugs, eliminating the requirement for independent proof that the generic version of a pioneer drug is safe and effective.<sup>32</sup> Under the ANDA, the safety and efficacy of the generic drug is accepted if the manufacturer certifies generally that the generic drug has the same active ingredient(s) as the pioneer drug; that the route of administration, the dosage form, and the strength of the generic drug is the same as the pioneer drug; and that the generic drug is the bioequivalent of the pioneer drug.<sup>33</sup>

Title II of the Act also provided some relief for the manufacturers of brand-name pharmaceuticals by restoring a portion of the patent term lost while a pioneer drug is in the regulatory process.<sup>34</sup> It also requires the generic manufacturer to certify that no patent exists on the pioneer drug; or if there is a patent, that the patent has expired or will expire, or that the patent is invalid or will not be infringed by the actions of the generic manufacturer.<sup>35</sup> If there is no patent, or the patent has expired, the generic drug may enter into the market immediately upon the granting of FDA approval.<sup>36</sup> If there is a patent in force, the generic drug may not enter the market—even if it has received FDA approval—until the expiration of the patent.<sup>37</sup> If the generic manufacturer certifies that a patent is invalid or will not be infringed, the holder of the patent has forty-five days after receiving notice to bring an infringement suit.<sup>38</sup> If a suit is brought, approval of the application will be withheld for thirty months, or until a court decision is rendered or the patent at issue expires.<sup>39</sup>

In addition, the Act overruled the federal court's decision in *Roche v. Bolar*<sup>40</sup> by providing a safe harbor provision for generic manufacturers against charges of infringement:

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

<sup>32</sup> *Id.* at 110-11.

<sup>33</sup> Federal Food, Drug, and Cosmetic Act, 21 U.S.C.S. § 355(j)(2)(A)(ii-iv) (1997).

<sup>34</sup> Grabowski & Vernon, *supra* note 11, at 118. *See also* 35 U.S.C.S. § 156.

<sup>35</sup> 21 U.S.C. § 355(j)(2)(A)(vii).

<sup>36</sup> *Id.* § 355(j)(5)(B)(i).

<sup>37</sup> *Id.* § 355(j)(5)(B)(i-ii).

<sup>38</sup> *Id.* § 355(j)(5)(B)(iii).

<sup>39</sup> *Id.*

<sup>40</sup> *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.*, 733 F.2d 858, 221 U.S.P.Q. (BNA) 937 (1984). *See supra* notes 22-28 and accompanying text.

It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.<sup>41</sup>

### 1. *Litigation of the Waxman-Hatch Safe Harbor Provision*

The courts of the United States have been called upon to determine what types of activities are “solely for uses reasonably related to” developing information to comply with a federal regulatory process, and thus qualify for the safe harbor protection. In *Scripps Clinic & Research Foundation v. Genentech, Inc.*,<sup>42</sup> the court interpreted the language of the statute literally, finding that infringing uses that were not *solely* for meeting FDA requirements would not be afforded a defense under 35 U.S.C. § 271(e)(1).<sup>43</sup> Genentech had manufactured a generic version of a Scripps patented human blood product and entered into a research and development agreement with another party to develop a method for commercial-scale manufacture of the generic product and to produce bioequivalency data required by the FDA.<sup>44</sup> Genentech also filed for a European patent on its product.<sup>45</sup> The court ruled that Congress intended the exemption to be narrow. Thus, even though some of the uses of the product were reasonably related to obtaining FDA approval, since the uses served multiple purposes they were beyond the protection of the safe harbor.<sup>46</sup>

In *Intermedics, Inc. v. Ventritex, Inc.*,<sup>47</sup> however, the court took a broader view and undertook an extensive analysis of the statute to determine the standard for deciding whether or not an activity by a generic manufacturer was entitled to the benefit of the safe harbor under § 271(e)(1).<sup>48</sup> The court stated, “Congress clearly decided that it wanted potential competitors to be able to ready themselves, fully, during the life of the patent, to enter the commercial marketplace in a large scale way as soon as the relevant patents expired.”<sup>49</sup>

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<sup>41</sup> Patent Act, 35 U.S.C.S. § 271(e)(1) (2000).

<sup>42</sup> 666 F. Supp. 1379 (N.D. Cal. 1987).

<sup>43</sup> *Id.* at 1396. See *supra* note 41 and accompanying text.

<sup>44</sup> *Id.* at 1384.

<sup>45</sup> *Id.* at 1384-85.

<sup>46</sup> *Id.* at 1396.

<sup>47</sup> 755 F. Supp. 1269 (N.D. Cal. 1991).

<sup>48</sup> *Id.* at 1276-80.

<sup>49</sup> *Id.* at 1277.



The *Intermedics* court determined that only those acts of manufacture, use, and sale, which would be acts of infringement except for the safe harbor, were required to be “solely for uses reasonably related to” meeting FDA requirements.<sup>50</sup> In other words, acts that were non-infringing were allowed purposes.<sup>51</sup> The court ruled, therefore, that use of clinical data for the purpose of raising capital was a non-infringing use.<sup>52</sup> The *Intermedics* court also determined that Congress intended the inquiry to be objective, not subjective; that is, the court should “focus on *conduct* (‘uses’) that *actually has occurred* (as opposed to uses to which a party might put its product in the future) and that would constitute infringement but for the exemption.”<sup>53</sup> Based on these principles, a “use” that has a commercial or business purpose, in addition to meeting FDA requirements, will not lose the benefit of the safe harbor.<sup>54</sup>

The alleged infringing activities at issue in *Intermedics* involved the manufacture and sale of a medical device by Ventritex to institutions and clinicians, both domestic and foreign, for the purpose of conducting clinical trials and generating data for submission to the FDA.<sup>55</sup> The court found that these uses fell within the safe harbor, especially in light of the fact that the clinical data had only been submitted to the FDA and had not been submitted to any foreign regulatory agency.<sup>56</sup> The court also found that the demonstration of the device at trade shows was not an infringing activity because Ventritex had clearly indicated at the trade shows that the product was not for general commercial sale.<sup>57</sup>

Subsequent courts have generally followed the reasoning in *Intermedics*. For example, *Teletronics Pacing Sys., Inc. v. Ventritex, Inc.*,<sup>58</sup> the Federal Circuit<sup>59</sup> ruled that presenting clinical trial data at conferences and using the data for fund-raising purposes did not constitute infringing activity under the statute.<sup>60</sup> The *Teletronics* court noted that Congress must have been aware of the need for generic manufacturers to raise capital and

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<sup>50</sup> *Id.*

<sup>51</sup> *Id.*

<sup>52</sup> *Id.* at 1281 (citing *Eli Lilly & Co. v. Medtronic, Inc.*, 915 F.2d 670, 673 (Fed. Cir. 1990) (holding that infringing acts only involve the “actual making, using, or selling of the patented invention”).

<sup>53</sup> 755 F. Supp. 1269, 1278 (N.D. Cal. 1991)

<sup>54</sup> *Id.* at 1279.

<sup>55</sup> *Id.* at 1282.

<sup>56</sup> *Id.* at 1284.

<sup>57</sup> *Id.* at 1286.

<sup>58</sup> 982 F.2d 1520, 25 U.S.P.Q.2d (BNA) 1196 (1992).

<sup>59</sup> The Federal Circuit has national appellate jurisdiction over all patent cases, subject only to Supreme Court review. MARTIN J. ADELMAN ET. AL., CASES AND MATERIALS ON PATENT LAW 25 (1998).

<sup>60</sup> *Teletronics Pacing Sys.*, 982 F.2d at 1524.

therefore Congress did not intend to prevent the use of clinical trial data for business purposes.<sup>61</sup>

Although the Ventritex cases involved medical devices and not drugs, the reasoning in *Intermedics* is applicable to pharmaceuticals<sup>62</sup> and was used by the court in *NeoRx Corp. v. Immunomedics, Inc.*<sup>63</sup> The *NeoRx* court found the production of large commercial-scale quantities of a drug to be exempt under § 271(e)(1) because the FDA requires proof of commercial-scale manufacturing capacity.<sup>64</sup> The court also found that conducting clinical trials overseas, with an ultimate goal of obtaining foreign regulatory approval, was an exempt activity.<sup>65</sup> The court accepted Immunomedics' argument that the purpose of the trials was to obtain information for their FDA filings and found that a "commercial motivation does not necessarily deprive defendant of the section 271(e)(1) exemption."<sup>66</sup> However, the *NeoRx* court did not exempt the shipping by Immunomedics of product samples to foreign regulatory agencies.<sup>67</sup> This act was infringing because it involved shipping of the patented *invention* and not just use of clinical *data*. The infringing act was not exempt under § 271(e)(1) because the purpose "was not reasonably related to the submission of data to the FDA."<sup>68</sup>

Similarly, in *Biogen, Inc. v. Schering AG*,<sup>69</sup> the stockpiling of product in preparation for market entry was found to be a non-exempt infringing activity.<sup>70</sup> The court, citing *Scripps* and *NeoRx*, also found the shipping of product to foreign regulatory agencies to be a non-exempt infringing activity.<sup>71</sup>

As the above cases suggest, commercial activity involving manufacture or use of the patented *invention* is an infringement. However, use of *data* relating to the patented invention, even if the use is for commercial purposes in addition to meeting FDA requirements, is allowed.

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<sup>61</sup> *Id.* at 1525.

<sup>62</sup> The Supreme Court has ruled that § 271(e)(1) applies to medical devices as well as drugs. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990).

<sup>63</sup> 877 F. Supp. 202 (D.N.J. 1994).

<sup>64</sup> *Id.* at 206.

<sup>65</sup> *Id.* at 207.

<sup>66</sup> *Id.*

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

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

<sup>69</sup> 954 F. Supp. 391 (D. Mass. 1996).

<sup>70</sup> *Id.* at 397.

<sup>71</sup> *Id.* at 397 n.1.

## 2. *The Waxman-Hatch Act Achieved a Reasonable Balance*

The Waxman-Hatch Act and subsequent court interpretations limiting acts of infringement only to those involving the patented invention have achieved a reasonably balanced system of protection for pharmaceutical inventions. Pioneer drug manufacturers received restoration of patent term, while the generic drug manufacturers achieved faster entry into the market, as well as permission to engage in the marketing and fund raising which enables them to be competitive as soon as the patent expires. The public also benefits because pioneer companies continue to have incentives to invest in research and development, and generic manufacturers can bring less expensive drugs to market sooner.

### III. THE LAW IN CANADA

Canada has a system of nationalized medicine in which the government is directly involved in providing health care for all its citizens.<sup>72</sup> The government thus has a vested interest in keeping drug prices low. Therefore, although Canada provides patent protection for pharmaceuticals, the government weakened the rights of the patentee by instituting a compulsory licensing system.<sup>73</sup> When the government eventually abolished compulsory licensing, it instituted price controls.<sup>74</sup>

#### A. *Patent Protection for Pharmaceuticals*

##### 1. *The Patent Act*<sup>75</sup>

Patent protection in Canada is governed by the Patent Act, which provides that “[e]very patent granted under this Act shall . . . grant to the patentee . . . the exclusive right, privilege and liberty of making, constructing and using the invention and selling it to others to be used.”<sup>76</sup>

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<sup>72</sup> Aslam H. Anis, *Pharmaceutical Policies in Canada: Another Example of Federal—Provincial Discord*, 162(4) CAN. MED. ASSOC. J. 523 (2000), <http://gateway2.ovid.com/ovidweb.cgi>.

<sup>73</sup> Joel Lexchin, *After Compulsory Licensing: Coming Issues in Canadian Pharmaceutical Policy and Politics*, 40 HEALTH POLICY 69, 70 (1997).

<sup>74</sup> *Id.* at 73.

<sup>75</sup> R.S.C., ch. P-4, §§ 1-103 (2001) (Can.).

<sup>76</sup> R.S.C., ch. P-4, § 42.

## 2.    *Compulsory Licensing*

Whereas the United States did not limit the rights of pharmaceutical patent holders until the Waxman-Hatch Act of 1984, Canada began limiting the exclusive rights of pharmaceutical patentees as early as 1923, when parliament amended the Patent Act to provide for compulsory licensing of pharmaceuticals.<sup>77</sup> Under the amendment, a party could apply to the Commissioner of Patents for a license to manufacture and market a patented drug before the term of the patent expired.<sup>78</sup> The compulsory nature of the license meant that the patent owner could not prevent the Commissioner from granting the license.<sup>79</sup> In exchange for giving up the exclusivity of the patent, the patent owner received a small royalty fee.<sup>80</sup>

The idea behind the amendment was to contain the cost of drugs through competitive market forces by providing multiple sources for the patented drug.<sup>81</sup> The goal of the amendment was not realized, however, as only twenty-two licenses were granted between 1923 and 1969.<sup>82</sup> One of the main reasons for the failure of the policy was that the amendment required generic versions of a patented drug to be manufactured in Canada, and there were very few manufacturing facilities in Canada.<sup>83</sup> In 1969, the government eliminated this requirement and permitted drug import licensing.<sup>84</sup> This new policy resulted in the development of a strong generic industry in Canada.<sup>85</sup>

However, a negative result of the policy was that pharmaceutical companies in Canada decreased their investment in the research and development of new drugs.<sup>86</sup> In 1987, in an attempt to balance the interests of generic drug companies and the brand-name pharmaceutical companies, Parliament passed Bill C-22, amending the compulsory licensing regime.<sup>87</sup> Under Bill C-22, compulsory licensing was still mandated, but only after the first seven years of patent protection had expired.<sup>88</sup> This encouraged research and development by giving the pharmaceutical companies a period

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<sup>77</sup> Lexchin, *supra* note 73, at 70.

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

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

<sup>80</sup> Carter, *supra* note 16, at 241.

<sup>81</sup> Lexchin, *supra* note 73, at 70.

<sup>82</sup> *Id.*

<sup>83</sup> *Id.*

<sup>84</sup> *Id.*

<sup>85</sup> *Id.*

<sup>86</sup> Carter, *supra* note 16, at 242.

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

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

of exclusivity in the market, thus enabling them to recover their investments in research and development.<sup>89</sup>

In order to balance the new period of exclusivity granted to the pharmaceutical companies, another provision of Bill C-22 established the Patented Medicine Prices Review Board ("PMPRB") to monitor and control patented drug prices.<sup>90</sup> In 1993, in response to the North American Free Trade Agreement between Canada, the United States, and Mexico, Parliament passed Bill C-91 eliminating compulsory licensing.<sup>91</sup>

*B. Regulation of the Safety and Efficacy of Pharmaceuticals—The Food and Drugs Act*<sup>92</sup>

In 1963, Canada enacted major changes in the Canadian Food and Drugs Act.<sup>93</sup> The changes, using language very similar to the 1962 amendments to the United States' Federal Food, Drug and Cosmetic Act, required manufacturers to submit "substantial evidence" that a new drug was both safe and effective before market entry would be allowed.<sup>94</sup> Canada's administrative body, the Therapeutics Products Directorate (counterpart to the United States FDA), employed a regulatory process for market entry of new drugs very similar to that used by the FDA.<sup>95</sup> The Canadian drug approval process had similar implications for patent protection as in the United States: pioneer drugs lost effective patent term while in the regulatory process, but had *de facto* patent term extension because the generic drug company could not begin the regulatory process until the patent term expired.

*C. 1993 Waxman-Hatch-Type Amendments to the Patent Act*

In 1993, in addition to elimination of the compulsory licensing system, changes were made to the Patent Act and to the corresponding Patented Medicines (Notice of Compliance) ("NOC") Regulations which enabled the entrance of generic drugs into the market as soon as the patent

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<sup>89</sup> *Id.* at 242-43.

<sup>90</sup> Lexchin, *supra* note 73, at 73.

<sup>91</sup> Carter, *supra* note 16, at 243.

<sup>92</sup> R.S.C., ch. F-27, §§ 1-37 (2001) (Can.).

<sup>93</sup> Carter, *supra* note 16, at 220.

<sup>94</sup> *Id.*

<sup>95</sup> *Id.* at 231.

on the pioneer drug expired.<sup>96</sup> The changes were very similar to the changes in the drug approval process enacted by the United States in the 1984 Drug Price Competition and Patent Term Restoration Act.<sup>97</sup> The NOC Regulations generally allow a generic drug manufacturer to make reference to another approved drug to demonstrate bioequivalence.<sup>98</sup> If and when it is determined that the generic drug is both safe and effective, the Minister of National Health and Welfare will issue a notice of compliance permitting the drug to enter the market.<sup>99</sup> However, the generic manufacturer must certify that the patent on the referenced drug has expired or is invalid, or that the actions of the generic manufacturer will not infringe the patent.<sup>100</sup> If the generic manufacturer certifies that a patent is invalid or will not be infringed, it must give notice to the patent holder.<sup>101</sup> The patent holder has forty-five days in which to seek an injunction preventing the issuance of a notice of compliance.<sup>102</sup> Approval of the drug can be withheld for up to twenty-four months<sup>103</sup> or until a court decision has been rendered.<sup>104</sup>

As in the United States, Canada enacted a *Roche-Bolar*-type safe harbor amendment to allow generic manufacturers to make and use the patented product during the regulatory process without infringing the patent: "It is not an infringement of a patent for any person 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. . . ."<sup>105</sup>

The Canadian Patent Act included an additional provision that is not available in the United States:

It is not an infringement of a patent for any person who makes, constructs, uses or sells a patented invention in accordance with subsection (1) to make, construct or use the invention, during the applicable period provided for by the regulations, for the

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<sup>96</sup> *Hoffmann-La Roche Ltd. v. Minister of National Health and Welfare*, [1996] 67 C.P.R. (3d) 484, 487.

<sup>97</sup> The U.S. drug approval process is codified in the Federal Food, Drug, and Cosmetic Act, 21 U.S.C.S. § 355(j) (1997).

<sup>98</sup> Patented Medicines (Notice of Compliance) Regulations, SOR 93-133, § 5(1) (2001) (Can.).

<sup>99</sup> Carter, *supra* note 16, at 233.

<sup>100</sup> SOR 93-133, § 5(1)(b)(ii-iv).

<sup>101</sup> SOR 93-133, § 5(3).

<sup>102</sup> SOR 93-133, § 6(1).

<sup>103</sup> SOR 93-133, § 7(1)(e).

<sup>104</sup> SOR 93-133, § 7(2)(b).

<sup>105</sup> Patent Act, R.S.C., ch. P-4, § 55.2(1) (2001) (Can.).

manufacture and storage of articles intended for sale after the date on which the term of the patent expires.<sup>106</sup>

This provision of the Patent Act was implemented in the Manufacturing and Storage of Patented Medicines Regulations that permitted the manufacture and stockpiling of the generic drug for the “six month period immediately preceding the date on which the term of the patent expires.”<sup>107</sup> This provision sanctioned activities that, in the United States, the court in *Biogen* held to be non-exempt under the safe harbor provision.<sup>108</sup> However, Canada’s stockpiling provision was repealed in 2000 in response to a decision by the World Trade Organization (“WTO”) that found the stockpiling of a generic drug while the patent was still in effect to be a violation of the Uruguay Round of the General Agreement on Tariffs and Trade.<sup>109</sup>

The 1993 amendments to the Patent Act provided many advantages to the generic industry by allowing the generic manufacturer to reference the clinical data previously submitted by the pioneer drug company and to benefit from a safe harbor provision against charges of infringement. However, unlike in the United States, the Patent Act contains no provision for the restoration of patent term lost by the pharmaceutical company while the drug is in the regulatory process and not on the market.<sup>110</sup>

### 1. *Litigation of the Notice of Compliance Regulations*

While there has been litigation in the United States regarding what activities are entitled to the benefit of the safe harbor provision, there has been little if any litigation in Canada over this issue. This is in spite of the fact that both statutes use almost identical language: it is not infringement to make, use or sell a patented invention “solely for uses reasonably related to the development and submission of information” to a regulatory body. The litigation in Canada instead has centered on the issuance of the notice of compliance, and has been further complicated by compulsory licenses that are still in effect.

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<sup>106</sup> R.S.C., ch. P-4, § 55.2(2).

<sup>107</sup> Manufacturing and Storage of Patented Medicines Regulations, SOR 93-134, § 1 (2001) (Can.).

<sup>108</sup> *Biogen, Inc. v. Schering AG*, 954 F. Supp. 391 (D. Mass. 1996). See *supra* notes 69-70 and accompanying text.

<sup>109</sup> Patented Medicines (Notice of Compliance) Regulations, SOR 2000-373, § 1 (2001) (Can.). For a discussion of the World Trade Organization decision, see *infra* notes 195-205 and accompanying text.

<sup>110</sup> Lexchin, *supra* note 73, at 76.

Under the regulations,<sup>111</sup> when a party applies for a notice of compliance, they must allege that the patent has expired, the patent is not valid, or that “no claim for the medicine itself and no claim for the use of the medicine would be infringed by the making, constructing, using or selling by that person of the drug for which the submission for the notice of compliance is filed.”<sup>112</sup> When a party makes an allegation of non-infringement, the party shall “provide a detailed statement of the legal and factual basis for the allegation.”<sup>113</sup> The patent owner then “may, within 45 days after being served with a notice of an allegation . . . apply to a court for an order prohibiting the Minister from issuing a notice of compliance until after the expiration of a patent that is the subject of allegation.”<sup>114</sup> Subject to some conditions, “the Minister shall not issue a notice of compliance . . . [before] the court has declared that the patent is not valid or that no claim for the medicine itself and no claim for the use of the medicine would be infringed.”<sup>115</sup>

Some of the issues spawning litigation included whether the application for an injunctive order begins an action for infringement,<sup>116</sup> which party has the burden of proof in establishing whether or not the patent would be infringed,<sup>117</sup> and how detailed the statement of the legal and factual basis for the allegation must be.<sup>118</sup>

In 1994, the Federal Court of Appeals, in *David Bull Laboratories (Canada) Inc. v. Pharmacia Inc.*, ruled that an application to a court for an order prohibiting the Minister from issuing a notice of compliance does not constitute an action for infringement.<sup>119</sup> The court expressed confusion as to why the draftsman in SOR 93-133, § 7 used language indicating that a court would decide if the patent is valid or infringed.<sup>120</sup> The court emphasized that the regulations do not “create or abolish any rights of action

<sup>111</sup> The regulatory language is important to the outcome of the cases, and is thus cited extensively.

<sup>112</sup> Patented Medicines (Notice of Compliance) Regulations, SOR 93-133, § 5(1) (2001) (Can.).

<sup>113</sup> SOR 93-133, § 5(3)(a).

<sup>114</sup> SOR 93-133, § 6(1).

<sup>115</sup> SOR 93-133, §§ 7(1), 7(2)(b).

<sup>116</sup> *David Bull Laboratories (Canada) Inc. v. Pharmacia Inc.*, [1995] 1 F.C. 588, 599.

<sup>117</sup> *Syntex (U.S.A.) Inc. v. Novopharm Ltd.*, [1996] 65 C.P.R. (3d) 499, 505.

<sup>118</sup> *Id.* at 504.

<sup>119</sup> *David Bull Laboratories*, 1 F.C. at 599 (“[T]hese proceedings are not actions for determining validity or infringement: rather they are proceedings to determine whether the Minister may issue a notice of compliance. That decision must turn on whether there are allegations by the generic company sufficiently substantiated to support a conclusion for administrative purposes (the issue of a notice of compliance) that the applicant’s patent would not be infringed if the generic’s product is put on the market.”).

<sup>120</sup> *Id.* at 599 (citing *Merck Frosst Canada, Inc. v. Canada (Minister of National Health and Welfare)*, [1994] 55 C.P.R. (3d) 302, 319-20).



between the parties,”<sup>121</sup> and that the “summary procedure of a judicial review application” is not the appropriate forum for litigating validity and infringement issues.<sup>122</sup>

In 1996, the court in *Syntex (U.S.A.), Inc. v. Novopharm Ltd.*, ruled that when a patent owner applies for a court order prohibiting the issuance of a notice of compliance, the regulatory scheme places the burden on the patent owner to disprove the generic manufacturer’s non-infringement allegation.<sup>123</sup> However, the findings in *Syntex* regarding the burden of proof are no longer valid. In 1998, the federal government changed the regulations, shifting the burden of proof from the patent owner to the generic manufacturer.<sup>124</sup> It is no longer presumed that the allegation of non-infringement is true; instead, it is now presumed that the patent will be infringed.<sup>125</sup> The *Syntex* court also found that the generic manufacturer must do more than simply state that their product will not infringe the patent on the brand-name drug: “[T]here is an evidential burden paced on the [generic manufacturer] requiring it to advance facts which, if assumed or proven, can justify the allegation [of non-infringement].”<sup>126</sup>

In another case, *Faulding (Canada) Inc. v. Pharmacia S.P.A.*,<sup>127</sup> the court, as in the United States *Intermedics* case,<sup>128</sup> applied an objective standard when deciding whether or not the generic manufacturer, Faulding, had infringed the Pharmacia patent. Pharmacia counterclaimed charging that Faulding intended in the future to infringe the Pharmacia patent by making and/or importing the drug into Canada and selling the drug in Canada.<sup>129</sup> The court ruled that while the new drug submission was under review by the Minister, Faulding was entitled to the safe harbor protection of section 55.2(1) of the Patent Act.<sup>130</sup> The court also noted that “claims for infringement that are premised on indefinite acts in the future are in the realm of speculation. As such they are premature and will be struck out.”<sup>131</sup> However, the court noted that if and when Faulding attained a notice of compliance, if it then commenced to market the drug while the Pharmacia

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<sup>121</sup> *Id.* at 599.

<sup>122</sup> *Id.* at 600.

<sup>123</sup> *Syntex, (USA) Inc. v. Novopharm Ltd.*, [1996] 65 C.P.R. (3d) 499, 506.

<sup>124</sup> Wayne Kondro, *Canadian Hopes for Low-Cost Drugs Dashed*, THE LANCET 350 (Jan. 31, 1998).

<sup>125</sup> Patented Medicines (Notice of Compliance) Regulations, SOR 93-133, § 6(6) (2001) (Can.).

<sup>126</sup> *Syntex*, 65 C.P.R. (3d) at 505.

<sup>127</sup> [1998] 82 C.P.R. (3d) 435.

<sup>128</sup> *Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269 (N.D. Cal. 1991). See *supra* notes 47, 53 and accompanying text.

<sup>129</sup> *Faulding*, 82 C.P.R. (3d) at 439.

<sup>130</sup> *Id.*

<sup>131</sup> *Id.* (citation omitted).

patent was still in effect, Pharmacia would be free to bring an infringement action.<sup>132</sup>

The Canadian courts have expressed frustration with the amount of litigation that the regulations have spawned.<sup>133</sup> The courts find it difficult to protect private intellectual property rights provided by the Patent Act in light of the regulatory scheme enacted to provide for the public safety.<sup>134</sup> Furthermore, the courts have been frustrated because the regulations have not established a clear procedure to be followed when a patent holder challenges the notice of allegation.<sup>135</sup>

This type of litigation has been avoided in the United States. Perhaps this is because the United States statute clearly provides for an infringement action: "If the applicant made a certification [that the patent is invalid or has been infringed], the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification. . . ."<sup>136</sup>

This difference between the United States and Canadian law is significant because of the length of time required to adjudicate an infringement action as opposed to a summary proceeding. The sooner a court action for a stay of a notice of compliance is completed, the sooner the generic drug can enter the market (assuming the generic manufacturer is successful in preventing the issuance of a stay). An infringement action decided on the merits, however, will presumably take much longer to adjudicate. Thus, the probability is high that in the United States a pioneer drug company could delay approval of the generic drug, keeping it off the market, for up to the full thirty months allowed by law.

## 2. *Canadian Law, Though Still Favoring the Generic Manufacturer, Has Become More Balanced*

Early Canadian patent law governing pharmaceuticals, with its compulsory licensing system, clearly favored generic manufacturers. Abolishment of the compulsory licensing system provided a huge benefit to the brand-name pharmaceutical industry. However, as a trade-off, the

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<sup>132</sup> *Id.*

<sup>133</sup> *Hoffman-La Roche Ltd. v. Minister of National Health and Welfare*, [1996] 67 C.P.R. (3d) 484, 492 ("Appropriate refinements [of the Regulations] were needed from the beginning. The quantity of litigation, which has ensued from the lacuna in the Regulations, and its attendant cost for the respective pharmaceutical companies, and for the Court, is most disconcerting.")

<sup>134</sup> *Id.* at 491.

<sup>135</sup> *Id.*

<sup>136</sup> Federal Food, Drug and Cosmetic Act, 21 U.S.C.S. § 355(j)(5)(B)(iii) (1997).

government established the Patented Medicines Prices Review Board to control the price of patented drugs. Furthermore, Canada, unlike the United States, has no provisions for restoring patent term lost by the pioneer drug company while its product is in the regulatory process.

Although compulsory licensing has been abolished, there are still provisions in the law to support the generic drug industry. For instance, there is no counterpart agency to the PMPRB to monitor and control the price of generic drugs. In addition, the generic manufacturer can use the data of the pioneer drug manufacturer to hasten entry into the market and is also protected from infringement actions during the regulatory process by the safe harbor provision.

Although the law remains tilted in favor of the generic manufacturer, the Canadian government has made great strides in creating a more balanced system of patent protection for pharmaceutical inventions.

#### IV. INTERNATIONAL AGREEMENTS

##### A. *The North American Free Trade Agreement ("NAFTA")*

In 1992, the United States, Canada, and Mexico entered into the North American Free Trade Agreement ("NAFTA").<sup>137</sup> NAFTA requires a minimum patent term of "at least 20 years from the date of filing or 17 years from the date of grant."<sup>138</sup> NAFTA also allows, but does not require, the restoration of patent term lost during a regulatory process.<sup>139</sup> NAFTA requires patent protection for pharmaceuticals,<sup>140</sup> requires the same term of protection for all patented inventions,<sup>141</sup> and severely restricts compulsory licensing.<sup>142</sup>

##### 1. *Effect of NAFTA in the United States*

NAFTA has had little impact on patent protection for pharmaceuticals in the United States. The United States, at the time of the signing of NAFTA, had a seventeen-year from date of issue patent term and also had

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<sup>137</sup> North American Free Trade Agreement, Dec. 17, 1992, 32 I.L.M. 289 (1993) [hereinafter NAFTA].

<sup>138</sup> *Id.* art. 1709, § 12, at 674.

<sup>139</sup> *Id.*

<sup>140</sup> *Id.* art. 1709, § 7, at 673.

<sup>141</sup> *Id.*

<sup>142</sup> *Id.* art. 1709, § 10, at 674.

provisions for restoration of patent term lost due to regulatory procedures.<sup>143</sup> Furthermore, the United States did not have a compulsory licensing regime.

## 2. *Effect of NAFTA in Canada*

NAFTA had a much greater impact on the pharmaceutical industry in Canada. In anticipation of the signing of NAFTA, Parliament passed Bill C-91 in 1993.<sup>144</sup> Bill C-91 abolished the compulsory licensing system and extended the patent term for pharmaceuticals from seventeen years from date of issue to twenty years from date of filing.<sup>145</sup> However, to balance the added protection given to pharmaceuticals, the bill strengthened the Patented Medicines Prices Review Board.<sup>146</sup>

As could be expected, the end of compulsory licensing engendered much litigation. While no new licenses were issued, licenses in effect at the time of the legislation were allowed to continue. The Canadian Supreme Court addressed some of the issues surrounding residual compulsory licenses in two companion cases handed down on the same day, July 9, 1998: *Eli Lilly & Co. v. Novopharm Ltd.*<sup>147</sup> and *Merck Frosst Canada, Inc. v. Canada (Minister of National Health and Welfare)*.<sup>148</sup>

The cases involved an agreement made between Apotex and Novopharm, two major generic drug companies in Canada. Apotex and Novopharm each held compulsory licenses issued to them before the passage of Bill C-91.<sup>149</sup> In anticipation of the passage of the bill, they entered into an agreement to "share their rights under licences for any product for which only one of the parties may hold a useable licence."<sup>150</sup> The agreement further provided that "the licensed party shall supply material to the unlicensed party from the licensed party's source at a price equal to the fair market price of the material together with such royalties as shall be payable under the terms of the licence."<sup>151</sup> This agreement was the subject at issue in these both cases.

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<sup>143</sup> Patent Act, 35 U.S.C.S. § 156 (2000).

<sup>144</sup> Carter, *supra* note 16, at 243.

<sup>145</sup> *Id.*

<sup>146</sup> *Id.* at 245.

<sup>147</sup> [1998] 2 S.C.R. 129. This opinion was issued on a combined appeal of two cases: *Eli Lilly and Co. v. Novopharm*, [1996] 67 C.P.R. (3d) 377, and *Eli Lilly and Co. v. Apotex*, [1996] 66 C.P.R. (3d) 329.

<sup>148</sup> [1998] 2 S.C.R. 193.

<sup>149</sup> *Eli Lilly*, 2 S.C.R. at 141.

<sup>150</sup> *Id.* at 141.

<sup>151</sup> *Id.* at 142.

In *Eli Lilly*, Novopharm held a compulsory license from Eli Lilly that was non-transferable and prohibited the granting of sublicenses.<sup>152</sup> The license also gave Eli Lilly the option to terminate the license if its terms were breached.<sup>153</sup> In 1993 Apotex applied for a notice of compliance and filed a notice of allegation that it would not infringe the Eli Lilly patent because of its agreement with licensee Novopharm.<sup>154</sup> Novopharm also began efforts to obtain a notice of compliance, alleging that it would not infringe Eli Lilly's patent because of its license.<sup>155</sup> Eli Lilly argued that the license was no longer valid because Novopharm breached its terms upon entry into the agreement with Apotex,<sup>156</sup> and, therefore, both Apotex and Novopharm would infringe the patent. Disposition of both cases turned on whether the agreement between Apotex and Novopharm was a sublicense or a supply agreement.

In the infringement cases brought by Eli Lilly against Novopharm and Apotex, the federal appellate courts had found the agreement to be a sublicense.<sup>157</sup> In *Eli Lilly*, the Supreme Court addressed the issue of sublicense versus purchase and sale agreement at some length.<sup>158</sup> The Court found that despite terms of the agreement between Apotex and Novopharm that they would "share rights," in actuality no rights were transferred.<sup>159</sup> "The agreement does not grant Apotex the right to do independently of Novopharm anything which only Novopharm is licensed to do."<sup>160</sup> The Court found the agreement not to be a sublicense, but a supply agreement.<sup>161</sup> Although the Court emphasized that its decision was confined to the facts of the case,<sup>162</sup> its very detailed discussion of the issue serves as guidance as to how the issue should be analyzed in future controversies.

In *Merck Frosst*, the issue again was whether Novopharm had breached the terms of a licensing agreement it had with Kyorin Pharmaceutical Co. when it entered into the supply agreement with Apotex.<sup>163</sup> In that case, the Court reaffirmed its ruling in *Eli Lilly* that the

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<sup>152</sup> *Id.* at 139-41.

<sup>153</sup> *Id.* at 140.

<sup>154</sup> *Id.* at 145.

<sup>155</sup> *Id.* at 146.

<sup>156</sup> *Id.*

<sup>157</sup> *Id.* at 148, 149.

<sup>158</sup> *Id.* at 161-80.

<sup>159</sup> *Id.* at 178.

<sup>160</sup> *Id.*

<sup>161</sup> *Id.*

<sup>162</sup> *Id.* at 179.

<sup>163</sup> *Merck Frosst*, 2 S.C.R. at 193, 197. Novopharm had a licensing agreement to sell the patented drug outside of Canada, whereas Merck Frosst was the exclusive licensee for sale of the patented drug in Canada until July 2, 1993. *Id.* at 199. After that date, Novopharm's licensing agreement permitted it to

Novopharm-Apotex agreement was not a sublicense and therefore Novopharm had not breached the agreement.<sup>164</sup> However, in *Merck Frosst* the Court also addressed the issue of when a court should assess whether or not an allegation of non-infringement is a valid statement.<sup>165</sup> Because of the complexities of the notice of compliance regulations and the former regulations governing compulsory licensing, the possibility exists that when a notice of allegation is made, it may not be technically true that the party will not be infringing a patent if the notice of compliance were to be granted on that date or on the forty-sixth day after the filing of the notice of compliance (the patent owner having forty-five days to apply to a court for a stay).<sup>166</sup>

The *Merck Frosst* court was also concerned with the provisions in the regulations prohibiting the Minister from awarding a notice of compliance for a period of thirty months<sup>167</sup> from the day it is notified that the patent owner has filed an application for a stay with the court, or until the court decides the merits of the application.<sup>168</sup> The Court stated that "it would be manifestly unjust to subject generic drug producers to such a draconian regime without at least permitting them to protect themselves and reduce the length of the presumptive injunction by initiating the NOC process as early as possible."<sup>169</sup> Consequently, the Court found that the proper time to decide the validity of the notice of allegation was the hearing date on the application for a stay.<sup>170</sup>

*B. The Uruguay Round of the General Agreement on Tariffs and Trade ("GATT")/Trade Related Aspects of Intellectual Property Rights ("TRIPS")*

Both the United States and Canada are signatories to the GATT/TRIPS agreement of 1993.<sup>171</sup> GATT/TRIPS provides that "patents shall be available for any inventions, whether products or processes, in all

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produce and sell the drug in Canada. *Id.* Apotex filed for a notice of compliance based on its supply agreement with Novopharm. *Id.* at 198-99.

<sup>164</sup> *Id.* at 208.

<sup>165</sup> *Id.* at 209.

<sup>166</sup> *Id.* at 212-13.

<sup>167</sup> *Id.* at 214-15. This period has been reduced to twenty-four months. See Patented Medicines (Notice of Compliance) Regulations, SOR 93-133, § 7(e) (2001) (Can.).

<sup>168</sup> *Merck Frosst*, 2 S.C.R. at 214.

<sup>169</sup> *Id.*

<sup>170</sup> *Id.* at 215.

<sup>171</sup> General Agreement on Tariffs and Trade, Dec. 15, 1993, 33 I.L.M. 1 (1994) [hereinafter GATT].

fields of technology.”<sup>172</sup> Exceptions were provided for some inventions, but the language appears to require patent protection for pharmaceuticals.<sup>173</sup> GATT/TRIPS allows for “limited exceptions to the exclusive rights conferred by a patent,”<sup>174</sup> and for limited compulsory licensing.<sup>175</sup> Furthermore, the agreement establishes the patent term as twenty years from the date of filing.<sup>176</sup>

### 1. *Effect of GATT/TRIPS in the United States*

In 1994, Congress passed the Uruguay Round Agreements Act<sup>177</sup> (“URAA”) to implement GATT. As a result, 35 U.S.C. § 154 was amended to provide for patent term protection of twenty years from the date of filing.<sup>178</sup> However, the change in patent term was complicated by the existence of the previous term of seventeen years from the date of issue, and by extensions granted to restore patent term lost during the FDA regulatory process.

Under the URAA, patents in effect or applied for during the six-month period after the enactment of the URAA would have a patent term that is the greater of twenty years from filing or seventeen years from issue,<sup>179</sup> extending the patent term for some inventions. This provision may create a situation where a competing product of a patented invention was on the market and not infringing because the patent had expired during the Delta period,<sup>180</sup> but, by virtue of the URAA patent term extension, the competing product becomes an infringer. The URAA addressed this situation by providing that the normal remedies for infringement—injunction, damages, and attorneys fees—would not be available to the patent owner for acts that became infringing during the Delta period.<sup>181</sup> Instead, the URAA provided for equitable remuneration for the injured patentee.<sup>182</sup>

It fell to the courts to determine how these provisions applied to the pharmaceutical industry in the context of FDA regulations and the ANDA

<sup>172</sup> *Id.* art. 27, at 93.

<sup>173</sup> *Id.*

<sup>174</sup> *Id.* art. 30, at 95.

<sup>175</sup> *Id.* art. 27, at 93.

<sup>176</sup> *Id.* art. 33, at 96.

<sup>177</sup> Pub. L. No. 103-465, 108 Stat. 4809 (1994).

<sup>178</sup> Patent Act, 35 U.S.C.S. § 154(a)(2) (2000).

<sup>179</sup> 35 U.S.C.S. § 154(c)(1).

<sup>180</sup> The period of time between the original expiration date and the new expiration date is known as the “Delta period.” *DuPont Merck Pharmaceutical Company v. Bristol-Myers Squibb Co.*, 62 F.3d 1397, 1399, 35 U.S.P.Q.2d (BNA) 1718 (1995).

<sup>181</sup> 35 U.S.C.S. § 154(c)(2).

<sup>182</sup> 35 U.S.C.S. § 154(c)(3).

process for generic drugs. For example, an ANDA application which certified the date the reference patent would expire could be invalidated because of the patent term extension granted under URAA.

In regulations implementing URAA, the FDA "required ANDA applicants who wished to market generic versions of drugs covered by a patent with a URAA-extended term to file paragraph IV certifications"<sup>183</sup> certifying that the reference patent is "invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted."<sup>184</sup> Filing of a paragraph IV certification would trigger the application of 35 U.S.C. § 271(e)(2), which states that "it shall be an act of infringement [to file an ANDA] if the purpose of such submission is to obtain approval . . . to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent before the expiration of such patent."

In *DuPont Merck Pharmaceutical Co. v. Bristol-Myers Squibb Co.*, DuPont Merck had filed an ANDA in 1993 certifying that the Bristol-Myers Squibb patent would expire on August 8, 1995.<sup>185</sup> However, under the URAA, the patent term had been extended six months until February 13, 1996.<sup>186</sup> DuPont Merck was in an untenable situation because 21 U.S.C. § 355(j)(5)(B)(iii) allowed Bristol-Myers forty-five days from the date of the filing of the paragraph IV certification to file an infringement action. Filing of an infringement action delays approval of the ANDA for up to thirty months,<sup>187</sup> or until the extended patent term expires, effectively preventing DuPont from marketing its product during the Delta period.<sup>188</sup>

DuPont sought injunctive relief from the court to compel Bristol-Myers to waive the forty-five day period and to prevent Bristol-Myers from filing an infringement action.<sup>189</sup> DuPont also claimed the benefit of 35 U.S.C. § 154(c)(2) and (3), maintaining that it had made "substantial investments" and that as long as it paid Bristol-Myers remunerations, it would not infringe the patent by making and selling the patented product during the Delta period.<sup>190</sup> The court denied the relief requested, stating:

<sup>183</sup> *DuPont Merck*, 62 F.3d at 1400. Paragraph IV certifications refer to 21 U.S.C.S. § 355(j)(2)(A)(vii)(IV).

<sup>184</sup> Federal Food, Drug and Cosmetic Act, 21 U.S.C.S. § 355(j)(2)(A)(vii)(IV) (2001).

<sup>185</sup> *DuPont Merck*, 62 F.3d at 1400.

<sup>186</sup> *Id.* at 1399.

<sup>187</sup> 21 U.S.C.S. § 355(j)(5)(B)(iii).

<sup>188</sup> *DuPont Merck*, 62 F.3d at 1401.

<sup>189</sup> *Id.* at 1400.

<sup>190</sup> *Id.*



[T]he URAA, by its terms, exempts a qualified infringer from the remedies of sections 283, 284, and 285 of Title 35. The URAA, however, works no change on the definition of infringement under section 271(e)(2) and has no affect on the statutory provisions relating to FDA approval of ANDAs that are triggered by that act of infringement.<sup>191</sup>

In another suit involving the same Bristol-Myers Squibb patent, the defendant Royce Lab filed the required paragraph IV certification, but did not claim that the patent was invalid or that it would not be infringed; instead, Royce Lab claimed that it would fall within the safe harbor provision of the URAA, 35 U.S.C. § 154(c).<sup>192</sup> The *Royce* court also held that the URAA does not make “infringing activity non-infringing during the Delta period. It merely provides that infringing conduct will not give rise to the entire panoply of traditional statutory remedies for patent infringement.”<sup>193</sup>

## 2. *Effect of GATT/TRIPS in Canada*

The effect of the GATT agreement on patent protection for pharmaceuticals in Canada was initially limited because Bill C-91 had already eliminated compulsory licensing and extended patent term protection to twenty years from filing.<sup>194</sup> However, Canada has been subject to actions before the WTO, brought by the European Union and the United States, alleging that certain provisions of Canada’s patent law violate the GATT/TRIPS agreement.

The European Union brought an action against Canada alleging that Sections 55.2(1) and 55.2(2) of the Patent Act violated Articles 27.1,<sup>195</sup> 28.1,<sup>196</sup> and 33<sup>197</sup> of GATT/TRIPS.<sup>198</sup> Section 55.2 is the *Roche-Bolar* safe

<sup>191</sup> *Id.* at 1402.

<sup>192</sup> *Bristol-Myers Squibb Co. v. Royce Lab*, 69 F.3d 1130, 1133, 36 U.S.P.Q.2d (BNA) 1641 (1995).

<sup>193</sup> *Id.* at 1136.

<sup>194</sup> See *supra* text accompanying note 145.

<sup>195</sup> GATT, *supra* note 171, art. 27.1, 33 I.L.M. at 93 (“[P]atent rights [shall be] enjoyable without discrimination as to the . . . field of technology”).

<sup>196</sup> *Id.* art. 28.1, at 93 (providing that a patent owner shall have the exclusive right “to prevent third parties not having his consent from the acts of: making, using, offering for sale, selling, or importing” the patented invention).

<sup>197</sup> *Id.* art. 33, at 96 (providing for a patent term of twenty years from date of filing).

<sup>198</sup> World Trade Organization (“WTO”), Canada—Patent Protection of Pharmaceutical Products—Complaint by the European Communities and Their Member States—Report of the Panel, Document No. 00-1012, WT/DS114/R, § 7.11 (2000), [http://docsonline.wto.org/gen\\_search.asp](http://docsonline.wto.org/gen_search.asp) [hereinafter WTO, Canada—Patent Protection of Pharmaceutical Products].

harbor provision that allows generic manufacturers to “make, use, or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada,”<sup>199</sup> and also allows for the manufacture and storage of generic drugs in preparation for market entry before the patent has expired.<sup>200</sup>

The European Union argued that Canada discriminated against the pharmaceutical patent holder by allowing acts of infringement that are not permitted against other types of inventions.<sup>201</sup> Canada claimed a defense under Article 30 of GATT/TRIPS:

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.<sup>202</sup>

The WTO panel agreed with Canada that the safe harbor provision of the Patent Act § 55.2(1) falls within the “limited exceptions” of Article 30.<sup>203</sup> However, the panel found that the manufacture and storage provision of § 55.2(2) violated GATT.<sup>204</sup> Canada subsequently repealed this provision in 2000.<sup>205</sup>

The U.S. action against Canada alleged that Section 45 of Canada’s Patent Act violated Articles 33<sup>206</sup> and 70<sup>207</sup> of GATT/TRIPS.<sup>208</sup> Canada’s Patent Act provides for two different patent terms: for patents issued on applications filed on or after October 1, 1989, the term is twenty years from the date of filing,<sup>209</sup> for patents issued on applications filed before 1989, the

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<sup>199</sup> Patent Act, R.S.C., ch. P-4, § 55.2(1) (2001) (Can.).

<sup>200</sup> R.S.C., ch. P-4, § 55.2(2).

<sup>201</sup> WTO, Canada—Patent Protection of Pharmaceutical Products, *supra* note 198, at § 4.5.

<sup>202</sup> *Id.* § 7.12.

<sup>203</sup> *Id.* § 7.50.

<sup>204</sup> *Id.* § 7.38.

<sup>205</sup> Patented Medicines (Notice of Compliance) Regulations, SOR 2000-373, § 1 (2001) (Can.).

<sup>206</sup> GATT, *supra* note 171, art. 33, 33 I.L.M. at 96 (providing for a patent term of twenty years from filing).

<sup>207</sup> *Id.* art. 70, at 109 (providing that the terms of GATT/TRIPS shall apply to “all subject matter existing at the date of application of the Agreement . . . and which is protected . . . on the said date”).

<sup>208</sup> WTO, Canada—Term of Patent Protection—Report of the Panel, Document No. 00-1695, WT/DS170/R, § 2.1 (2000), [http://docsonline.wto.org/gen\\_search.asp](http://docsonline.wto.org/gen_search.asp) (last visited Oct. 28, 2001) [hereinafter WTO, Canada—Term of Patent Protection].

<sup>209</sup> Patent Act, R.S.C., ch. P-4, § 44 (2001) (Can.).

term is seventeen years from the issue date.<sup>210</sup> The United States argued that Canada should be required to bring the term for patents applied for before 1989 into compliance with the GATT/TRIPS twenty-years-from-filing term.<sup>211</sup> The WTO panel agreed and found Canada in violation of the GATT/TRIPS agreement.<sup>212</sup> Canada is not yet in compliance on this issue.

*C. International Agreements Have Brought Uniformity to the Patent Laws of Canada and the United States*

As a result of NAFTA and GATT/TRIPS, patent protection for pharmaceutical inventions has approached uniformity in the United States and Canada. Canada abolished its compulsory licensing system; both countries have a patent term of twenty years from the date of filing; and patent protection for pharmaceutical inventions is virtually guaranteed by the treaties. Despite some remaining differences, such as price controls in Canada and Canada's decision not to restore patent term lost during the regulatory process, international treaties have given the pharmaceutical industry strong patent protection in both countries. In spite of political pressures in both countries to reduce the price of drugs, strong patent protection is likely to remain given that NAFTA and GATT/TRIPS are multi-national agreements which would take many years to renegotiate. Major changes in the patent laws of either country would be difficult to achieve without violating the agreements.

V. CONCLUSION

Although the United States and Canada share a common political heritage, both with roots in the English system, the two countries have fundamental differences regarding the government's role in the health care industry. The success of each government in meeting its obligations to balance competing public interests, to protect intellectual property rights, to encourage research and development, to maximize access to new drugs, and to ensure the safety and efficacy of drugs should be judged in light of the political and economic realities in each country.

As the Canadian government modified and eventually abolished the compulsory licensing system, it had two goals: to develop a strong generic drug industry and to increase expenditures on research and development.

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<sup>210</sup> R.S.C., ch. P-4, § 45.

<sup>211</sup> WTO, Canada—Term of Patent Protection, *supra* note 208, § 3.1.

<sup>212</sup> *Id.* § 7.1.

There is evidence that it has been successful in accomplishing both goals—of the top drug manufacturers in Canada, two generic firms ranked sixth and sixteenth in sale in 1999.<sup>213</sup> Furthermore, expenditures on research and development by pharmaceutical companies increased from 6.5% of revenues in 1988 to 11.3% in 1999.<sup>214</sup> Although patent protection for pharmaceuticals is not as strong in Canada as it is in the United States, the pharmaceutical industry is thriving in Canada, as evidenced by the fact that patented medicines accounted for 61% of all drugs sold in 1999.<sup>215</sup>

In the United States, one of the goals of the Waxman-Hatch Act was to contain the cost of drugs by promoting a strong generic drug industry. It appears the Act has been successful as evidenced by the fact that sales of generic drugs in the United States as a percentage of prescription volume has increased from 18.6% in 1984, the year the Act was passed, to 47.1% in 1999.<sup>216</sup>

Although problems remain, both governments have been successful in creating a balanced system that promotes both a strong pharmaceutical industry and a strong generic drug industry. Creative solutions must be found to make new drug discoveries affordable and accessible. However, both governments should maintain a strong commitment to protecting the intellectual property rights of the companies that make the new discoveries in order to ensure the continued production of new medicines.

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<sup>213</sup> *Sales of Drugs in Canada, in 1999* PATENTED MEDICINES PRICES REVIEW BOARD, ANNUAL REPORT 16 n.2 (1999), [http://www.pmprb-cepmb.gc.ca/english/06-e/06ann99\\_e.htm](http://www.pmprb-cepmb.gc.ca/english/06-e/06ann99_e.htm).

<sup>214</sup> *Analysis of Research and Development (R&D) Expenditures, in 1999* PATENTED MEDICINES PRICES REVIEW BOARD, *supra* note 213, at 37 tbl.6.

<sup>215</sup> *Sales of Drugs in Canada, supra* note 213, at 17.

<sup>216</sup> *Managed-Care, Generic Competition are Changing the Pharmaceutical Marketplace, in* PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, *supra* note 3.

