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# Protection of Pharmaceuticals as Foreign Policy: The Canada-U.S. Trade Agreement and Bill C-22 Versus the North American Free Trade Agreement and Bill C-91

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**Cover Page Footnote**

International Law; Commercial Law; Law

# Protection of Pharmaceuticals as Foreign Policy: The Canada-U.S. Trade Agreement and Bill C-22 Versus the North American Free Trade Agreement and Bill C-91

## I. Introduction<sup>1</sup>

From 1969 until 1987, Canada's compulsory licensing law for patented pharmaceuticals produced some of the lowest consumer drug prices in the industrialized world.<sup>2</sup> "Under this system, a manufacturer of generic drugs could produce in Canada a drug

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<sup>1</sup> Within the modern pharmaceutical industry there is a distinction made between those firms that predominately engage in research and development and those that produce copies of off-patent drugs. See Robert S. Tancer & Shoshana B. Tancer, *MERCOSUR and the Pharmaceutical Industry—Waiting for a Common Patent Regime*, 4 *LATIN AM. L. & BUS. REP.* 5 (1997).

The patent-protected firms represent the innovators; the firms that develop new drugs and receive patent protection, allowing a period of exclusive use for 20 years commencing with the date of filing. The generic firms are those who market copies of the drugs once the patent has expired. Understandably, the patent-driven firms advocate strong intellectual property protection, and argue that their ability to conduct creative research and development (R&D) is dependent upon their ability to recoup these costs through patent protection. The generic firms argue that they are a major factor in lowering the cost of medicine. As these latter firms do not have R&D expenses commensurate with the innovators, they are able to sell their products at a lower cost than the patent-protected equivalents. *Id.*

<sup>2</sup> *E.g.*, John F. Burns, *Canada Split on Drug Patents*, *N.Y. TIMES*, Aug. 24, 1987, at D1 (noting that Canada's use of compulsory licensing allowed "so-called generic drug manufacturers . . . to copy brand-name products in Canada and sell them for as much as 50 percent less than the originals"); Peter N. Williamson, *C-91 Ignited Passions, but Loosened Purse Strings*, *CAN. CHEMICAL NEWS*, Jan. 1, 1994, at 26 ("[Bill] C-102 [was] introduced in 1969. C-102 gave four years of patent protection and introduced compulsory licensing."); see also Michael Halewood, *Regulating Patent Holders: Local Working Requirements and Compulsory Licenses at International Law*, 35 *OSGOODE HALL L.J.* 243, 246 (1997).

"Compulsory licensing" refers to the practice of governments allowing parties other than the original patentees to exploit patented products and processes. *Id.* In such cases, the patentee is forced to grant a licence [sic] to a third-party licensee to exploit the patented product or process, in return for which the patentee generally receives a royalty payment at a rate set by legislative fiat. *Id.*

newly patented in the United States or another country simply by notifying the patentee and paying a fixed four percent royalty fee.”<sup>3</sup> University of Toronto economist Harry Eastman found that compulsory licensing saved Canadian consumers \$211 million each year.<sup>4</sup> Then, on December 7, 1987, the Progressive Conservative Prime Minister Brian Mulroney, despite large-scale domestic opposition,<sup>5</sup> succeeded in passing Bill C-22, which stripped the Canadian Patent Act of much of its compulsory licensing language.<sup>6</sup> The new patent regime granted a ten-year period of patent exclusivity to pharmaceutical products patented outside of Canada, and a seventeen-year period of exclusivity to those fully developed within Canada.<sup>7</sup>

At about the same time, U.S. politicians were openly questioning the feasibility of various measures intended to control rising domestic drug prices.<sup>8</sup> In the United States, “[p]ricing of pharmaceuticals is perhaps the most controversial aspect of the industry. Consumers, and their elected legislative representatives, are highly attuned to drug prices.”<sup>9</sup> Democrat Henry Waxman of

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<sup>3</sup> Christina Del Valle, *Intellectual Property Provisions of the NAFTA*, 4 NO. 11 J. PROPRIETARY RTS. 8 (1992).

<sup>4</sup> David Crane, *New Debate over Generic Drugs Looms*, TORONTO STAR, June 9, 1987, at A18.

<sup>5</sup> *Id.* “Ninety percent of the people we’ve heard are against this legislation” (quoting Senator Lorne Bonnell, chairman of a Senate committee conducting hearings on the proposed legislation, Bill C-22). *Id.*

<sup>6</sup> See ROBERT M. CAMPBELL & LESLIE A. PAL, *THE REAL WORLDS OF CANADIAN POLITICS* 46 (1994).

<sup>7</sup> See Del Valle, *supra* note 3, at 9.

<sup>8</sup> See, e.g., Robert Pear, *Panel Endorses Price Controls on Drugs*, N.Y. TIMES, Mar. 17, 1994, at B8 (describing a proposal approved by the House Ways and Means Subcommittee on Health establishing that “the Government would review drug prices and could deny Medicare coverage for drugs whose prices were deemed excessive”); Judy Foreman, *Report Raps High Price Increases for Prescription Drugs*, BOSTON GLOBE, Feb. 1, 1994, at 10 (describing Senator Pryor’s vow to introduce a bill imposing tough restrictions, such as cutting back federal patent protections for companies with excessive price increases); Robert Pear, *Clinton Aides Seek New Review Board for Drug Pricing*, N.Y. TIMES, May 17, 1993, at A1 (describing the President’s Task Force on National Health Care Reform suggestion that the Government “establish a drug price review board to set guidelines for drug prices”); Don Colburn, *Drug Prices: What’s Up?*, WASH. POST, Dec. 15, 1992, at Z8 (detailing Senator David Pryor’s efforts to revoke certain tax breaks if drug companies raise prices faster than the rate of inflation).

<sup>9</sup> STUART O. SCHWEITZER, *PHARMACEUTICAL ECONOMICS AND POLICY* 8 (1997)

California suggested the possibility of a Canadian-style compulsory licensing system.<sup>10</sup> “Mr. Waxman thinks that American drugs are increasing in price too fast and talks of encouraging a little healthy competition through a compulsory licensing system for products on patent, as already happens in Canada.”<sup>11</sup>

In the late 1980s, a more cost-conscious federal government that became directly involved in the delivery of health care,<sup>12</sup> combined with an aging population, made drug prices a hot political issue in the United States.<sup>13</sup> In fact, judging by current rhetoric, U.S. politicians continue to believe that domestic pharmaceutical prices are too high.<sup>14</sup> President Clinton recently argued that, “no American should ‘be forced to get on the bus to

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(“It appears that consumers are more sensitive to the prices of pharmaceuticals than they are to other health services which are far more expensive.”).

<sup>10</sup> *Pharmaceuticals*, THE ECONOMIST, Feb. 7, 1987.

<sup>11</sup> *Id.*; see also Marlene Cimon, *Waxman Blasts Cost of Prescription Drugs*, L.A. TIMES, Oct. 22, 1992, at A14 (quoting Representative Waxman as stating: “Once again, the United States is behind the rest of the world in providing health care to our people. Canada has found ways to control prescription drug prices. . . . It’s time for the United States to get on the bandwagon.”).

<sup>12</sup> BARRY R. FURROW ET AL., HEALTH LAW §13-1, at 561-62 (1995) (“In 1990, government accounted for 42% of health care expenditures, and health care expenditures constituted 15.3% of federal expenditures, 11% of state and local expenditures. By far the largest single government health care program is the Medicare program, which accounts for 17% of the nation’s health care spending.”).

<sup>13</sup> *E.g.*, Deborah Barfield, *Drug-Maker Lobby Is Tops in Spending*, AUSTIN AMERICAN-STATESMAN, Dec. 3, 1999, at A23 (quoting Jackie Cottrell, spokeswoman for the Pharmaceutical Research and Manufacturers of America, “[d]rug coverage for seniors is going to be a highly political . . . issue for the next election season”); Constance Sommer, *Senate Panel Assails Drug Price Boosts; Pharmaceuticals: Leaders Call for More Regulation, Citing a Report that Some Industry Hikes Far Outpaced Inflation*, L.A. TIMES, Feb. 4, 1993, at D2 (quoting Senator David Pryor (D-AR), “[w]e’re seeing thousands of elderly people who are saying that they must decide whether to put food on the table, heat their home or buy prescription drugs”).

<sup>14</sup> See, e.g., Gregg Birnbaum, *Hillary’s Rx: Buy Canadian*, N.Y. POST, Feb. 9, 2000, at 22 (quoting First Lady Hillary Rodham Clinton, campaigning in New York, “[p]rescription drugs are a necessity, and yet they’re priced like a luxury”); *Gore Pitches Plan to Lower Drug Prices*, UNION LEADER, Nov. 9, 1999, at A2 (quoting Vice President Gore, “[r]ight now, [prescription] drug prices are way too high”); Robert Pear, *Clinton Is Going on the Offensive To Offer the Elderly a Drug Plan*, N.Y. TIMES, Oct. 25, 1999, at A1 (describing President Clinton’s “new attack on drug companies, saying they charge too much”).

Canada” to obtain prescription drugs at lower prices.<sup>15</sup> However, simply to state that no American should be forced to purchase cheaper drugs in Canada begs the central question of this paper: to achieve this goal does one lower the prices of drugs in the United States, or does one raise the price of drugs in Canada? Clearly, the result is the same: Americans are no longer going to Canada to buy drugs. The implications of each strategy, however, could scarcely be more opposite.

The United States seems to have followed the latter strategy. Beginning in the early 1980s, at the same time they were seeking to restrict domestic pharmaceutical companies' pricing policies, U.S. politicians began to vigorously pursue the international agenda of the domestic research pharmaceutical industry.<sup>16</sup> For example, the United States insisted that intellectual property rights be included in the Uruguay Round of GATT negotiations.<sup>17</sup> In both the bilateral Canada-U.S. Free Trade Agreement and the multilateral North American Free Trade Agreement negotiations, the United States Trade Representative (U.S.T.R.) demanded that U.S. negotiating partners strengthen the protection afforded to intellectual property as a prerequisite to obtaining an agreement.<sup>18</sup>

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<sup>15</sup> Andrew Phillips, *America's Bitter Pills*, MACLEAN'S, Dec. 20, 1999, at 98.

<sup>16</sup> See, e.g., Paul C.B. Liu, *Taiwan: U.S. Industry's Influence on Intellectual Property Negotiations and Special 301 Actions*, 13 UCLA PAC. BASIN L.J. 87 (1994) (examining the ways in which U.S. industries and industrial organizations interact with the government, engage in the Special 301 process, and effectively influence the outcome of international intellectual property negotiations); Charles S. Levy & Stuart M. Weiser, *The NAFTA: A Watershed for Protection of Intellectual Property*, 27 INT'L LAW. 671 (1993) ("Over the last decade the United States has pursued an aggressive strategy for improving international protection of intellectual property."); Harvey J. Winter, *The Role of the United States Government in Improving International Intellectual Property Protection*, 2 J.L. & TECH. 325 (1987) (describing the United States's agenda for multilateral and bilateral actions to improve intellectual property protection in other countries).

<sup>17</sup> See THOMAS O. BAYARD & KIMBERLY ANN ELLIOTT, *RECIPROCITY AND RETALIATION IN U.S. TRADE POLICY 192-93* (1994) (describing U.S. efforts to strengthen GATT rules on intellectual property rights).

<sup>18</sup> E.g., MARCI McDONALD, *YANKEE DOODLE DANDY: BRAIN MULRONEY AND THE AMERICAN AGENDA* 213 (1995) (arguing that as the free trade negotiations with Canada dragged on, "the White House had threatened to throw the whole thing overboard unless Ottawa rammed through the pharmaceutical bill"); GARY CLYDE HUFBAUER & JEFFREY J. SCHOTT, *NORTH AMERICAN FREE TRADE: ISSUES AND RECOMMENDATIONS* (1992) (noting that "[t]he United States will seek to incorporate detailed obligations in the NAFTA that lock in the recent Mexican intellectual property reforms").

One measure of the success of the U.S. strategy is that, by the early 1990s, proponents of compulsory licensing as a means to control drug prices in Canada began to complain that "Canadians may become like Americans, having to choose between putting food on the table and prescription drugs."<sup>19</sup>

Why would U.S. politicians simultaneously seek to abolish compulsory licenses abroad and implement them at home? What explanation can there be for pursuing a foreign economic policy that "[champions] the advances in international intellectual property law which may increase pharmaceutical prices for people in foreign countries," while at the same time following a domestic economic policy that "[condemns] the pharmaceutical industry for its high prices and high profits"?<sup>20</sup> More bluntly, as Rafael Cadena Silva, president of ALIFAR, an umbrella organization for Latin American pharmaceutical industries, asked why

On the one hand, [is] U.S. President Clinton trying to get support for reform of the U.S. health system, while on the other the U.S.A. brings pressure to bear to maintain privileges that it holds unlawfully, and which are responsible for the collapse of the health care system in that country?<sup>21</sup>

This Comment seeks to answer this question. Part II describes the characteristics of intellectual property that make protection problematic.<sup>22</sup> Specifically, because intellectual property is a public good, it is susceptible to the free rider problem and is under-supplied due to market failure. Part III provides a brief review of the existing theories of international institutional solutions to the public good problems that plague intellectual

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<sup>19</sup> Art Chamberlain, *Generic Firms, Seniors Challenge Drug Law*, TORONTO STAR, Sept. 23, 1993, at D1 (quoting Brenda Drinkwalter, president of the Canadian Drug Manufacturers Association, a generic industry trade group).

<sup>20</sup> James M. Silbermann, *The North American Free Trade Agreement's Effect on Pharmaceutical Patents*, 12 J. CONTEMP. HEALTH L. & POL'Y 607, 633 (1996) (citing Marian Uhlman, *Pushing Drug Patents*, PHILA. INQUIRER, Nov. 7, 1993, at D1).

<sup>21</sup> *North and South Americans against Patents*, MARKETLETTER, May 30, 1994; see also Silbermann, *supra* note 20, at 633 (citing Uhlman, *supra* note 20, at D1) (quoting Agnes Varis, President of Agvar Chemicals, arguing "that while the United States is trying to reduce drug prices domestically, the international patent laws that the pharmaceutical industry and the U.S. government are seeking will raise pharmaceutical prices for people in foreign countries").

<sup>22</sup> See *infra* notes 31-64 and accompanying text.

property.<sup>23</sup> In particular, Part III emphasizes the redistributive nature of international institutions and explains how, in certain circumstances, domestic political actors can alter the choices available to domestic and foreign politicians.<sup>24</sup> Part III also provides a theory that describing international institutions as international solutions to domestic political problems.<sup>25</sup> Part IV details the research pharmaceutical industry in the United States in two distinct phases.<sup>26</sup> In the first instance, attention is paid to how this industry lost an important, and in many ways symbolic, domestic political battle.<sup>27</sup> In the second instance, attention is paid to how this industry shifted the public policy debate away from domestic prices and toward international piracy.<sup>28</sup> Part V focuses on the Canadian response to this shift in U.S. foreign economic policy.<sup>29</sup> This section describes how U.S. pressure, emanating from the U.S.-based research pharmaceutical industry, compelled Canada to abandon its system of compulsory licensing for a patent system that more closely mirrors that of the United States. Part VI offers conclusions and possible areas of further study.<sup>30</sup>

## II. The Practical Problem of International Intellectual Property Rights

### A. *Public Goods and Free Riders*

“Because of its intangible nature, intellectual property differs from the more familiar tangible property . . . . The intangible nature of intellectual property leads to special difficulties of protection. Once information is created . . . , it is difficult to prevent others from using it.”<sup>31</sup> Intellectual property is a public

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<sup>23</sup> See *infra* notes 65-148 and accompanying text.

<sup>24</sup> See *infra* notes 85-124 and accompanying text.

<sup>25</sup> See *infra* notes 125-48 and accompanying text.

<sup>26</sup> See *infra* notes 149-265 and accompanying text.

<sup>27</sup> See *infra* notes 149-201 and accompanying text.

<sup>28</sup> See *infra* notes 202-65 and accompanying text.

<sup>29</sup> See *infra* notes 266-397 and accompanying text.

<sup>30</sup> See *infra* notes 398-401 and accompanying text.

<sup>31</sup> Marshall A. Leaffer, *Protecting United States Intellectual Property Abroad: Toward a New Multilateralism*, 76 IOWA L. REV. 273, 279 (1991); see also ALFONSO GAMBARDILLA, SCIENCE AND INNOVATION: THE U.S. PHARMACEUTICAL INDUSTRY



good.<sup>32</sup> Economist Paul Samuelson identified two distinguishing features of public goods.<sup>33</sup> Unlike private goods, a public good is non-rival in consumption and is non-excludable.<sup>34</sup> Non-rivalry in consumption means that “one person’s consumption of the good does not reduce its availability to anyone else.”<sup>35</sup> Theoretically, a pure public good is infinitely available; i.e., it is not scarce. Non-excludability indicates that the producer of the public good is unable to preclude those who did not pay for the good from consuming it.<sup>36</sup> “In other words, those who do not purchase or pay for any of the public . . . good cannot be excluded or kept from sharing in the consumption of the good, as they can where noncollective goods are concerned.”<sup>37</sup>

A central characteristic, then, of public goods is their susceptibility to the free rider problem, “wherein cheaters benefit from the collective good but refuse to pay their ‘fair’ share toward providing it.”<sup>38</sup> Because the enjoyment of public goods cannot easily be excluded from those who did not contribute to their production, individuals have an incentive to “free ride” on the efforts of others.<sup>39</sup> Therefore, public goods suffer from the

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DURING THE 1980s 5 (1995) (“[I]nformation is a peculiar commodity in that it can be reproduced at zero cost. Any buyer of the information, or anyone who happens to have it, can become a producer of it.”).

<sup>32</sup> Paul A. David, *Intellectual Property Institutions and the Panda’s Thumb: Patents, Copyrights, and Trade Secrets in Economic Theory and History*, in GLOBAL DIMENSIONS OF INTELLECTUAL PROPERTY RIGHTS IN SCIENCE AND TECHNOLOGY 24 (Mitchel B. Wallerstein et al. eds., 1993) [hereinafter GLOBAL DIMENSIONS OF INTELLECTUAL PROPERTY RIGHTS] (“Modern economic analysis recognizes that the peculiar, ‘public good’ nature of information as a commodity creates serious resource allocation problems for competitive market systems.”).

<sup>33</sup> Paul A. Samuelson, *The Pure Theory of Public Expenditure*, 36 REV. ECON. & STAT. 387 (1954).

<sup>34</sup> THE MIT DICTIONARY OF MODERN ECONOMICS 352 (David W. Pearce ed., 1992).

<sup>35</sup> *Id.*; see also David, *supra* note 32, at 26 (“[K]nowledge differs from ordinary ‘private’ commodities in being what economists refer to as a *nonrival* good; that is, it can be possessed and enjoyed jointly by as many as care to make use of it.”).

<sup>36</sup> THE MIT DICTIONARY OF MODERN ECONOMICS, *supra* note 34, at 352; see also David, *supra* note 32, at 25 (noting that information is indivisible and durable).

<sup>37</sup> MANCUR OLSON, *THE LOGIC OF COLLECTIVE ACTION* 14-15 (1965).

<sup>38</sup> ROBERT GILPIN, *THE POLITICAL ECONOMY OF INTERNATIONAL RELATIONS* 74 (1987).

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

collective action problem.<sup>40</sup> Internationally, “[f]ree riding in relation to intellectual property is simply shorthand for what happens when technical knowledge is treated as property in one country but not in another.”<sup>41</sup>

### *B. Public Goods and Market Failures*

Markets will fail to produce at socially optimal levels those products or services where “exclusion costs are high, . . . consumption tends to be nonrival, and . . . the prospects for payment and profit are low” or if “some gains or costs to society are not reflected in market prices.”<sup>42</sup> Of the reasons economist Francis Bator offers for market failure, two are most relevant to public goods.<sup>43</sup> First, public goods may be undersupplied due to a

<sup>40</sup> DENNIS CHONG, *COLLECTIVE ACTION AND THE CIVIL RIGHTS MOVEMENT* 5 (1991).

A collective action problem arises when individuals, acting out of pure self-interest, are unable to coordinate their efforts to produce and consume certain public goods they find desirable. Each individual, figuring that he can enjoy with impunity the fruits of the public good without contributing [to its production], tries to get a free ride on the efforts of others. Unfortunately, since everyone thinks alike, no public good is produced, and everyone is worse off than he would have been had each contributed his fair share and the public good been provided.

*Id.*

<sup>41</sup> Robert M. Sherwood, *Why a Uniform Intellectual Property System Makes Sense for the World*, in *GLOBAL DIMENSIONS OF INTELLECTUAL PROPERTY RIGHTS*, *supra* note 32, at 75.

<sup>42</sup> JOE B. STEVENS, *THE ECONOMICS OF COLLECTIVE CHOICE* 62 (1993); *see also* Francis M. Bator, *The Anatomy of Market Failure*, 72 *Q.J. ECON.* 351 (1958) (a market failure is “the failure of a more or less idealized system of price-market institutions to sustain ‘desirable’ activities or to stop ‘undesirable’ activities”); Robert Keohane, *The Demand for International Regimes*, in *INTERNATIONAL REGIMES* 141 (Stephen Krasner ed., 1983).

In situations of market failure, economic activities uncoordinated by hierarchical authority lead to inefficient results, rather than to the efficient outcomes expected under conditions of perfect competition. In the theory of market failure, the problems are attributed not to inadequacies of the actors themselves . . . but rather to the structure of the system and the institutions, or lack thereof, that characterize it. Specific attributes of the system impose transaction costs (including information costs) that create barriers to effective cooperation among the actors.

*Id.* at 51.

<sup>43</sup> *See* Bator, *supra* note 42, at 354-71; *THE MIT DICTIONARY OF MODERN*

market failure by enforcement.<sup>44</sup> Bator calls this an ownership externality.<sup>45</sup> An ownership externality exists because of nonappropriability.<sup>46</sup> When effective ownership of public goods, such as intellectual property, is compromised by lack of adequate enforcement, individuals have little incentive to undertake research and development, the income from which they cannot enjoy.<sup>47</sup>

The total revenue created from information is inappropriable because its consumption cannot be excluded from those who did not pay for it.<sup>48</sup> The degree of appropriability depends, in large measure, on the nature of the product itself. "For certain technology, the ability to free ride is remarkably easy. Software and medicine are . . . classic examples . . . of technology that is costly and risky to develop, yet quite easy to copy."<sup>49</sup>

Second, according to Bator, public goods may be undersupplied due to a market failure by existence.<sup>50</sup> This case is

ECONOMICS, *supra* note 36, at 267 (noting that markets may fail because of the characteristics of the goods or service. Specifically, public goods, characterized by non-excludability and non-rivalry in consumption, will not be optimally supplied by the market because no individual can exclude those who did not pay from consuming it.).

<sup>44</sup> Bator, *supra* note 42, at 354.

<sup>45</sup> *Id.* at 364; *see also* LANCE E. DAVIS & DOUGLASS C. NORTH, INSTITUTIONAL CHANGE AND AMERICAN ECONOMIC GROWTH 16 (1971) ("Externalities in production exist whenever the firm making the production decision does not bear all the costs inherent in the decision or *whenever it is unable to accrue all the revenues from selling the output that results from that decision.*") (emphasis added).

<sup>46</sup> Bator, *supra* note 42, at 365.

<sup>47</sup> *Id.* at 370.

[With public goods], a pricing game will not induce consumers truthfully to reveal their preferences. It pays each consumer to understate his desire for *X* relative to *Y*, since his enjoyment of *X* is a function only of total *X*, rather than, as is true of a pure private good, just of that fraction of *X* he pays for.

*Id.*

<sup>48</sup> David J. Teece, *Capturing Value from Technological Innovation: Integration, Strategic Partnering, and Licensing Decisions*, in TECHNOLOGY AND GLOBAL INDUSTRY: COMPANIES AND NATIONS IN THE WORLD ECONOMY 65 (Bruce R. Guile & Harvey Brooks eds., 1987). "A regime of appropriability refers to the environmental factors, excluding firm and market structure, that govern an innovator's ability to capture the profits generated by an innovation. The most important dimensions of such a regime are the nature of the technology and the efficacy of legal mechanisms of protection." *Id.* at 67.

<sup>49</sup> Sherwood, *supra* note 41, at 76.

<sup>50</sup> *See* Bator, *supra* note 42, at 371.

best exemplified by the above-referenced free rider problem. Because public goods cannot easily be excluded from those who did not contribute to their provision, the prices that producers wish to charge and that consumers are willing to pay are never equated.<sup>51</sup> Therefore, producers have no price incentive to provide public goods.<sup>52</sup>

In countries that offer effective intellectual property protection, such as the United States, research pharmaceutical companies spend millions of dollars on research and development, confident in their ability to appropriate the value of that research in the form of patent rights.<sup>53</sup> Those countries that do not offer effective protection receive very little in the way of research and development investment.<sup>54</sup> Because intellectual property is non-excludable, however, these countries can receive the benefits of research done in the United States.<sup>55</sup>

In those countries that do not protect intellectual property, manufacturers can produce pharmaceuticals that are patented in

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<sup>51</sup> *Id.* at 370-71.

<sup>52</sup> STEVENS, *supra* note 42, at 62 (arguing that "market output will be inefficiently small if exclusion costs are high, if consumption tends to be nonrival, and if the prospects for payment and profit are low").

<sup>53</sup> Gerald Mossinghoff & Thomas Bombelles, *The Importance of Intellectual Property Protection to the American Research-Intensive Pharmaceutical Industry*, 31 COLUM. J. WORLD BUS. 38 (1996).

<sup>54</sup> *Id.* (citing a study by Dr. Edwin Mansfield of the International Finance Corporation, an arm of the World Bank, noting the uniqueness of intellectual property by arguing that "[w]hile most companies may undertake basic investments abroad, such as establishing sales and distribution outlets or new factories, intellectual property protection in foreign countries is considered a must if R&D investment or any subsequent investment in distribution and factories is to occur").

<sup>55</sup> Ed Hore, *Abolition of Compulsory Licensing Means Foreigners Won't Subsidize Our Health Care System Anymore*, THE LAWYERS WEEKLY, Nov. 26, 1993.

The magic of Canada's compulsory licensing scheme was that, in actual fact, medical research was of course going to go on around the world, regardless of what we did here with our patent system. The big drug companies were not going to stop investing in R&D, just because some bureaucrats in Ottawa were in effect taking away their patent protection in Canada, and our patent mandarins knew it. Canada was just too small a market to really matter. So we Canucks got to have our cake and eat it, too: we could, in effect, abolish patent protection for drugs, confident that progress on new drugs would still go forward, paid for by consumers outside Canada.

*Id.*

other countries without the additional costs of research and development.<sup>56</sup> Therefore, these manufacturers can sell these “pirated” products for less money.<sup>57</sup> Alan Sager, a health-policy expert at Boston University, calls this “an odd system of ‘foreign aid’ from U.S. consumers to people in other rich countries.”<sup>58</sup> Representative Henry Waxman argues further that “[i]t appears that our citizens are bearing a disproportionate portion of the burden of drug research, while other countries get both the benefits of the research and significantly lower prices.”<sup>59</sup>

This is true of Canada’s use of compulsory licensing of pharmaceuticals. “We Canadians . . . used our patent system as a way to get foreigners to subsidize our deluxe health care system.”<sup>60</sup>

The scheme was simple: international drug companies were forced by the Canadian government to give licenses to Canadian companies at below-market rates to manufacture or import generic equivalents of patented drugs. Because the Canadian companies did not have to pay for the research that went into inventing the new drug, they were naturally able to sell their equivalents cheaper, allowing the Canadian consumer to buy drugs at bargain prices.<sup>61</sup>

The above description of intellectual property rights suggests that any approach to solve the appropriability problem must be global in nature, so as to avoid the free rider problem.<sup>62</sup> A solution that would allow the holders of intellectual property, such as

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<sup>56</sup> Bruce A. Lehman, *Intellectual Property Under the Clinton Administration*, 27 GEO. WASH. J. INT’L L. & ECON. 395, 395 (1993) (“Other nations often look for a free ride, seeking to build their economies not by encouraging the innovation and creativity of their own people through strong protection for all forms of intellectual property, but by promoting intellectual property piracy through weak laws or no protection at all.”).

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

<sup>58</sup> Phillips, *supra* note 15, at 98.

<sup>59</sup> Cimons, *supra* note 11, at A14.

<sup>60</sup> Hore, *supra* note 55.

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

<sup>62</sup> See Leaffer, *supra* note 31, at 275 (“Today’s research and development costs require large-scale production, open international markets, and protection against free-riding imitators to recoup costs of production.”); see also Peter Drahos, *Global Law Reform and Rent-Seeking: The Case of Intellectual Property*, 7 AUSTL. J. CORP. L. 45, 49 (1996) (“The U.S. faced a massive free rider problem. The way in which it chose to solve that problem was through forging a link between the international trade regime and the development and enforcement of intellectual property standards.”).

research pharmaceutical firms, to appropriate fully the value of their property would require participation by those who would wish to utilize that property for free. In the United States, the solution to the public good problem of intellectual property has been to grant the inventor a period of market exclusivity known as a patent.<sup>63</sup> Therefore, from the perspective of the U.S. research pharmaceutical industry, the key to an international solution to the appropriability problem associated with intellectual property is the creation of an international institution that establishes a minimum standard for patent protection.<sup>64</sup>

### III. Theories of International Institutions and Domestic Politics

Two of the most popular schools of international relations thought employed by political scientists to explain international cooperation are neorealism and neoliberal institutionalism.<sup>65</sup>

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<sup>63</sup> See *N.V. Philips' Gloeilampenfabrieken v. Atomic Energy Comm'n.*, 316 F.2d 401 (1963) ("If there were no patent system at all, anyone would be free to use any invention. A patent, however, gives one person the right to exclude all others. This monopoly is the property right in the patent."). *But see* Richard Rapp & Richard Rozek, *Benefits and Costs of Intellectual Property Protection in Developing Countries*, 24 J. WORLD TRADE 75, 91 (1990):

[I]t is important to clarify the meaning of the fundamental characteristic of all patents; namely, exclusivity for a limited time for a product or process narrowly defined by the claims of the patent. This narrowly defined right to exclusivity must not be confused with monopoly power. Economists define monopoly as a situation where one firm is the only supplier of a product or service *for which there are no close substitutes*. A producer of a patented pharmaceutical product often faces competition from products that are found in the same chemical or therapeutic class.

*Id.*

<sup>64</sup> See Silbermann, *supra* note 20, at 608 (quoting Arthur Wineburg, *NAFTA to Break Down Barriers*, LEGAL TIMES, Oct. 26, 1992, at 21) (noting that "[a]lthough intellectual property has become a global commodity," the rights in this commodity are "limited by national borders").

<sup>65</sup> Emerson Niou & Peter Ordeshook, "*Less Filling, Tastes Great*," 46 WORLD POLITICS 209 (1994) ("The debate between realists and neoliberals focuses on two issues: (1) delineating the goals that best account for the actions of states, especially patterns of cooperation and conflict; and (2) assessing whether institutions of different types ameliorate conflict in an otherwise anarchic environment."); *see also* INTERNATIONAL RULES: APPROACHES FROM INTERNATIONAL LAW AND INTERNATIONAL RELATIONS (Robert J. Beck et al. eds., 1996); Kenneth W. Abbott, *Modern International Relations Theory: A Prospectus for International Lawyers*, 14 YALE J. INT'L L. 335

Sharing a common theoretical foundation, these two theories offer diametric conclusions about the likelihood, importance, and endurance of international cooperation. For neorealists, international cooperation is either ephemeral or epiphenomenal.<sup>66</sup> In the former, cooperation that does occur is the result of the presence of a common threat—usually military—that, once receded, yields the dissolution of cooperation.<sup>67</sup> In the latter, cooperation is merely an extension of power politics and mirrors the power distribution already evident in the international system.<sup>68</sup> For neorealists, states' relative gains concerns imply that cooperation fails to enduringly change the states' relationships or behaviors.<sup>69</sup>

In contrast, neoliberal institutionalism has focused on the ability of international institutions to constrain state behavior in an anarchic international environment by changing state preferences, thereby increasing the shadow of the future,<sup>70</sup> and providing effective monitoring and enforcement.<sup>71</sup> For the neoliberal, states

(1989); *NEOREALISM AND ITS CRITICS* (Robert O. Keohane ed., 1986).

<sup>66</sup> See *infra* notes 67-69 and accompanying text.

<sup>67</sup> See Stephen M. Walt, *Alliance Formation and the Balance of World Power*, in *THE PERILS OF ANARCHY: CONTEMPORARY REALISM AND INTERNATIONAL SECURITY* 208 (Michael E. Brown et al. eds., 1995) (arguing that alliances are formed in response to military threats).

<sup>68</sup> Robert G. Gilpin, *The Richness of the Tradition of Political Realism*, in *NEOREALISM AND ITS CRITICS*, *supra* note 65, at 301 (arguing that "the final arbiter of things political is power").

<sup>69</sup> Joseph M. Grieco, *Anarchy and the Limits of Cooperation: A Realist Critique of the Newest Liberal Institutionalism*, 42 *INT'L ORG.* 485, 487 (1988) ("For realists, a state will focus both on its absolute and relative gains from cooperation, and a state that is satisfied with a partner's compliance in a joint arrangement might nevertheless exit from it because the partner is achieving relatively greater gains."); see also JOSEPH M. GRIECO, *COOPERATION AMONG NATIONS: EUROPE, AMERICA, AND NON-TARIFF BARRIERS TO TRADE* 39 ("[R]ealists find that the fundamental goal of states in any relationship is not to attain the highest possible individual gain or payoff, instead it is to prevent others from achieving advances in their relative capabilities.").

<sup>70</sup> Geoffrey Garrett & Barry Weingast, *Ideas, Interests and Institutions: Constructing the European Community's Internal Market*, in *IDEAS AND FOREIGN POLICY: BELIEFS, INSTITUTIONS, AND POLITICAL CHANGE* 173 (Judith Goldstein & Robert O. Keohane eds., 1993) ("Without a doubt, repeated interaction and the 'long arm of the future' play large roles in enabling actors to capture the gains from cooperation.").

<sup>71</sup> WALTER MATTLI, *THE LOGIC OF REGIONAL INTEGRATION: EUROPE AND BEYOND* 13-14 (1998) (In order to improve compliance with the rules of cooperation, countries must establish "'commitment institutions' such as centralized monitoring and third party

are more concerned—particularly in economic issues such as intellectual property—with achieving absolute gains from cooperation. Cooperation serves the functional purpose of overcoming market failures and reducing transaction costs.<sup>72</sup> By cooperating, states can overcome collective action problems,<sup>73</sup> internalize externalities,<sup>74</sup> solve disequilibrium problems,<sup>75</sup> and provide for efficiencies of scale and scope.<sup>76</sup>

Political scientist Robert Keohane provides a useful starting point for analyzing neoliberalism's ability to explain international cooperation.<sup>77</sup> First, according to Keohane, the demand for

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enforcement"); see also Robert Axelrod & Robert Keohane, *Achieving Cooperation under Anarchy: Strategies and Institutions*, in COOPERATION UNDER ANARCHY 237 (Kenneth Oye ed., 1986) (noting that institutions "provide information about actors' compliance, . . . and they may even apportion responsibility for decentralized enforcement of rules").

<sup>72</sup> James Morrow, *Social Choice and System Structure in World Politics*, 41 WORLD POLITICS 75, 80 (1988) (institutions "reduce transaction costs and uncertainty among actors and facilitate coordination of action among them").

<sup>73</sup> Kenneth Oye, *Explaining Cooperation Under Anarchy: Hypothesis and Strategies*, 38 WORLD POLITICS 1 (1985); Robert Axelrod & Robert Keohane, *Achieving Cooperation Under Anarchy: Strategies and Institutions*, 38 WORLD POLITICS 226 (1986).

<sup>74</sup> LANCE E. DAVIS & DOUGLASS C. NORTH, INSTITUTIONAL CHANGE AND AMERICAN ECONOMIC GROWTH 12 (1971) (arguing that institutions change when "arrangemental innovation can successfully internalize [external profits]").

<sup>75</sup> Kenneth A. Shepsle & Barry R. Weingast, *Structure-Induced Equilibrium and Legislative Choice*, 37 PUBLIC CHOICE 503 (1981) (arguing that institutions such as committee rules and structure constrain the possible alternatives available to legislators and, thereby, reduce cycling under majority rule voting by reducing log-rolling, vote trading, coalition formation, and bargaining); William H. Riker, *Implications from the Disequilibrium of Majority Rule for the Study of Institutions*, 74 AM. POL. SCI. REV. 432 (1980) (arguing that stability in the political system is a function of institutional constraints).

<sup>76</sup> YEONG HEOK LEE, VERTICAL INTEGRATION AND TECHNOLOGICAL INNOVATION: A TRANSACTION COST APPROACH (1994) (arguing that vertical integration, not firm size, accounts for economies of scale in "informational economies" in firms); OLIVER WILLIAMSON, MARKETS AND HIERARCHIES: ANALYSIS AND ANTITRUST IMPLICATION (1975) (arguing that firm structure is driven by transaction costs and the desire to overcome them through vertical integration).

<sup>77</sup> E.g., Keohane, *supra* note 42; ROBERT KEOHANE, AFTER HEGEMONY: COOPERATION AND DISCORD IN THE WORLD POLITICAL ECONOMY (1985); Robert Keohane & Joseph Nye, *Power and Interdependence Revisited*, 41 INT'L ORG. 725 (1987).



international institutions is produced by market failures.<sup>78</sup> Second, Keohane argues that cooperation must be Pareto-improving.<sup>79</sup> The Pareto criterion defines a social welfare function. Specifically, “[s]ociety’s scarce resources are optimally allocated when no one could be better off without making someone worse off.”<sup>80</sup> A Pareto improvement, also known as Pareto superiority, is any reallocation of resources that benefits at least one person without making anyone else worse off.<sup>81</sup>

Neoliberals assume that states voluntarily choose whether or not to enter into cooperative agreements with other states.<sup>82</sup> In other words, the neoliberal assumes “that states enter the market of international relations in order to obtain gains from exchange. One corollary of this assumption is that, where states find no gains from trade, there should be no trade: no cooperation and no integration.”<sup>83</sup> This focus on voluntarism and Pareto optimality provides neoliberals with a convenient test for the Pareto efficiency of international institutions: “whether each state accepts its operating rules.”<sup>84</sup>

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<sup>78</sup> Keohane, *supra* note 42, at 151.

<sup>79</sup> See Axelrod & Keohane, *supra* note 71, at 226.

<sup>80</sup> NEIL K. KOMESAR, *IMPERFECT ALTERNATIVES: CHOOSING INSTITUTIONS IN LAW, ECONOMICS, AND PUBLIC POLICY* 30 (1994).

<sup>81</sup> *Id.*; see also RICHARD A. POSNER, *ECONOMIC ANALYSIS OF LAW* 14 (1998) (noting that when transactions are purely voluntary, “the criterion of Pareto superiority is unanimity of all affected persons”).

<sup>82</sup> Keohane, *supra* note 42, at 146 (“The use of rational-choice theory implies that we must view decisions involving international regimes as in some meaningful sense voluntary.”).

<sup>83</sup> Joel P. Trachtman, *Institutions for International Economic Integration: The Theory of the Firm and the Theory of the International Economic Organization: Toward Comparative Institutional Analysis*, 17 J. INT’L L. & BUS. 470, 489 (1996).

<sup>84</sup> *Id.* at 516. In organizational terms, “an organization is considered to be efficient if the members unanimously accept the general rules under which it operates. Thus, the test for Pareto efficiency of an [international economic organization] is whether each state accepts its operating rules.” Bruno S. Frey & Beat Gygi, *International Organizations from the Constitutional Point of View*, in *THE POLITICAL ECONOMY OF INTERNATIONAL ORGANIZATIONS* 58, 60 (Roland Vaubel & Thomas D. Willett eds., 1991) (citing GEOFFREY BRENNAN & JAMES M. BUCHANAN, *THE REASON OF RULES: CONSTITUTIONAL POLITICAL ECONOMY* (1986)).

### A. *Redistributive International Institutions*

Several scholars have taken issue with the neoliberal interpretation of institutional cooperation.<sup>85</sup> Paul A. Samuelson has described how

the rational self-interest of each of two free wills does not necessitate that there will emerge, even in the most idealized game-theoretic situation, a Pareto-optimal solution that maximizes the sum of two opponent's profits, in advance of and without regard to how that maximized profit is to be divided up among them. Except by fiat of the economic analyst or by his tautologically redefining what constitutes non-rational behavior we cannot rule out a non-Pareto-optimal.<sup>86</sup>

Rephrasing Samuelson, "domestic politics can lead national governments to create international institutions that are politically efficient but do not lie on the Pareto frontier."<sup>87</sup> From this perspective, international institutions are seen as mechanisms for the redistribution of wealth or resources.<sup>88</sup> Cooperation does not necessarily lead to greater goods for all, but may, in fact,

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<sup>85</sup> See, e.g., John Richards, *Towards a Positive Theory of International Relations* (1998) (unpublished manuscript, on file with author) ("International institutions necessarily alter the marketplace from what would have occurred absent regulation, and are thus inherently redistributive institutions which benefit some actors at the expense of others."); Jack Knight & Lee Epstein, *On the Struggle for Judicial Supremacy*, 30 L. & SOC'Y REV. 87, 90 (1996), cited in Christopher P. Manfredi & Scott Lemieux, *Judicial Discretion and Fundamental Justice: Sexual Assault in the Supreme Court of Canada*, 47 AM. J. COMP. L. 489, 514 (arguing that institutional development is "a contest among actors to establish rules which structure political competition to those outcomes most favorable to them"); James K. Sebenius, *Challenging Conventional Explanations of International Cooperation: Negotiation Analysis and the Case of Epistemic Communities*, 46 INT'L ORG. 323, 327 (1992) ("Sub-optimal 'cooperation' in the presence of distributional conflict—cooperation below the Pareto frontier—is quite a general phenomenon.").

<sup>86</sup> PAUL A. SAMUELSON, *FOUNDATIONS OF ECONOMIC ANALYSIS* (1947), quoted in R.H. COASE, *THE FIRM, THE MARKET, AND THE LAW* 161 (1988).

<sup>87</sup> John E. Richards, *Toward a Positive Theory of International Institutions: Regulating International Aviation Markets*, 53 INT'L ORG. 1, 9 (1999).

<sup>88</sup> See Thomas Oatley & Robert Nabors, *Redistributive Cooperation: Market Failure, Wealth Transfers, and the Basle Accord*, 52 INT'L ORG. 35, 37 (1998) (arguing that "politicians propose international institutions to resolve domestic political dilemmas and that the international institutions they propose sometimes will be intentionally redistributive").

reapportion existing goods from the many to the few.<sup>89</sup>

Still, political scientist John Richards notes that “arguing that national politicians can create international institutions that transfer wealth from domestic interests in other states to their own domestic constituents seems to contradict the literature on international cooperation—which implies that all international agreements are voluntary.”<sup>90</sup> However, Richards supplies two reasons why politicians might voluntarily accept Pareto-inferior agreements:

First, wealth-transferring international regulations can benefit national politicians if the domestic actors who actually transfer wealth abroad are not part of the politicians’ coalition or if coalition members stand to gain from an international agreement . . . . The second reason national politicians might voluntarily accept wealth-reducing international regulations stems from the potential for states with market power to unilaterally define the reversion point of international negotiations.<sup>91</sup>

### *1. Redistributive International Institutions—The Importance of the Reversion Point*

As political scientists Thomas Oatley and Robert Nabors correctly point out,

“[c]ooperative” international redistribution is possible . . . only if two stringent conditions are met: unanimity is the choice rule and no actor has the ability to manipulate the choice set, that is, the set of alternatives from which the outcome is selected. If either of these conditions is missing, politicians can construct an international institution that transfers wealth.<sup>92</sup>

Therefore, regardless of the voting rule, an actor with the ability to manipulate the choice set can obtain a redistributive outcome. This is true because politicians “might voluntarily accept wealth-reducing international regulations . . . [when] states with market power . . . unilaterally define the reversion point of international

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<sup>89</sup> Richards, *supra* note 87, at 1.

<sup>90</sup> *Id.* at 12.

<sup>91</sup> *Id.* at 12-13.

<sup>92</sup> Oatley & Nabors, *supra* note 88, at 41.

negotiations.”<sup>93</sup> “States with market power are . . . able to dictate the reversion point of no international agreement and are thereby able to define the choice set available to other national politicians.”<sup>94</sup>

Unlike neoliberals who have focused on international agreements that are Pareto improvements over the status quo, this comment asks the question: What happens if the status quo is removed from the choice set?<sup>95</sup> Economist Francis Edgeworth argued that two individuals engaged in exchanging goods would end up on the Pareto frontier because, if they did not, there would remain positions to which they could move by exchange that would make them both better off.<sup>96</sup> Samuelson disagreed with Edgeworth’s prediction about the necessity of Pareto solutions to voluntary negotiations because “one or both [may be] unwilling to discuss the possibility of making a mutually favorable movement for fear that the discussion may imperil the existing tolerable status quo.”<sup>97</sup> Samuelson’s conclusion illustrates the importance of the status quo and the reversion point in determining both the nature of the negotiating process (including whether negotiating will occur at all) and the predictability of the resultant agreements (i.e., whether those agreements will fall along the Pareto frontier or at some Pareto-inferior solution).

An agenda-setter who can eliminate the status quo as the reversion point may be able to impose Pareto inferior outcomes. If the status quo is not the outcome associated with no-agreement,

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<sup>93</sup> Richards, *supra* note 87, at 12-13 (defining the reversion point as the outcome obtained in the absence of a new agreement); *see, e.g.*, William F. Shugart, II & Robert D. Tollison, *Inter-Institutional Analysis: Interest Groups and the Courts*, 6 GEO. MASON L. REV. 953, 956 (1998) (defining the reversion point as a fallback position); Linda A. Schwartzstein, *Bureaucracy Unbounded: The Lack of Effective Constraints in the Judicial Process*, 35 ST. LOUIS U. L.J. 597, 611 (1991) (defining the reversion point as “what will happen if the voters defeat the proposal”).

<sup>94</sup> Richards, *supra* note 87, at 13.

<sup>95</sup> This paper employs the terms “reversion point” and “status quo” to differentiate between two possible no-agreement outcomes: (1) status quo—the return to circumstances as they existed prior to entering into negotiations; and (2) reversion point—a non-status quo, no-agreement alternative dictated by the participant with market power.

<sup>96</sup> FRANCIS EDGEWORTH, *MATHEMATICAL PSYCHICS* (1881), *noted in* COASE, *supra* note 86, at 160.

<sup>97</sup> COASE, *supra* note 86, at 160.

then the alternatives offered for consideration are compared not to the status quo but to each other.

The ability to control the agenda gives the setter a monopoly power which he can exploit to an extent that depends on the status quo. By facing the voters with a 'take-it-or-leave-it' choice, the setter exercises a threat over the voters. The worse the status quo, the greater the threat and, consequently, the greater the gain to the setter from being able to propose the alternative.<sup>98</sup>

When an actor can set a reversion point that is not the status quo, the Pareto criterion is rendered void. An actor who can manipulate the choice set to include only Pareto inferior possibilities—including the reversion point—will be able to obtain a redistributive international institutional agreement even under unanimity. In fact, the farther the reversion point is from the status quo, the greater the concessions that the actor setting the reversion point can successfully demand.<sup>99</sup> As Oatley and Nabors summarize, "[w]ith the status quo no longer a relevant choice, foreign politicians must choose among costly outcomes and will choose the least costly—the powerful actor's desired regulation—even though it entails a negative wealth transfer."<sup>100</sup>

Arvind Subramanian calls this "status quo reciprocity because the status quo is offered as the concession in return for changes demanded of others. In other words, the denial of existing market access concessions was the threat for refusal to increase [intellectual property] protection."<sup>101</sup> According to Subramanian, "Section 301 of the US trade law has pre-empted and indeed defined the outcome in TRIPs to a considerable extent. '[S]tatus quo' reciprocity appears to have played an important role, so that the abstention from withdrawal of existing market access appears

<sup>98</sup> Thomas Romer & Howard Rosenthal, *Political Resource Allocation, Controlled Agendas, and the Status Quo*, 33 PUB. CHOICE 27, 35-36 (1978).

<sup>99</sup> *Id.*

The ability to control the agenda gives the setter a monopoly power which he can exploit to an extent that depends on the [reversion point]. By facing the voters with a 'take-it-or-leave-it' choice, the setter exercises a threat over the voters. The worse the [reversion point], the greater the threat and, consequently, the greater the gain to the setter from being able to propose the alternative. *Id.*

<sup>100</sup> Oatley & Nabors, *supra* note 88, at 41.

<sup>101</sup> Arvind Subramanian, *TRIPs and the Paradigm of the GATT: A Tropical, Temperate View*, 13 WORLD ECON. 509, 510 (1990).

to have been presented as 'compensation.'"<sup>102</sup> This means that traditional notions of issue-linkage bargaining in the context of the Canada-U.S. Free Trade negotiations and the use by the United States of unilateral trade actions aimed at countries that failed to adequately protect U.S. intellectual property interests may not provide comprehensive explanations of the resultant agreements.<sup>103</sup> "In other words, multilateral outcomes need not always be determined by multilateral bargaining, which is thought to protect the small against the strong, but might serve to legitimize the objectives of bilateralism."<sup>104</sup>

All political systems have rules governing how, when, and by whom alternatives may be considered. From Athenian democracy to bicameral legislatures, societies find it necessary to somehow restrict the political options available for consideration. As political scientist William Riker argues:

In any organized decision-making body, committee, legislature, or whole government, one function of leaders is to guide the operation of the body. . . . Despite institutional variations, the leaders in every such body must select the alternatives among which decisions will be made, and they must select the procedures for coming to a choice.<sup>105</sup>

These restricted groups of "alternatives among which decisions will be made" are the agenda.<sup>106</sup> Those in positions of control over what gets on the agenda are agenda-setters.<sup>107</sup>

"A dynamic method of controlling the agenda is the introduction of new dimensions and issues in order to generate

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<sup>102</sup> *Id.* at 520.

<sup>103</sup> Michael P. Ryan, *Function-Specific and Linkage-Bargain Diplomacy of International Intellectual Property Lawmaking*, 19 U. PA. J. INT'L ECON. L. 535, 542 (1998) ("U.S. trade diplomats hypothesized that a linkage-bargain conducted within the GATT forum could achieve an unprecedented multilateral intellectual property agreement. The 'South' would get apparel and agricultural liberalization; the 'North' would get globally universal, minimum-standard intellectual property protections . . .").

<sup>104</sup> Subramanian, *supra* note 101, at 520.

<sup>105</sup> WILLIAM H. RIKER, *LIBERALISM AGAINST POPULISM: A CONFRONTATION BETWEEN THE THEORY OF DEMOCRACY AND THE THEORY OF SOCIAL CHOICE* 169 (1982).

<sup>106</sup> *Id.*

<sup>107</sup> Thomas Romer & Howard Rosenthal, *Political Resource Allocation, Controlled Agendas, and the Status Quo*, 33 PUB. CHOICE 27, 27 (1978).

disequilibrium.”<sup>108</sup> This dynamic form of agenda setting is known as heresthetics.<sup>109</sup> Heresthetics involve “changing the space or the constraints on the voters in such a way that they are encouraged . . . to move themselves to the advantage of the heresthetician.”<sup>110</sup> In contrast to rhetoric where the rhetorician attempts to change the preferences of voters through persuasion and argument, heresthetics alters the relevant voting space so that, by necessity, a new majority forms that is consistent with—or at least more consistent with—the preferences of the heresthetician. Heresthetics creates this new winning majority without changing the underlying preferences of voters. Instead, this new majority is obtained by altering the relevant voting space by adding new dimensions, strategic voting, or agenda-setting. In Riker’s words, “[m]anipulating the social agenda with a new issue that generates disequilibrium allows old losers to become new winners.”<sup>111</sup>

## 2. *Redistributive International Institutions—The Importance of How Gains Are Distributed*

Along with manipulation of the choice set, the other reason why politicians might accept a Pareto-inferior international institution is how the benefits from that institution will be distributed domestically. “Wealth-transferring international regulations can benefit national politicians if the domestic actors who actually transfer wealth abroad are not part of the politician’s coalition or if coalition members stand to gain from an international agreement.”<sup>112</sup> Richards’ analysis points out that the focus on the distributional aspects of international regulations and the institutions that embody them must not only include how wealth is divided *among* nations, but also how that wealth is divided *within* nations.<sup>113</sup>

Since most international institutions have some distributional

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<sup>108</sup> RIKER, *supra* note 105, at 237.

<sup>109</sup> William H. Riker, *Heresthetic and Rhetoric in the Spatial Model*, in *ADVANCES IN THE SPATIAL THEORY OF VOTING* 46, 47 (James M. Enelow & Melvin J. Hinich eds., 1990).

<sup>110</sup> *Id.*

<sup>111</sup> RIKER, *supra* note 105, at 215.

<sup>112</sup> Richards, *supra* note 87, at 12.

<sup>113</sup> *Id.* at 13-14.

aspect, the choice among available institutions may revolve around (1) which institutional arrangement provides the greatest amount of wealth to an individual politician's constituents, or (2) which institutional arrangement most constrains the constituents of the politician's opponents. In either case, the national politicians' focus is not only on the distribution of benefits between his country as a whole and those other countries which are parties to the agreement, but also on the distribution of benefits within his country. National politicians will support those proposed institutions that offer the greatest gains, not for the country as a whole, but for his or her elective constituency.<sup>114</sup> According to this view, the "development of . . . institutions is not best explained as a Pareto-superior response to collective goals or benefits but, rather, as a by-product of conflicts over distributional gains."<sup>115</sup>

The domestic distributional consequences of international institutions can be characterized within the framework of regulation theory.<sup>116</sup> Theories of regulation attempt to answer questions such as the following: why do governments regulate some industries and not others and, given the possible universe of

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<sup>114</sup> Oatley & Nabors, *supra* note 88, at 38.

[Politicians face] a trade-off between efforts to maximize one's number of votes and efforts to maximize one's campaign contributions. Regulation extended to producers in exchange for campaign contributions imposes costs (deadweight losses) on society, causing those who bear the costs of these regulations to vote for another candidate. Removing regulation that provides rents to producers will increase votes but will cause producers to contribute to candidates that promise to reimpose the regulation. Given this trade-off, politicians maximize utility by equating the marginal campaign contribution from regulation with the marginal loss in votes caused by the resulting transfers. The result is a market in which producer and consumer groups compete for wealth transfers.

*Id.*

<sup>115</sup> JACK KNIGHT, INSTITUTIONS AND SOCIAL CONFLICT 19 (1992).

Put simply, if self-interested actors want institutional arrangements that favor them as individuals, they will prefer institutional rules that constrain the actions of others with whom they interact. That is, they will want to structure the choices of others in such a way as to produce social outcomes that give them the distributional advantage.

*Id.* at 64.

<sup>116</sup> A. STONE, REGULATION AND ITS ALTERNATIVES 10 (1982) (defining regulation as "a state-imposed limitation on the discretion that may be exercised by individuals or organizations, which is supported by the threat of sanction").



regulations, why does regulation take the form that it does?<sup>117</sup> According to positive theories of regulation, “[r]egulation is one avenue by which an interest group can increase its income by having the state redistribute wealth from other parts of society to that interest group.”<sup>118</sup>

As the economic theory of regulation predicts, it is likely that no single group can ever completely capture the regulator but that several groups will temporarily and alternatively hold him hostage. Indeed, at times the regulator appears to be attempting to dance not to a single fiddle but to an entire orchestra, the individual members of which are all playing different tunes.<sup>119</sup>

There may, however, be circumstances when one group finds itself part of a series of losing minorities. That is to say, some organized interests may be unable to reorganize the political space in such a way as to become part of a winning majority. In such a case, Riker argues, “[o]ne can expect that losers on a series of decisions under a particular set of rules will attempt (often successfully) to change institutions and hence the kind of decisions produced under them.”<sup>120</sup> In other words, finding themselves losers in the domestic political process, an organized interest may choose to switch to the international level.<sup>121</sup> By moving their political demands out of the domestic political process and into an international setting, organized interests may be changing the relevant players in the game and possibly the game’s outcome.

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<sup>117</sup> George J. Stigler, *The Theory of Economic Regulation*, 2 BELL J. ECON. & MGMT. SCI. 3, 3 (1971).

<sup>118</sup> W. KIP VISCUSI ET AL., *ECONOMICS OF REGULATION AND ANTITRUST* 314 (1998); see also Rodney T. Smith, *Canons of Public Choice Analysis of International Agreements*, in *THE POLITICAL ECONOMY OF INTERNATIONAL ORGANIZATIONS: A PUBLIC CHOICE APPROACH* 49 (Roland T. Vaubel & Thomas D. Willett eds., 1991) (“Individuals and organizations spend resources to influence the choice of rules and to affect their standing within a given set of rules.”).

<sup>119</sup> David L. Kaserman et al., *To Which Fiddle Does the Regulator Dance? Some Empirical Evidence*, in *REGULATORY ISSUES SINCE 1964: THE RISE OF THE DEREGULATION MOVEMENT* 170 (Robert F. Himmelberg ed., 1994).

<sup>120</sup> Riker, *supra* note 75, at 445.

<sup>121</sup> The obverse is also true; that is, “what majorities may win at one level of government may be undone by minorities at another level.” KOMESAR, *supra* note 80, at 75-76.

As economist Gary Becker argues, it is not the absolute efficiency of interest groups in producing political pressure that is important.<sup>122</sup> Instead, it is the relative efficiency of interest groups that ultimately determines regulatory outcomes.<sup>123</sup> Therefore, combining the insights of Riker and Becker, one should expect that political actors would move from an arena in which they were relatively politically inefficient into an arena in which they were relatively politically efficient. In cases in which an interest group is relatively weak domestically, this positive theory of regulation would suggest that this group would attempt to move the policy setting process out of that domestic setting and into a more advantageous one. That is to say, this domestically disadvantaged interest group will seek to shift the policy making process from the domestic arena to, for example, the international arena. "International institution building is thus domestic politics by other means."<sup>124</sup>

### *B. The Current State of the Literature*

A new body of literature has developed to explain the emergence of intellectual property as a major international trade issue.<sup>125</sup> "Inadequate protection of intellectual property undermines

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<sup>122</sup> Gary Becker, *A Theory of Competition Among Pressure Groups for Political Influence*, 98 Q.J. ECON. 371 (1983).

<sup>123</sup> *Id.*; see also KOMESAR, *supra* note 80, at 91:

Since the degree to which any expenditures on political action are efficacious depends in part on the extent of activity by the opposition, increased costs of political action that decrease the activity of opponents can increase the productivity of and hence the expenditure on political activity. . . . Whether and to what extent increases in costs will decrease political action in general or political action by any given special interest depends on the *net* impact of [indirect or relative cost and direct or absolute cost] changes.

<sup>124</sup> Richards, *supra* note 87, at 11.

<sup>125</sup> See Susan K. Sell, *The Origins of a Trade Based Approach to Intellectual Property Protection*, 17 SCI. COMM. 163 (1995) ("One of the most significant new issues in international trade is the protection of intellectual property."); see also Robert Weissman, *A Long, Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries*, 17 U. PA. J. INT'L ECON. L. 1069 (1996) ("[I]ntellectual property protection has become a central part of the free trade agenda, as well as the major global trade agreements."); see generally, MICHAEL P. RYAN, *KNOWLEDGE DIPLOMACY: GLOBAL COMPETITION AND THE POLITICS OF INTELLECTUAL PROPERTY* (1998) (explaining contemporary changes in international law and

the goal of free trade because it leads to trade distortions. Absent sufficient protection, creators can no longer recover the cost of their investment in research and development, resulting in lower production, fewer trading opportunities, and higher costs to the consumer."<sup>126</sup> "The protection of IP rights becomes an international trade issue due to the transfer of products, services and knowledge across borders in connection with international trade and business transactions."<sup>127</sup>

From a global economic point of view, permitting piracy distorts trade like any affirmative governmental intervention. As exporters or investors are reluctant to introduce products or transfer technology containing key intellectual property for fear that such property will be pirated, piracy becomes a barrier to trade. To the extent that such a trade barrier discourages free trade, it contributes to a decline in competitiveness in the affected countries.<sup>128</sup>

Susan Sell explores theoretical explanations for the rise of intellectual property rights onto the trade agenda of the world's more industrialized countries.<sup>129</sup> Sell tackles the issue of intellectual property rights in a North-South context.<sup>130</sup> She argues that "neorealism provides a compelling explanation for the adoption and substance of stronger policies for intellectual property protection, but interpretivist neoliberalism offers important insights to explain the discrepancy between policy

government policy regarding intellectual property protection); SUSAN K. SELL, *POWER AND IDEAS: NORTH-SOUTH POLITICS OF INTELLECTUAL PROPERTY AND ANTITRUST* (1998) (examining the politics and diplomacy of intellectual property rights and antitrust between developed and developing countries).

<sup>126</sup> Leaffer, *supra* note 31, at 276.

<sup>127</sup> Frank J. Garcia, *Protection of Intellectual Property Rights in the North American Free Trade Agreement: A Successful Case of Regional Trade Regulation*, 8 AM. U. J. INT'L L. & POL'Y 817 (1993).

<sup>128</sup> *Id.* ("Piracy has been defined as 'any unauthorized and uncompensated reproduction or use of someone else's creative intellectual achievement.'") (quoting J.H. Reichman, *Intellectual Property in International Trade: Opportunities and Risks of a GATT Connection*, 22 VAND. J. TRANSNAT'L L. 747, 775 (1989)).

<sup>129</sup> Susan K. Sell, *Intellectual Property Protection and Antitrust in the Developing World: Crisis, Coercion, and Choice*, 49 INT'L ORG. 315 (1995); SELL, *The Origins of a Trade-Based Approach to Intellectual Property Protection*, *supra* note 125; Sell, *POWER AND IDEAS*, *supra* note 125.

<sup>130</sup> SELL, *POWER AND IDEAS*, *supra* note 125.

adoption and implementation.”<sup>131</sup> For Sell, neorealism fails to capture the domestic political support for and opposition to changes in intellectual property regimes.<sup>132</sup>

Sell argues that a variant of neoliberalism that includes a state learning component is better able to account for changes in state preferences.<sup>133</sup> Interpretivism inquires into “the origin of preferences and the substance and redefinitions of interests.”<sup>134</sup> States’ interests are seen as intersubjective, defined by the relationship between would-be partners.<sup>135</sup> A process of learning produces a reevaluation of preferences that ultimately leads to a redefinition of interests. When this process fails to persuade leaders in a particular state, one of two outcomes is likely. Either states will fail to agree upon a cooperative solution or the cooperative solution obtained will go unheeded by certain states. In Sell’s words, “[i]f targeted countries do not accept the value orientation preferred by the powerful state, and no politically influential domestic constituency favors the new policies, one can expect nonimplementation and robust domestic resistance.”<sup>136</sup>

Sell’s interpretation of state action is open to criticism on at least two fronts. First, states must be immune to reputational considerations to domestically enact the outcomes of international negotiation with no intention of implementing that legislation.<sup>137</sup> In other words, states which develop a reputation for signing international agreements but not living up to their obligations under those agreements become very poor future bargaining partners.<sup>138</sup> Such states are likely to find themselves left out of

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<sup>131</sup> *Id.* at 176.

<sup>132</sup> *Id.* at 17 (“Structural neorealism is too indeterminate and diffuse to provide satisfactory explanations of the cases at issue here.”).

<sup>133</sup> *Id.* at 21-27.

<sup>134</sup> *Id.* at 22.

<sup>135</sup> *Id.* at 25; see, e.g., Alexander Wendt, *Anarchy Is What States Make of It: The Social Construction of Power Politics*, 46 INT’L ORG. 391 (1996).

<sup>136</sup> SELL, POWER AND IDEAS, *supra* note 125, at 177.

<sup>137</sup> THOMAS C. SCHELLING, ARMS AND INFLUENCE 55 (1966) (arguing, in a seminal work on interstate bargaining, that a state’s reputation is important).

<sup>138</sup> Barry Nalebuff, *Rational Deterrence in an Imperfect World*, 43 WORLD POL. 313, 315 (1991) (arguing that because states often have imperfect information about the intentions of other states, “[o]ne primary component of communication is the use of reputation . . . . Reputation, based on a long and consistent history of behavior, helps

future negotiations, as other states find such disregard for international arrangements unacceptable.<sup>139</sup>

Second, national governments must demonstrate to their domestic constituency that the new international agreement will not be enforced. That is to say, the government must be able to credibly commit to ignore laws it has enacted. This is important for two reasons. On the one hand, if the government enacts laws it has no intention of implementing, it runs the same problem domestically as outlined above internationally. More specifically, national governments that routinely pass laws that they do not enforce will have more difficulty enforcing laws in the future. On the other hand, if a national government cannot effectively commit, then it runs the risk of creating an incentive for domestic actors to take advantage of new rules and win sets and alter their actions—thereby creating a new domestic constituency who wants enforcement.

Other authors have argued that the United States was ill-served by placing intellectual property rights on the international trade agenda.<sup>140</sup> While these authors agree that “U.S. unilateral actions pushed the issue of intellectual property rights to the fore of the international negotiating agenda and sufficiently aggravated countries throughout the world to bring them to the multilateral negotiating table,”<sup>141</sup> they argue that bilateral negotiations were preferable to multilateral talks because bilateral talks avoided domestic costs. Gero and Lannan argue that “the multilateral approach meant that certain U.S. laws and practices would also have to be altered and thus create domestic American costs, which were not necessitated by unilateralism.”<sup>142</sup>

This conclusion is also incorrect. As illustrated by recent occurrences in Brazil, when the United States imposes trade sanctions against a Special 301 target country, those industries in

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predict the future”).

<sup>139</sup> Keohane & Nye, *supra* note 77, at 743 (arguing that states whose actions are counter to the principles of international agreements “may incur costs to their reputations, and therefore to their ability to make future agreements”).

<sup>140</sup> John Gero & Kathleen Lannan, *Trade and Innovation: Unilateralism v. Multilateralism*, 21 CAN.-U.S. L.J. 81 (1995).

<sup>141</sup> *Id.* at 89.

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

the United States that rely on importing targeted products and consumers who wish to purchase targeted products are adversely affected.<sup>143</sup> After trade sanctions were announced against Brazil in retaliation for lax intellectual property rights,

Opposition to products potentially subject to the sanctions was heard . . . from [c]orporate officials from General Electric, Xerox, Dow Chemical, Rohm & Haas Co., Ford Motors, Black & Decker and others [who] testified that proposed tariffs would increase costs from U.S. companies and consumers and would affect U.S. interests more than Brazilian interests.<sup>144</sup>

This clearly indicates that economic sanctions such as Special 301 are not without domestic opponents.<sup>145</sup> By not addressing the domestic opponents of international economic policy, of which trade-related intellectual property is a component, these authors failed to capture the true dynamics of the domestic bargaining that must accompany international institution building.

Michael Ryan's research suffers in much the same respect as Gero and Lannan.<sup>146</sup> Ryan's works on the politics of intellectual property have been excellent studies, but only so far as they go. Ryan is correct to argue that the pharmaceutical industry "demonstrated in the 1980s and 1990s an impressive capacity to push their interests in Washington and Geneva."<sup>147</sup> The lobbying groups who pushed for increased international intellectual

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<sup>143</sup> Myles Getlan, *TRIPs and the Future of Section 301: A Comparative Study in Trade Dispute Resolution*, 34 COLUM. J. TRANSNAT'L L. 173, 218 (1995).

<sup>144</sup> *Id.* at 189 n.90. General Electric opposed inclusion of imported electrical breakers; Rohm & Haas opposed inclusion of pesticides; Xerox objected to inclusion of copying paper; Dow Chemical objected to the inclusion of carbon tetrachloride; Ford Motor called for the removal of sound amplifiers and windshield wipers; Black and Decker objected to the inclusion of waffle-makers; and Carrier Corp claimed that it would have lost \$60-\$65 million if air conditioners were not removed from the list. *Id.*; see also *Administration Opens Hearings on Proposed Sanctions in Brazilian Pharmaceuticals Case*, 5 INT'L TRADE REP. (BNA) 1247 (1988) (noting that General Electric, Rohm & Haas, Xerox, and Dow Chemical "called for elimination of specific items from the list of possible targets for sanctions").

<sup>145</sup> See *Sanctions Hurt U.S. Hong Kong Firms More than China, Executives Say*, 9 INT'L TRADE REP. 56, 56-57 (1992) (noting that manufacturers and importers of appliances, electronic goods, magnets, and antibiotics objected to the use of punitive tariffs as a means of punishing China because "the decreases in sales as a result of higher prices would lead to the loss of 39,000 jobs [in the United States]").

<sup>146</sup> See, e.g., Ryan, *supra* note 103; RYAN, *supra* note 125.

<sup>147</sup> RYAN, *supra* note 125, at 9.

property standards, of which the pharmaceutical industry was a major factor, were “well managed, well staffed, well funded, and effective.”<sup>148</sup>

What is largely absent from Ryan’s analysis is the consideration of the competitive domestic political environment. The same Pharmaceutical Research Manufacturers Association (PRMA) that was so effective in promoting its members’ international policy objectives was ineffective in achieving success domestically. The question that Ryan never asks is: “Why was the PRMA not as “effective” in the domestic arena as it was in the international arena?”

#### IV. Pharmaceuticals in the United States

##### *A. Domestic Losses—The Drug Price Competition and Patent Term Restoration Act of 1984*

In the United States, where new drugs must pass rigorous safety and efficacy tests before they can be marketed, the effective life of a patent is shortened by the length of time a drug is under review.<sup>149</sup> Initially, U.S. politicians defined their policy choice set as shorter FDA review times or longer effective patent terms.<sup>150</sup> Then in 1978, President Jimmy Carter formed an advisory committee to investigate industrial innovation in the U.S.<sup>151</sup> One of the conclusions of those studies was that “the effective patent life for pharmaceutical products had fallen from 13.6 years to 9.5

<sup>148</sup> *Id.*

<sup>149</sup> See STUART O. SCHWEITZER, *PHARMACEUTICAL ECONOMICS AND POLICY* 200-201 (1997) (“Because firms usually seek patent protection as soon as a potential drug compound is identified, a large portion of the patent period can be taken up by the sponsor’s R&D activities and the US FDA’s review of the [New Drug Application] marketing application.”); see generally PETER TEMIN, *TAKING YOUR MEDICINE: DRUG REGULATION IN THE UNITED STATES* (1980) (providing a history of the regulation of the drug industry in the United States).

<sup>150</sup> *E.g.*, Morton Mintz, *Reagan Backed Repeal of Drug Effectiveness Law*, WASH. POST, Dec. 20, 1980, at A9 (quoting President Ronald Reagan, “[a]s long as a drug is safe, individuals and their doctors should be free to determine whether its use might be beneficial”); Morton Mintz, *Reagan Urged to Lift Price Lid on U.S. Drug Purchases*, WASH. POST, Nov. 21, 1980, at A14 (quoting Reagan, “[s]tart the clock on the 17-year drug patent monopolies not when the patent issues, . . . but when the FDA . . . approves the product for sale”).

<sup>151</sup> Peter Gwynee, *A Growing R&D Gap*, NEWSWEEK, July 3, 1978, at 3.

years and that this trend was continuing."<sup>152</sup>

After Ronald Reagan won the presidency, he too formed a commission to study U.S. competitiveness.<sup>153</sup> Reagan's Health Policy Advisory Group, headed by William Walsh, recommended, among other things, that patents be extended to cover a period equal to the time required for pre-market testing and regulatory review.<sup>154</sup> At the opening of the 97th Congress, "the highest drug-related legislative priority of the pharmaceutical industry, the Pharmaceutical Manufacturers Association [PMA], Congress, and the Reagan Administration [were] to extend effective patent lives."<sup>155</sup>

The idea of increasing patent protection to account for the time lost due to regulatory compliance had widespread support. The Washington Post supported the idea because "[i]f 17 years is the right period for protecting the exclusive rights of inventors, there is no reason why those subject to federal regulation should be denied it solely by reason of that regulation."<sup>156</sup> Echoing the Post, the New York Times offered editorial support for the measure, citing "the central issue [as] fairness."<sup>157</sup> Support in both chambers for patent term restoration was extensive; estimates ranged as high as 90 senators and two-thirds of the House backed the idea.<sup>158</sup>

Legislation was introduced in 1981 that called for patent extension only for time under regulatory review, thereby limiting the effective patent life to seventeen years.<sup>159</sup> S 255, as the measure was known, passed by voice vote of the full Senate on July 9 of that year.<sup>160</sup> Representatives Robert Kastenmeier of Wisconsin and

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<sup>152</sup> Alan D. Lourie, *A Political History of Patent Term Restoration: Part 1*, PHARMACEUTICAL EXECUTIVE, Jan. 1985, at 46.

<sup>153</sup> See Mintz, *supra* note 150, at A14.

<sup>154</sup> Marilou Sturges, *Cut! Chop! Energize!*, 1 PHARMACEUTICAL EXECUTIVE, Mar. 1981, at 21-26.

<sup>155</sup> Paul Clark, *A Question of Priorities*, 1 PHARMACEUTICAL EXECUTIVE, Oct. 1981, at 46.

<sup>156</sup> *Patently Fair*, WASH. POST, May 20, 1981, at A22.

<sup>157</sup> *The Half-Life Patents*, N.Y. TIMES, May 23, 1981, at A22.

<sup>158</sup> Judee Shuler, *Bill Haddad*, PHARMACEUTICAL EXECUTIVE, Mar. 1986, at 24, 27.

<sup>159</sup> S 255 was introduced on Jan. 27, 1981 by Charles Mathias of Maryland. Lourie, *supra* note 152, at 47.

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



Howard Sawyer of Illinois introduced a House version of S 255.<sup>161</sup> Before action could be taken in the House, however, a coalition of opponents of patent term extensions began to form.<sup>162</sup> Bill Haddad, who had worked for Senator Kefauver during his famous Senate hearings on the pharmaceutical industry,<sup>163</sup> had recently taken the post as president and chief executive officer of the Generic Pharmaceutical Industry Association (GPIA).<sup>164</sup> Haddad immediately began to mobilize opposition to the House bill, which, according to Haddad, “would have destroyed the generic industry.”<sup>165</sup>

Haddad and the GPIA faced an uphill battle. Support in both chambers for patent term restoration was extensive.<sup>166</sup> To change congressional minds, Haddad mobilized the generic drug industry’s natural allies: the elderly, represented by the National Council of Senior Citizens, the American Association of Retired Persons, the National Retired Teachers Association, big labor, represented by the AFL-CIO, and consumer advocacy groups such as Ralph Nader’s Health Research Group.<sup>167</sup> Haddad, who had also worked at the New York Post and New York Herald Tribune, presented the GPIA’s case to the Washington Post and the New York Times and succeeded in changing both papers’ editorial position on the issue of patent restoration.<sup>168</sup> After endorsing the original Senate bill because “[i]t would seem to make no sense to protect a toy for 17 years but an important drug . . . for only half that time,”<sup>169</sup> the New York Times reversed field and declared that “the law did not intend to guarantee every inventor a clear 17

<sup>161</sup> *Id.* (recording the House version as HR 1937).

<sup>162</sup> Caroline E. Mayer, *Drug Industry War Heats Up Over Generics; Name Brands Claim Generics Stifle Research*, WASH. POST, Dec. 20, 1981, at K1.

<sup>163</sup> ESTES KEFAUVER, *IN A FEW HANDS: MONOPOLY POWER IN AMERICA* (1965).

<sup>164</sup> Under Haddad’s leadership, the Generic Pharmaceutical Industry Association replaced the National Association of Pharmaceutical Manufacturers as the political voice of the generic drug industry. Shuler, *supra* note 158, at 26-27.

<sup>165</sup> *Id.* at 27.

<sup>166</sup> *Id.* (Haddad estimated “that the bill had the support of about 90 senators and two-thirds of the House”).

<sup>167</sup> *Id.*

<sup>168</sup> *Id.*

<sup>169</sup> *The Half-Life Patents*, *supra* note 157, at A22.

years of market monopoly."<sup>170</sup>

Because the patent restoration measure had already passed the Senate, the GPIA focused its efforts on the House vote. Haddad found support in Democratic Representatives Al Gore of Tennessee and Henry Waxman of California.<sup>171</sup> Through extensive lobbying, generic proponents were able to add a 'prospectivity' amendment that precluded extension of patents obtained before the bill's enactment.<sup>172</sup> By denying extensions to patents already granted, generic manufacturers were assured "that no extension would come into effect until almost the year 2000."<sup>173</sup>

After the bill was reported out of the Judiciary Committee on July 28, 1982, HR 6444 (as the bill was now known) was placed on the suspension calendar.<sup>174</sup> This meant that the bill could not be amended on the House floor, but it would require a two-thirds majority vote to pass. On September 15, 1982, HR 6444 "fell short by 5 votes of the two-thirds majority required."<sup>175</sup> The House Rules Committee did not schedule another vote and the measure died in the House.

When the 98th Congress began, the PMA found that the political climate had changed considerably. The GPIA and its supporters had galvanized a core of Democrats in the House led by Henry Waxman. Waxman introduced HR 3605 which eliminated the need for generic drug manufacturers to conduct their own safety and efficacy studies for drugs previously approved for marketing so long as the generic product was chemically and biologically equivalent.<sup>176</sup> Henry Waxman wanted to reinstate the

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<sup>170</sup> *An Unwarranted Patent Stretch*, N.Y. TIMES, Aug. 7, 1982, at A26.

<sup>171</sup> See Shuler, *supra* note 158, at 27.

<sup>172</sup> See Lourie, *supra* note 152, at 48.

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

<sup>174</sup> *Id.*

<sup>175</sup> *Id.* (On the day of the vote "morning fog grounded airplanes in the East and Midwest and kept a number of positive votes from getting to Washington").

<sup>176</sup> See generally TEMIN, *supra* note 149, at 142 (noting that "the increase in regulatory stringency during the 1960s roughly doubled the amount of resources needed to get a drug onto the market"). Before 1962, the FDA had allowed firms wishing to market copies of approved off-patent drugs to submit Abbreviated New Drug Applications (ANDA). An ANDA used the safety and efficacy studies performed by the pioneering firms as evidence of the safety and efficacy of the proposed generic copy. After 1962, generic drug manufacturers lost this condensed approval process, thereby

Abbreviated New Drug Application (ANDA) for generics and HR 3605, which he introduced in July of 1983, was the vehicle.<sup>177</sup>

While negotiations among the various interests were taking place, the Court of Appeals for the Federal Circuit decided the case of *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.*<sup>178</sup> This decision defined patent infringement as any activity of a commercial nature conducted before a patent's expiration for the purpose of obtaining data for submission to a federal regulatory agency.<sup>179</sup> In other words, the *Bolar* decision made it a crime to do what the Waxman bill proposed. Now any new legislation would have to overturn *Bolar* and redefine patent infringement in such cases. The ruling made the research pharmaceutical industry "believe that it was paying too high a price for much more limited patent term restoration than they had expected to receive."<sup>180</sup> Without congressional action on a new ANDA, which seemed unlikely without a compromise, the *Bolar* decision provided the research pharmaceutical industry with a powerful barrier to generic competition.

Unfortunately for the PMA, a congressional compromise was forthcoming. The compromise took the form of the Drug Price Competition and Patent Term Restoration Act of 1984.<sup>181</sup> "The Drug Price Competition and Patent Term Restoration Act is an outgrowth of demands for legislative relief by two segments of the pharmaceutical industry: the marketers of brand-name and generic

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increasing the time and cost associated with bringing a generic to market. *Id.*

<sup>177</sup> Alan D. Lourie, *A Political History of Patent Term Restoration: Part II*, PHARMACEUTICAL EXECUTIVE, Feb. 1985, at 44.

<sup>178</sup> 733 F.2d 858 (1984).

<sup>179</sup> *Id.* at 863.

*Bolar's* intended "experimental" use is solely for business reasons and not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry. *Bolar's* . . . use . . . to derive FDA required test data is thus an infringement of the [Roche] patent. *Bolar* may intend to perform "experiments," but unlicensed experiments conducted with a view to the adaption of the patented invention to the experimenter's business is a violation of the rights of the patentee to exclude others from using his patented invention.

*Id.*

<sup>180</sup> Lourie, *supra* note 152, at 49.

<sup>181</sup> Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 15 U.S.C. §§ 68b-68c, 70b (1994); 21 U.S.C. §§ 301 NOTE, 355, 360cc (1994); 28 U.S.C. § 2201 (1994); 35 U.S.C. §§ 156, 271, 282 (1994)).

drugs.”<sup>182</sup> For the innovators, the Act provides for the extension of certain patents, under particular conditions, for a finite period of time. The Act calls for the original patent applicant to apply for an extension within 60 days of marketing approval and while the patent is still valid.<sup>183</sup> The patent may then be extended, at the discretion of the Commissioner of Patents and Trademarks, for a term equal to the regulatory review period, which the Act defines as the sum of half the investigational period and the full post-investigational review period, less any time attributable to the applicant.<sup>184</sup> In any event, the patent extension cannot exceed five years or produce more than 14 years of effective patent life.<sup>185</sup>

The generic industry received its coveted ANDA provisions. To accomplish this, the Act overrules the *Roche v. Bolar* decision by making it legal for generic firms to use information gathered by the innovating firm in proving that the generic version of a particular drug is safe and effective.<sup>186</sup> To obtain ANDA approval, a generic firm “need only show that it has the requisite manufacturing capabilities, that its product is properly labeled,” and that the product is bioequivalent to the innovating drug.<sup>187</sup> To

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<sup>182</sup> James J. Wheaton, *Generic Competition and Pharmaceutical Innovation: The Drug Price Competition and Patent Term Restoration Act of 1984*, 35 CATH. U. L. REV. 433, 434 (1986); see also S. REP. NO. 104-394, at 10 (1996).

The Act struck a careful balance between two important public policy goals. One goal was to “make available more low cost generic drugs by establishing a generic drug approval procedure,” and the other was to strengthen incentives for pioneering research and development expenditures by pharmaceutical companies through the “restoration of some of the time lost on patent life while the product is awaiting pre-market clearance” from the FDA. *Id.* (citing H.R. REP. NO. 857 (Part I), 98th Cong., 2d Sess., at 14, 15 (1984)).

<sup>183</sup> Alan Kaplan & Robert Becker, *An Examination of the ANDA/Patent Restoration Law*, PHARMACEUTICAL EXECUTIVE, Dec. 1984, at 60, 63.

<sup>184</sup> Jonah Shacknai & Gregory M. Fisher, *The ANDA/Patent Extension Law: What Lies Within*, PHARMACEUTICAL EXECUTIVE, Jan. 1985, at 36, 41.

<sup>185</sup> *Id.*

<sup>186</sup> See 35 U.S.C. § 271(e) (1) (1999).

<sup>187</sup> Kaplan & Becker, *supra* note 183, at 60; see also Larry Thompson, *How Safe Are the Drugs You Take; Scandal at FDA Raises New Questions About Generic Medicines*, WASH. POST, Aug. 22, 1989, at Z12.

To see if a generic drug is bioequivalent to a brand-name medicine, researchers test a group of 10 to 24 healthy volunteers, usually males between the ages of 21 and 35 who are within 10 percent of their ideal body weight. The volunteers take one dose of the drug while fasting. If the levels of the generic compound in

facilitate the process of granting ANDAs, the Act requires that the original patent applicant submit to the FDA the expiration dates of all patents associated with the product.<sup>188</sup> The Act also provides the patent holder only forty-five days within which to file an action for infringement against an ANDA applicant.<sup>189</sup> If the patent holder fails to bring such an action within the forty-five days, the ANDA applicant is entitled to bring his or her product to market and remain there pending the outcome of the litigation.<sup>190</sup>

*Table 1: Effect of Waxman-Hatch Act on Overall Market Exclusivity for Pioneer Drugs<sup>191</sup>*

	Before Act	After Act
Effective Patent Life	9 years	11.7 years
Period between patent expiry and entry of generics	5-8 years	0 years
Total period of intellectual property protection	14-17 years	11.7 years
Financial Investment by generic firms to gain approval	\$10-100 million	> \$1 million

The impact of the Drug Price Competition and Patent Term Restoration Act of 1984 on the research pharmaceutical industry has been significant. A Congressional Budget Office study concluded that the Act's streamlined, abbreviated new drug approval process has increased generic competition.<sup>192</sup> The expansion of generic competition has "lowered the average returns

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the blood are the same as the blood levels of the brand-name drug, the two are considered equivalent and the drug is approved.

*Id.*

<sup>188</sup> Kaplan & Becker, *supra* note 183, at 60.

<sup>189</sup> Shacknai & Fisher, *supra* note 184, at 43.

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

<sup>191</sup> SCRIP'S YEARBOOK 1997 tbl.5.3.20 (1997).

<sup>192</sup> S. REP. NO. 104-394, at 11 ("ANDA's are vastly less expensive to secure than approval for a pioneer drug. Some ANDA's are obtained with an investment of less than \$100,000 and most cost less than \$1 million.").

from marketing a new drug by roughly 12 percent (or \$27 million in 1990 dollars).<sup>193</sup>

Before the Act (in 1983), only 35% of the top-selling drugs no longer under patent had generic copies available. Today, nearly all do. At the same time, the share of their market that those drugs lose to generic competition has also expanded dramatically. In 1980, generic drugs accounted for only about 13% of the total quantity of prescriptions sold for multi-source drugs. Fourteen years later, they constituted 58% of the total quantity of multiple-source prescriptions dispensed.<sup>194</sup>

A sign of the success of the Act is the speed with which research firms lose market share after patent expiry:

In the first half of 1993, U.S. brand-name pharmaceutical companies lost an average of 53% of market share to generic competition within a year after expiry of patent protection on their products. In 1989-91, the average loss of market share within a year on products whose patents had expired was 39 percent, rising to 49 percent in 1992.<sup>195</sup>

The situation is even worse if one looks at the top selling drugs.<sup>196</sup>

In one of the most celebrated cases, Glaxo Wellcome's anti-ulcer drug Zantac, the most prescribed drug in the world, lost 60 percent of its U.S. market share within four months of its patent expiry in August of 1997.<sup>197</sup> Glaxo Wellcome estimates that in a worst case scenario, 70-80 percent of Zantac's U.S. sales would be eroded in the first year following generic competition.<sup>198</sup> Given Zantac's 1996 sales, that represents a loss for Glaxo Wellcome of some \$1.3 billion.<sup>199</sup> Assuming Glaxo Wellcome would have maintained its sales of Zantac at 1996 levels, the passage of the Drug Price Competition and Patent Term Restoration Act reduced

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<sup>193</sup> CONG. BUDGET OFF., HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY ix (1998).

<sup>194</sup> *Id.* at 37.

<sup>195</sup> SCRIP'S YEARBOOK 1995 376 (1995).

<sup>196</sup> *See infra* notes 197-201 and accompanying text.

<sup>197</sup> SCRIP'S YEARBOOK 1998 1 (1998).

<sup>198</sup> *Id.* at 201.

<sup>199</sup> Glaxo Wellcome's sales of Zantac in the US totaled \$1.63 billion in 1996. *Generic Zantac Marketing Pact*, N.Y. TIMES, Aug. 5, 1997, at D4.

Glaxo's U.S. sales figures between \$4.89 and \$13.1 billion.<sup>200</sup>

Given the above, it seems hard to argue that the research pharmaceutical industry won the battle over patent term restoration.<sup>201</sup> Therefore, it seems equally premature to assume that the political power of the U.S. research pharmaceutical industry made the imposition of increased intellectual property rights abroad a foregone conclusion. Rather, it is entirely consistent with the then current domestic political climate that the U.S. research pharmaceutical industry would find itself losing support not only for increased patent rights abroad, but also for effective patent rights at home.

### *B. Pharmaceuticals—The International Environment*

Beginning in the late 1970s and early 1980s, new technology made reverse engineering of drugs easier and less expensive. This trend led to the proliferation of firms, primarily in the developing world, "pirating" the patented products of U.S. and European pharmaceutical manufacturers.<sup>202</sup> Many third world countries had developed production-scale chemical synthesis capabilities similar to what was available in the United States in the 1950s.<sup>203</sup> While this level of technological sophistication is inadequate to innovate new drugs, it is entirely adequate to reproduce an existing

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<sup>200</sup> The Act reduced the time between patent expiry and generic marketing approval from between three ( $3 \times 1.63 = 4.89$ ) to eight ( $8 \times 1.63 = 13.1$ ) years to less than one year. See SCRIP'S YEARBOOK 1997 tbl.5.3.20, *supra* note 191; CONG. BUDGET OFF., *supra* note 193.

<sup>201</sup> See, e.g., Raymond Brastow & David Rystrom, *Wealth Effects of the Drug Price Competition and Patent Term Restoration Act of 1984*, 32 AM. ECONOMIST 59 (1988) (arguing that, based on stock values, the generic drug companies benefited more than research firms); Ralph A. Lewis, *The Emerging Effects of the Drug Price Competition and Patent Term Restoration Act of 1984*, 8 J. CONTEMP. HEALTH L. & POL'Y 361, 367 (1992) (arguing that "[t]he tremendous growth of the generic drug industry has come at the expense of the brand name industry and has fostered stiff competition between the two").

<sup>202</sup> Leaffer, *supra* note 31, at 280 ("The incidence of piracy, both in the United States and abroad, has increased exponentially in the past decade. This trend will continue in large part because reproductive technologies have improved and become cost efficient, and the gap between the creation costs and reproduction costs has increased."). Pirating is the term that pharmaceutical companies use to describe the unlicensed production of patented drugs. Weissman, *supra* note 125, at 1088-89.

<sup>203</sup> Letter from Gary M. Pollack, Ph.D., University of North Carolina at Chapel Hill, Department of Pharmacy (July 30, 1998) (on file with author).

formulation. The chemical structure of a patented drug, and often its chemical synthesis, can be found either in the patent application or published in the pharmaceutical literature.<sup>204</sup> To begin unlicensed production of a patented drug, an interested party need merely invest in the "scale-up" process, a method which involves transferring a bench-level synthesis or extraction scheme to a procedure that could produce kilogram quantities of the active drug.<sup>205</sup> "If one ignores the patent protection, then the 'development process' is really quite simple."<sup>206</sup>

The industrialization of those developing countries that did not offer patent protection for pharmaceuticals encouraged domestic firms to engage in the unlicensed production of drugs that were under patent in other countries. U.S. pharmaceutical firms became concerned about this practice for two reasons.<sup>207</sup> First, unlicensed sales of patented drugs translated into current dollars lost. The unlicensed producers paid no royalty for the right to sell a patented drug, and therefore the patent-holder was unable to fully appropriate the income that his or her innovation generated.

Second, those countries without adequate intellectual property protection could be classified as higher risk countries for investment. As pharmaceutical firms in the developed countries searched for external markets for their products, they were confronted with the prospect of greater risks and lower appropriability. According to Harvey Bale, Vice President of the PMA, "[c]ompeting overseas is . . . the difference in reaching the

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<sup>204</sup> Glenn Law, *Liability under the Process Patent Amendments Act of 1988 for the Use of a Patented Process Outside the United States*, 60 GEO. WASH. L. REV. 245, 247 (1991).

<sup>205</sup> Letter from Gary M. Pollack, *supra* note 203; *see also* Milt Freudenheim, *Johnson & Johnson Looks Abroad*, N.Y. TIMES, Oct. 18, 1995, § 2, at 27 (quoting the chairman of Johnson & Johnson: "With computers and chemistry, scientists can go around patents much faster now. Within a year or two, you usually have somebody else right on your heels.").

<sup>206</sup> Letter from Gary M. Pollack, *supra* note 203.

<sup>207</sup> Carla A. Hills, *Trade-Related Aspects of Intellectual Property Rights*, Statement before the Subcomm. on Cts., Intell. Prop., and the Admin. of Justice of the House Judiciary Comm. on July 25, 1989, *reprinted in* DEP'T OF STATE BULL., Nov., 1989 hereinafter Statement of Carla A. Hills] ("First, U.S. companies lose exports and foreign sales, royalties, and the value of investments in the market where the American intellectual property right is appropriated without compensation. Second, our firms lose sales in third markets when unauthorized products are sold there.").



break-even point on the financial curve.”<sup>208</sup> The more foreign markets offering strict intellectual property protection for pharmaceuticals, the quicker U.S. research pharmaceutical firms could recoup the enormous research and development costs associated with bringing a new drug to market.

*C. Pharmaceuticals—An International Solution to a Domestic Problem: The Omnibus Trade Act of 1988*

The U.S. research pharmaceutical industry recognized the need to couple an international strategy for improving intellectual property standards with a domestic strategy of increasing the significance of intellectual property protection in U.S. trade policy.<sup>209</sup> In short, they sought to act as herestheticians, adding “theft” or “piracy” as another dimension in the domestic debate about pharmaceuticals and patents. The strategy that the research pharmaceutical industry adopted was a two-pronged effort. First, the research pharmaceutical industry began educating lawmakers and the public about the importance of the intellectual property-intensive sector to the U.S. economy and of intellectual property rights to that sector.<sup>210</sup> Second, the intellectual property-intensive industries began to lobby Congress to revise U.S. trade law to incorporate the enforcement of intellectual property as a prerequisite for continued, unfettered access to the U.S. market.<sup>211</sup>

First, the pharmaceutical industry was able to frame the issue of intellectual property protection by using the term “piracy” to refer to the unlicensed use of intellectual property. According to Weissman, “[t]he piracy metaphor effectively changed a policy debate into an absolutist moral drama. Theft is simply wrong, and theft by violence is even worse. There is no room for a policy discussion about the merits of piracy, nor any space for compromise in the direction of pirates.”<sup>212</sup>

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<sup>208</sup> Freudenheim, *supra* note 205, at 27.

<sup>209</sup> See Weissman, *supra* note 125, at 1075 (arguing that the pharmaceutical industry’s “main strategy was to persuade U.S. policy makers to coerce Third World countries to adopt restrictive patent rules”).

<sup>210</sup> *Id.* at 1076-77; see also RYAN, *supra* note 125, at 69.

<sup>211</sup> Weissman, *supra* note 125, at 1076.

<sup>212</sup> *Id.* at 1088. *But see* Leaffer, *supra* note 31, at 274 (“The term ‘piracy’ has no settled meaning in international law.”).

The pharmaceutical industry, acting as a heresthetician, was incredibly successful in adding the "piracy" dimension to the debate regarding drugs.<sup>213</sup> The industry spokespeople began to characterize the lack of patent protection in foreign countries as criminal.<sup>214</sup> Harvey E. Bale, Jr., Senior Vice-President of the PMA, called the theft of intellectual property "the biggest obstacle to foreign market access."<sup>215</sup> PMA President Gerald J. Mossinghoff alleged that "[t]here is no country in the world where patent piracy of valuable patented medicines has been more rampant or unchecked than India."<sup>216</sup> A PMA press release condemned "[t]he Thai government's support for patent piracy [that] allowed drug pirates to produce low quality and dangerous medicines."<sup>217</sup>

The U.S. media followed suit soon thereafter, criticizing foreign governments for supporting such illegal behavior. India and Brazil were called the "worst villains."<sup>218</sup> The Washington Post, the same paper that flip-flopped on patent term extension, exclaimed, "[p]iracy of copyrights, patents and other intellectual property costs the U.S. economy tens of billions of dollars and thousands of lost jobs every year."<sup>219</sup> The New York Times, which also reversed its position during the patent term extension debate, declared "[p]iracy of intellectual property . . . costs American manufacturers between \$8 billion and \$20 billion a year."<sup>220</sup>

Finally, the U.S. government began to portray the lack of intellectual property protection as stealing. President Reagan became convinced of the vulnerability of the intellectual property of U.S. corporations and pledged new efforts to protect intellectual property rights, stating that "[w]hen governments permit counterfeiting or copying of American products, it is stealing our

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<sup>213</sup> See *infra* notes 218-30 and accompanying text.

<sup>214</sup> See *infra* notes 215-17 and accompanying text.

<sup>215</sup> John Pearson et al., *The Patent Pirates Are Finally Walking the Plank*, BUS. WK., Feb. 17, 1992, at 125.

<sup>216</sup> *U.S. Cites India for Lack of Adequate Patent Protection but Delays Retaliation*, 9 INT'L TRADE REP. (BNA) 385 (Mar. 4, 1992).

<sup>217</sup> *USTR Finds Against Thailand on Patents, Delays Action Until After Thai Election*, 9 INT'L TRADE REP. (BNA) 478, 479 (Mar. 18, 1992).

<sup>218</sup> Pearson, *supra* note 215, at 125.

<sup>219</sup> Gary M. Hoffman & George T. Marcou, *Who's Stealing America's Ideas?*, WASH. POST, Nov. 5, 1989, at C3.

<sup>220</sup> Calvin Sims, *Wounded by Patent Piracy*, N.Y. TIMES, May 13, 1987, at D1.

future and it is no longer free trade.”<sup>221</sup> U.S. Trade Representative Clayton K. Yeutter said in a press conference, “I see no difference at all between stealing the patent for a product and stealing the product itself . . . . Thievery is thievery.”<sup>222</sup> Referring to the lack of strong intellectual property protection Yeutter stated, “[t]hat’s really an indefensible way to run a society. I don’t see how any nation in the world can defend piracy as a means of keeping consumer costs down.”<sup>223</sup> Pete Wilson, then Senator from California, called “for an end to foreign rip-offs of U.S. companies that produce records, movies, pharmaceuticals, computer software, and other products that have been pirated to the tune of billions of dollars each year.”<sup>224</sup> Senator Frank Lautenberg (D-NJ) said that “America’s economic advantage is its technology and innovation” and that “we need to stop the piracy of American intellectual property in order to protect this edge.”<sup>225</sup>

However, action in Congress was more important than the declarations of politicians. Hearings were held to address the inadequacy of intellectual property protection abroad. The hearing titles ranged from the innocuous (“Intellectual Property and Trade”)<sup>226</sup> to the aggressive (“International Piracy Involving Intellectual Property”).<sup>227</sup> Regardless of the title, the outcome was

<sup>221</sup> Bruce Stokes, *Intellectual Piracy Captures the Attention of the President and Congress*, NAT’L J., Feb. 22, 1986, at 443.

<sup>222</sup> John Burgess, *Global Product Piracy May Be Costing Firms Billions*, WASH. POST, Feb. 27, 1988, at B2.

<sup>223</sup> John Burgess, *U.S. Fighting to Protect ‘Intellectual Property’*, WASH. POST, Dec. 6, 1987, at H1.

<sup>224</sup> *USTR Defends Administration’s Naming of Japan, India, Brazil Under Super 301*, 6 INT’L TRADE REP. 684, 685 (May 31, 1989).

<sup>225</sup> *Problems of Trade, Intellectual Property Are Focus of American Bar Showcase Session*, 3 INT’L TRADE REP. 1063 (Aug. 20, 1986).

<sup>226</sup> *Hearings Before the Subcomm. on Courts, Civil Liberties, and the Administration of Justice, Comm. on the Judiciary*. House, Feb. 19, Apr. 23, May 21, 1986; see also *Intellectual Property Rights, Hearings Before the Subcomm. on International Trade, Comm. on Finance*. Senate, May 14, 1986; *Status of Intellectual Property Protection, Hearings Before the Subcomm. on Int’l Econ. Pol’y and Trade, Comm. on Foreign Affairs*. House, July 31, 1986; *Intellectual Property and Trade: 1987, Hearings Before the Subcomm. on Courts, Civil Liberties, and the Administration of Justice, Comm. on the Judiciary*. House, Mar. 18, 26, 1987.

<sup>227</sup> *Hearings Before the Subcomm. on Trade, Productivity, and Economic Growth, Comm. on Econ. Joint*, Mar. 31, 1986; see also *Unfair Foreign Trade Practices, Stealing American Intellectual Property: Imitation Is Not Flattery, Comm. Print* issued by the

the same: Congress became convinced that stronger intellectual property protection abroad was of fundamental importance to continuing U.S. international economic competitiveness.<sup>228</sup> As Carla A. Hills told the Subcommittee on Courts, Intellectual Property, and the Administration of Justice of the House Judiciary Committee,

Americans who engage in international trade are very concerned about the harm to U.S. trading interests that results from the lack of adequate and effective protection of intellectual property rights in many foreign markets. Our businesses are losing money, but more importantly, our economy is losing the competitive edge we gain from research and development, innovation and creativity. As a nation, we simply cannot afford it.<sup>229</sup>

A 1988 study by the U.S. International Trade Commission concluded that U.S. companies could be losing between \$43 billion and \$61 billion in worldwide sales because foreign competitors were unfairly copying or stealing U.S. intellectual property.<sup>230</sup>

Given their exposure to intellectual property piracy, it is not surprising to find that the research pharmaceutical industry led the

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*Comm. on Energy and Com.* House, Feb. 1984.

<sup>228</sup> See Burgess, *supra* note 222.

Washington once tended to look on piracy abroad as a nuisance. Now it is seen as a threat to U.S. economic vitality and one of the most serious of trade barriers facing U.S. manufacturers, on the assumption that piracy in a foreign country means that legitimate U.S. products will be shut out. "We get down to technology as the principle determinant of our competitiveness," said [U.S. Trade Representative Carl] Yeutter. *Id.*

19 U.S.C. § 2242 states:

(a) The Congress finds that

(A) international protection of intellectual property rights is vital to the international competitiveness of United States persons that rely on protection of intellectual property rights; and

(B) the absence of adequate and effective protection of United States intellectual property rights, and the denial of fair and equitable market access, seriously impede the ability of the United States persons that rely on protection of intellectual property rights to export and operate overseas, thereby harming the economic interests of the United States.

§ 1303, 19 U.S.C. § 2242 NOTE.

<sup>229</sup> Statement of Carla A. Hills, *supra* note 207.

<sup>230</sup> Burgess, *supra* note 222, at B2.

way among the U.S. intellectual property-intensive industries. The pharmaceutical industry relies on intellectual property protection more than any other U.S. industry.<sup>231</sup> As such, the industry's trade association, the PMA,<sup>232</sup> took the lead in promoting the need for increased intellectual property protection internationally. "PMA, one of the best organized, sufficiently funded, and powerful associations, has a long history of promoting IP protection around the world, with a specific focus on patent, trademark, and trade secret laws."<sup>233</sup> The pharmaceutical industry increased its considerable political clout by remaining one of the few U.S. industries to enjoy a trade surplus throughout the deficit-plagued 1980s.<sup>234</sup>

*Table 2: US Pharmaceutical and Medicinal Products Trade in 1988 in \$ million*<sup>235</sup>

	1988	% change	1987
Exports	3,941.3	+23.8	3,182.1
Imports	1,859.2	+27.7	1,455.6
Trade Surplus	2,082.1	+20.6	1,726.5

<sup>231</sup> Julio Nogues, *Patents and Pharmaceutical Drugs: Understanding the Pressures on Developing Countries*, 24 J. OF WORLD TRADE 81 (1990) (citing a survey of American industry reporting that the pharmaceutical industry would not have developed or introduced sixty-five percent of its inventions in the absence of patent protection. The next highest response, the closely related chemical industry, was only thirty percent.) (citing Edwin Mansfield, *Patents and Innovation: An Empirical Study*, MGMT. SCI., Feb. 1986)); see also Richard Levin et al., *Appropriating the Returns from Industrial Research and Development*, Yale University Working Paper, 1984 ("Recent interesting work suggests that there are wide differences among industries in the efficacy of patents. In the drug industry patents appear to be fairly effective, while in the semiconductor industry, they are considerably less so.") (cited in SHARON M. OSTER, MODERN COMPETITIVE ANALYSIS (1994)).

<sup>232</sup> The association would later change its name to the Pharmaceutical Research Manufacturers Association to better differentiate itself from the generic drug industry.

<sup>233</sup> Liu, *supra* note 16, at 106-07.

<sup>234</sup> Milt Freudenheim, *Pharmaceuticals Are Amongst the Few U.S. Products that Generate a Trade Surplus*, N.Y. TIMES, Jan. 1, 1992, at A49; see also Burgess, *supra* note 223, at H1 ("In an era of high trade deficits, products that fall under the rubric of intellectual property are among the few that consistently are running a surplus. The world . . . uses U.S. medicines and pharmaceuticals en masse . . . , with \$3.1 billion worth sold abroad in 1986.").

<sup>235</sup> SCRIP'S YEARBOOK 1989 (1989).

One of the reasons the pharmaceutical industry was so capable in its lobbying efforts was their liberal use of former government officials. The Pharmaceutical Manufacturers Association hired Gerald Mossinghoff as its president.<sup>236</sup> Mr. Mossinghoff had spent the previous five years as the Assistant Commerce Secretary and Commissioner of Patents and Trademarks in the Reagan administration.<sup>237</sup> As Vice President, the PMA hired Harvey E. Bale, Jr., who had worked for twelve years at the U.S. Trade Representative's Office.<sup>238</sup>

The first major foreign economic policy victory for the pharmaceutical industry came in the 1984 revisions to Section 301 of the Trade Act of 1974.<sup>239</sup> The 1974 Section 301 legislation was "broadly directed at foreign restrictions on US trade and [was] used to enforce trade rights as conferred by GATT and by bilateral treaties."<sup>240</sup> As amended in the Trade and Tariff Act of 1984, the scope of Section 301 has expanded beyond unreasonable trade practices to include such things as inadequate workers' rights, export targeting and anticompetitive practices.<sup>241</sup> Ambassador Clayton Yeutter, U.S. Trade Representative, called Section 301 "the H-bomb of trade policy" because it authorized the U.S.T.R. to demand unrequited trade concessions from America's trading partners.<sup>242</sup> Many in Congress felt, however, that the United States was not using its H-bomb enough.<sup>243</sup>

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<sup>236</sup> Weissman, *supra* note 125, at 1076.

<sup>237</sup> *Id.*

<sup>238</sup> *Id.*

<sup>239</sup> See Trade and Tariff Act of 1984, Pub. L. No. 98-573, 98 Stat. 2948. Ironically, the revisions to Section 301 that were included in the Trade and Tariff Act of 1984 came in the same year that the pharmaceutical industry was forced to compromise with the generic drug industry on a piece of domestic legislation titled the Drug Price Competition and Patent Term Restoration Act—a measure that benefited generic firms more than research firms. *Id.*

<sup>240</sup> Jagdish Bhagwati, *Aggressive Unilateralism: An Overview*, in AGGRESSIVE UNILATERALISM: AMERICA'S 301 TRADE POLICY AND THE WORLD TRADING SYSTEM 2 (Jagdish Bhagwati & Hugh T. Patrick eds., 1990).

<sup>241</sup> *Id.*

<sup>242</sup> Judith Hippler Bello & Alan F. Holmer, *The Heart of the 1988 Trade Act: A Legislative History of the Amendments to Section 301*, in AGGRESSIVE UNILATERALISM: AMERICA'S 301 TRADE POLICY AND THE WORLD TRADING SYSTEM 49, 52 (Jagdish Bhagwati & Hugh T. Patrick eds., 1990).

<sup>243</sup> *Id.* at 58.

Congress' answer, its "thermonuclear bomb" of foreign economic policy, came in the form of the Omnibus Trade and Competitiveness Act of 1988 (Omnibus Trade Act).<sup>244</sup> The Omnibus Trade Act declares that the "international protection of intellectual property rights is vital to the international competitiveness of United States persons that rely on protection of intellectual property rights."<sup>245</sup>

The Omnibus Trade Act defined the "Overall and Principal Trade Negotiating Objectives of the United States."<sup>246</sup> To ensure

<sup>244</sup> Pub. L. No. 100-418, 102 Stat. 1107 (1988); *see also U.S.T.R. Fact Sheets on Super 301 Trade Liberalization Priorities and Special 301 on Intellectual Property*, 6 INT'L TRADE REP. (BNA) 715, 719 (1989):

The U.S.T.R. also noted that the focus on . . . intellectual property efforts in trade negotiations coincided with the inclusion of provisions on intellectual property in various U.S. trade statutes. This statutory development began almost a decade ago with an amendment to section 301 in Senator Danforth's reciprocity bill which was enacted as part of the Trade and Tariff Act of 1984. The Omnibus Trade and Competitiveness Act of 1988's Special 301 provisions continued this Congressional priority, and its implementation has contributed positively to U.S. efforts to ensure adequate and effective intellectual property protection.

<sup>245</sup> Omnibus Trade Act, § 1303(a)(1)(A), 102 Stat. 1179 (1988).

<sup>246</sup> 19 U.S.C. § 2901, 100 Pub. L. No. 418, 102 Stat. 1107, §1101(b)(10). According to the Act,

The principal negotiating objectives of the United States regarding intellectual property are:

(A) to seek the enactment and effective enforcement by foreign countries of laws which

(i) recognize and adequately protect intellectual property, including copyrights, patents, trademarks, semiconductor chip layout designs, and trade secrets, and

(ii) provide protection against unfair competition;

(B) to establish in the GATT obligations

(i) to implement adequate substantive standards based on

(I) the standards in existing international agreements that provide adequate protection, and

(II) the standards in national laws if international agreement standards are inadequate or do not exist,

(ii) to establish effective procedures to enforce, both internally and at the border, the standards implemented under clause (i), and

(iii) to implement effective dispute settlement procedures that improve on existing GATT procedures;

that the intellectual property rights of Americans were enforced abroad, the Act amended Section 301 of the Trade Act of 1974. As amended, the Act defines as unreasonable, “[a]n act, policy, or practice . . . while not necessarily in violation of, or inconsistent with, the international legal rights of the United States, is otherwise unfair and inequitable.”<sup>247</sup> The Act specifically includes as unreasonable “any act, policy, or practice, or any combination of acts, policies, or practices, which . . . denies fair and equitable provision of adequate and effective protection of intellectual property rights.”<sup>248</sup>

Within the Omnibus Trade Act is an intellectual property-specific measure titled Special 301.<sup>249</sup> Special 301 is the name commonly used to describe Section 182 of the Trade Act of 1974, as amended by the 1988 Omnibus Trade Act. Congress created Special 301 to address the “growing problem of inadequate and ineffective intellectual property protection.”<sup>250</sup> “Special 301 was, and continues to be, based on the assumption that the United States could use threats and negotiation to obtain meaningful changes in the intellectual property regimes of its trading partners.”<sup>251</sup>

Special 301 directs the U.S. Trade Representative to identify, within thirty days after submission of the annual National Trade Estimates (foreign trade barriers) report to Congress, those foreign countries that “deny adequate and effective protection of intellectual property rights,”<sup>252</sup> or “deny fair and equitable market access to United States persons that rely upon intellectual property

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(C) to recognize that the inclusion in the GATT of

- (i) adequate and effective substantive norms and standards for the protection and enforcement of intellectual property rights, and
- (ii) dispute settlement provisions and enforcement procedures.

*Id.*

<sup>247</sup> § 1301; *see also* 19 U.S.C. § 2411 (d)(3)(A).

<sup>248</sup> § 1301; *see also* 19 U.S.C. § 2411 (d)(3)(B).

<sup>249</sup> Omnibus Trade Act, §§ 1301, 1303, 102 Stat. 1164-76, 1179-81 (1988) (amending the Trade Act of 1974, Pub. L. No. 93-316, §§ 302(b), § 182 (1974)).

<sup>250</sup> S. REP. NO. 71, 100th Cong., 1st Sess. 74-75 (1987).

<sup>251</sup> John Gero & Kathleen Lannan, *Trade and Innovation: Unilateralism v. Multilateralism*, 21 CAN.-U.S. L.J. 81, 84 (1995).

<sup>252</sup> 19 U.S.C. § 2242(a)(1)(A) (1988).



protection.”<sup>253</sup> “Special 301 was devised solely to enhance the protection of intellectual property rights by foreign governments, and it demands that investigations be conducted on an expedited basis, faster than a normal section 301 investigation.”<sup>254</sup>

While Section 1303 of the Omnibus Trade and Tariff Act enumerates only one category—priority foreign country—in implementing this legislation, the Trade Representative has promulgated three additional classifications (bringing the total number to four, listed as follows in descending degree of severity): Priority Foreign Country, Priority Watch List, Watch List, and Special Mention.<sup>255</sup> The U.S.T.R. must then within six months complete an investigation and seek to negotiate a bilateral settlement. If the U.S.T.R. is unable to remedy the situation, it is authorized, but not required, to retaliate by increasing duties or imposing other trade restrictions.

The Watch List is the least serious of the Special 301 categories. Countries placed on the Watch List are put on notice that the U.S. believes that the country’s intellectual property regime is lacking in some capacity. The first Watch List contained Argentina, Canada, Chile, Colombia, Egypt, Greece, Indonesia, Italy, Japan, Malaysia, Pakistan, Philippines, Portugal, Spain, Turkey, Venezuela, and Yugoslavia.<sup>256</sup> Watch List-ed countries can expect to be in regular contact with the U.S.T.R.

If a Watch List-ed country fails to satisfy U.S. demands for improved intellectual property protection, that country faces the possibility of being upgraded to Priority Watch List grading. Typically, for a Priority Watch List country the U.S.T.R. has formed some set of precise objectives towards which the relevant country must work in order to satisfy U.S. demands. The U.S.T.R. initially listed Brazil, India, Republic of Korea, Mexico, China, Saudi Arabia, Taiwan, and Thailand on the Priority Watch List.<sup>257</sup>

<sup>253</sup> 19 U.S.C. § 2242(a)(1)(B) (1988).

<sup>254</sup> Judith H. Bello & Alan F. Holmer, “Special 301”: *Its Requirements, Implementation, and Significance*, 13 FORDHAM INT’L L.J. 259, 263 (1990).

<sup>255</sup> 19 U.S.C. § 2420, § 310(a)(1)(B).

<sup>256</sup> Office of the United States Trade Representative, *Fact Sheet “Special 301” on Intellectual Property*, May 25, 1989, reprinted in 6 INT’L TRADE REP. (BNA) 22, 719 (May 31, 1989).

<sup>257</sup> *Id.*

If the U.S.T.R.'s efforts fail at this second stage, a country may be designated a Priority Foreign Country (PFC). "Priority Foreign Countries are those on trade's death row."<sup>258</sup> These countries have "the most onerous or egregious acts, policies, or practices" with respect to intellectual property protection.<sup>259</sup> Priority Foreign Countries are likely to face retaliatory trade sanctions if they do not quickly move to remedy their intellectual property regime's shortcomings.

The U.S.T.R. must employ three criteria to identify a Priority Foreign Country. First, does the country's intellectual property regime deny adequate protection or market access to those who rely on intellectual property protection?<sup>260</sup> Second, does the country's intellectual property regime have an actual or potential impact on the relevant U.S. products?<sup>261</sup> Third, has the country entered into negotiations or made significant progress towards remedying the inadequate protection problem?<sup>262</sup> When the answer to the first two questions is yes, and the answer to the last question is no, the U.S.T.R. designates the country as a Priority Foreign Country and begins Special 301 proceedings.

Special 301 relies on the "fire-alarm" oversight method.<sup>263</sup> Clearly neither Congress nor the U.S.T.R. can be expected to closely monitor the intellectual property regimes of all U.S. trading partners. Therefore, the provisions of Special 301 allow private interests—for example, U.S. intellectual property-intensive industries—to submit complaints to the U.S.T.R. regarding what those interests consider to be actionable Special 301 violations.<sup>264</sup> "U.S. industries, associations, and private persons play a major role in the Special 301 process by providing firsthand information

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<sup>258</sup> Drahos, *supra* note 62, at 51.

<sup>259</sup> *Id.*

<sup>260</sup> 19 U.S.C. § 2242(b)(1)(A) (1994).

<sup>261</sup> *Id.* § 2242(b)(1)(B).

<sup>262</sup> *Id.* § 2242(b)(1)(C).

<sup>263</sup> Mark D. McCubbins & Thomas Schwartz, *Congressional Oversight Overlooked: Police Patrols Versus Fire Alarms*, 28 AM. J. POL. SCI. 165 (1984).

<sup>264</sup> 19 U.S.C. § 2412(a)(1) (1994). "Any interested person may file a petition with the Trade Representative requesting that action be taken under section 301 [19 U.S.C.S. § 2411] and setting forth the allegations in support of the request." *Id.*; see also Liu, *supra* note 16, at 98 (stating that by the end of 1992, there had been ninety cases of Section 301 investigations, seventy-two of which were instituted by industries).

on foreign trade practices and assisting in the development of trade strategy. Throughout the review process, the United States Trade Representative solicits and accepts submissions from interested parties.<sup>265</sup> The U.S.T.R. uses that information in determining whether Special 301 actions should be initiated against those countries alleged to be violating the intellectual property rights of U.S. intellectual property-intensive industry.

## V. Canada

### A. Canada—A History of Compulsory Licensing

Canada is an important trading partner for the U.S. pharmaceutical industry. In 1992, U.S. pharmaceutical companies exported \$845 million in pharmaceuticals to Canada.<sup>266</sup> Together, Canada and Mexico account for fifteen percent of all U.S. exported pharmaceuticals.<sup>267</sup> It should come as no surprise, therefore, that Canada's system of granting compulsory licenses for patented pharmaceuticals is considered unfair by the U.S. research pharmaceutical industry.<sup>268</sup> It is also not surprising that the U.S. research pharmaceutical industry attempted to make compulsory licensing an important issue in U.S.-Canada trade relations.<sup>269</sup>

Because Canada and the United States share a common

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<sup>265</sup> Thomas C. Bickham, *Protecting U.S. Intellectual Property Rights Abroad with Special 301*, 23 AIPLA Q.J. § 2, 195, 197 (1995).

<sup>266</sup> Silberman, *supra* note 20, at 621 (citing *Pharmaceuticals*, MEX. TRADE & L. REP., July 1, 1994, at 24).

<sup>267</sup> *Id.* (noting that of the \$987 million in U.S. pharmaceutical exports to Canada and Mexico, only \$142 million, or just over fourteen percent, are to Mexico, indicating that as between Canada and Mexico, Canada is by far the larger consumer of U.S. pharmaceutical products).

<sup>268</sup> *A Licensing Law that Hurts U.S. Drugmakers*, BUS. WK., Mar. 1, 1982, at 34 (quoting William M. Robson, President of the research pharmaceutical company Smith Kline & French Canada Ltd., as saying the law amounted to expropriation of patent rights).

<sup>269</sup> David Crane Star, *Trade Talks Jeopardizing Drug Prices, Expert Says*, TORONTO STAR, Nov. 20, 1991, at C9 (reporting that Robert Sherwood, a U.S. expert on intellectual property law, had stated that the "granddaddy" issue in the North American Free Trade Area negotiations was the Canadian treatment of compulsory licenses for pharmaceutical patents). "It is a repeat of the issue fought out so intensely in the Canadian-U.S. free trade agreement just a few years ago." *Id.*

jurisprudence, it is not surprising that the intellectual property regimes of the two countries are rather similar.<sup>270</sup> The most significant difference between the U.S. and Canada is that the Canadian regime has historically been very liberal in granting compulsory licenses.<sup>271</sup>

Canada's use of compulsory licensing dates back to the 1923 amendments to the Patent Act.<sup>272</sup> Those amendments allowed "individuals or corporations to apply to the Commissioner of Patents for a compulsory license to use a patented process to manufacture a drug in Canada."<sup>273</sup> Given the size of the Canadian market, the requirement that the compulsory licensed drug be manufactured domestically led to an underutilization of compulsory licensing for pharmaceuticals.<sup>274</sup>

During the late 1950s and early 1960s, the price of patented drugs became a growing political concern. In 1961, the Restrictive Trade Practices Commission (RTPC) issued its Report Concerning the Manufacture, Distribution and Sale of Drugs.<sup>275</sup> This report concluded that "drug prices were excessive; that there was little price competition; and that patents inhibited competition."<sup>276</sup> The Royal Commission on Patents, Copyrights and Industrial Designs, also known as the Ilsley Commission, had reached similar conclusions in 1960.<sup>277</sup> The Royal Commission on Health Services,

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<sup>270</sup> Garcia, *supra* note 127, at 829. "Canada and the United States are familiar with each other's [intellectual property] enforcement system because of geographic proximity and similar common law traditions." *Id.* But see Silberman, *supra* note 20, at 620-21 (noting that while patent laws in both the United States and Canada perceive patent rights as a vehicle to encourage invention, the two differ philosophically in that the Canadian system is also designed to insure that new inventions will be manufactured in Canada on a commercial scale without delay).

<sup>271</sup> See *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980) (stating that compulsory licensing is a rarity in the U.S. patent system).

<sup>272</sup> Joel Lexchin, *Pharmaceuticals, Patents, and Politics: Canada and Bill C-22*, 23 INT'L J. HEALTH SERVS. 147, 148 (1993).

<sup>273</sup> *Id.*

<sup>274</sup> *Id.*; see generally David J. Fowler & Myron J. Gordon, *The Effect of Public Policy Initiatives on Drug Prices in Canada*, 10 CAN. PUB. POL'Y 64, 65 (1984).

<sup>275</sup> CAMPBELL & PAL, *supra* note 6, at 32 (citing RESTRICTIVE TRADE PRACTICES COMMISSION, REPORT CONCERNING THE MANUFACTURE, DISTRIBUTION AND SALE OF DRUGS (1963)).

<sup>276</sup> *Id.*

<sup>277</sup> *Id.* (citing ROYAL COMMISSION ON PATENTS, COPYRIGHTS AND INDUSTRIAL

also known as the Hall Commission, concluded in its 1964 report that “either the industry will make . . . drugs available at the lowest possible cost, or it will be necessary for . . . government to do so.”<sup>278</sup>

Rising drug costs and greater political scrutiny led the Liberal government in 1967 to introduce Bill C-190.<sup>279</sup> As proposed, C-190 would allow compulsory licensing to import prescription drugs.<sup>280</sup> Allowing compulsory licensees to import patented drugs would eliminate the largest barrier to entry: the manufacturing restriction.

The compliance provisions were fairly simple. According to the compulsory licensing provisions, the Commissioner of Patents was obliged, under the Act as it then existed, to grant a license to the applicant unless there was a good reason not to grant the license.<sup>281</sup> The Commission of Patents also had the power to set the royalty rates, which were somewhat arbitrarily set at four percent of the “licensee’s selling price.”<sup>282</sup>

Needless to say, the research pharmaceutical industry was adamantly opposed to C-190. Industry experts “estimated that the net present value to the originator of Canadian sales of such a drug would be reduced through compulsory licensing by 44% of the original value.”<sup>283</sup> The lobbying group that represents those interests, the Pharmaceutical Manufacturers Association of Canada (PMAC) lobbied furiously against the change.<sup>284</sup> The

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DESIGNS, REPORT (1960)).

<sup>278</sup> *Id.* at n.9 (citing ROYAL COMMISSION ON HEALTH SERVICES, REPORT 40 (1964)).

<sup>279</sup> *Id.* at 33.

<sup>280</sup> *Id.*

<sup>281</sup> *Eli Lilly & Co. v. Novopharm Ltd.*, [1998] S.C.R. LEXIS 37, 19; *see also* *Frank W. Horner v. Hoffman-La Roche Ltd.*, [1970] 61 C.P.R. 243, 243.

<sup>282</sup> Paul K. Gorecki & Ida Henderson, *Compulsory Patent Licensing of Drugs in Canada*, 7 CAN. PUB. POL’Y 559, 560 (1981); *see Horner*, 61 C.P.R. at 245 (stating that the royalty was fixed at 4% of the net selling price of the medicine by the applicant in its final dosage form as sold to purchasers at arm’s length); *see also* BRIAN G. BRUNSVOLD & DENNIS P. O’REILLY, *DRAFTING PATENT LICENSE AGREEMENTS* 94 (4th ed. 1998) (noting that under U.S. practice, royalty rates are not fixed and can be more than fifty percent).

<sup>283</sup> *Smith Kline & French Labs., Ltd. et al. v. Att’y Gen. of Can.*, [1985] 7 C.P.R.3d 145, 164.

<sup>284</sup> Joel Lexchin, *Drug Lobby Hasn’t Finished with Canada Yet*, TORONTO STAR, Sept. 19, 1990, at A25 (arguing that the Pharmaceutical Manufacturers Association of

PMAC's opposition effort cost the group an estimated CDN\$250,000 annually.<sup>285</sup> The compulsory licensing system was challenged on civil rights grounds,<sup>286</sup> on constitutional grounds,<sup>287</sup> and as ultra vires of the Parliament.<sup>288</sup> "By 1971, of the 69 licenses issued there had been 43 appeals before the courts."<sup>289</sup> The Canadian courts took notice of this trend and admonished PMAC members to cease the seemingly reflexive practice of bringing suit challenging all compulsory licenses.<sup>290</sup>

Even though the compulsory licensing law was already more than a decade old, compulsory licensing became an important trade issue for the United States when Ronald Reagan became president in 1981.<sup>291</sup> U.S. research drug companies began to report that the effects of Canada's compulsory licensing system were threatening the industry's profitability.<sup>292</sup> The industry was also

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Canada (PMAC) fought compulsory licensing every step of the way).

<sup>285</sup> Lexchin, *supra* note 272, at 148.

<sup>286</sup> *Am. Home Prods. Corp. v. Comm'r of Patents*, [1970] 62 C.P.R. 155, 160 (O.A.C.) (expressing the court's opinion that the amending legislation did not deal with civil rights as such, but only as incidental to the matter of patents and was not ultra vires Parliament).

<sup>287</sup> *Am. Home Prods. Corp. v. Comm'r of Patents*, [1982] 68 C.P.R.2d 257 (F.C.) (holding that Canada's compulsory licensing laws did not conflict with Canada's Bill of Rights protection of property).

<sup>288</sup> *Smith Kline et al.*, 7 C.P.R.3d at 176 (concluding that "this subsection, by making the grant of a patent for medicine subject to compulsory licensing is simply limiting the scope of the property right, the monopoly, which Parliament is authorized but not obliged to grant").

<sup>289</sup> Lexchin, *supra* note 272, at 148.

<sup>290</sup> *See Lilly v. S & U Chemicals Ltd.*, [1973] 9 C.P.R.2d 17, 18.

Certainly, there is, in our view, some ground for thinking that many appeals under s. 41 of the Patent Act are brought regardless of any considered opinion that there is, under the authorities, any valid ground for attacking the Commissioner's decision. In this case, we have decided to give the appellant the benefit of the doubt but we do not wish it to be thought that we will be so charitable in the future.

*Id.*

<sup>291</sup> David Crane, *Drug Bill Concessions Seem Tied to Trade Talks*, TORONTO STAR, Dec. 7, 1986, at B1 ("U.S. pressure for change in the Canadian legislation began before the Canada-U.S. free trade talks, intensifying in the early 1980s with the election of the Reagan administration.").

<sup>292</sup> *A Licensing Law that Hurts U.S. Drugmakers*, *supra* note 268, at 34 (noting that the after-tax profit margin of research pharmaceutical firms fell from 7% in the early

worried about the impact of compulsory licenses on the future of the industry as technological breakthroughs loomed in a whole series of drugs used in the treatment of heart ailments, hypertension, and ulcers.<sup>293</sup> As early as 1982, U.S. Trade Representative William E. Brock raised the issue of compulsory licensing with Canadian counterpart Trade Minister Edward Lumley.<sup>294</sup>

So long as the Canadian economy was strong, there was little effective political opposition to compulsory licensing.<sup>295</sup> However, when the economy began to experience the effects of the slow-down in the U.S. economy,<sup>296</sup> “the discourse surrounding drug

1970s to 4% in 1981); see also Bernard Simon, *Drug Groups Press for Protection*, FIN. TIMES, Mar. 12, 1985, at 6 (noting that the Canadian market was then the ninth largest pharmaceutical market in the world, with sales estimated at CND \$1.2 billion). Because of the size of the Canadian market, it was an important one for U.S. drug companies. *Id.*

<sup>293</sup> *A Licensing Law that Hurts U.S. Drugmakers*, *supra* note 268, at 34. Donald D. Davies, President of Ayerst Laboratories, a division of American Home Products Corp., was quoted as saying, “[t]he licenses are on the most spectacular drugs that have taken the biggest investment.” *Id.*; see also *An Anti-Depressant for America’s Drug Industry*, THE ECONOMIST, Jan. 12, 1985, at 70-71 (noting that the drug companies grumble about generic equivalents coming on the market in Canada before the patents on their products have expired).

<sup>294</sup> *A Licensing Law that Hurts U.S. Drugmakers*, *supra* note 268, at 34; see also Crane, *supra* note 291, at B1.

At a Canada-U.S. conference in November, 1983, a top U.S. trade official, William Merkin of the Office of the U.S. Trade Representative, included the pharmaceutical legislation as an example of a “protectionist” Canadian policy. “While the legislation was intended to address assertions that foreign pharmaceutical companies were making inordinately high profits,” Merkin complained, “its effect has been to allow companies that have not contributed to the costly and risky research and development process to invade the market of the innovator, reducing his return and his incentive to invest in new product research and development.” *Id.*

<sup>295</sup> See CAMPBELL & PAL, *supra* note 6, at 33.

<sup>296</sup> Winston Williams, *Glory Days End for Pharmaceuticals*, N.Y. TIMES, Feb. 24, 1985, § 3, at 1.

After years of profits so fat that they immunized the \$30 billion American pharmaceutical industry against economic downturns, the big drug companies have suddenly found themselves mired in the same sort of troubles that have plagued less-glamorous industries for years. Spiraling imports, legislative changes and new competition at home and abroad have struck hard. And with new blockbuster products harder and harder to come by, America’s supremacy as the world’s premier maker and seller of prescription drugs could be in jeopardy.

*Id.*

patent policy changed gradually but inexorably."<sup>297</sup> The Liberal Canadian Prime Minister Trudeau, a longtime advocate of compulsory licensing, became concerned about the lack of research being undertaken in Canada.<sup>298</sup>

Trudeau was potentially vulnerable to the protests of the research pharmaceutical industry because it was concentrated in Quebec, where half the Liberal caucus was based.<sup>299</sup> When Smith, Kline and French, Hoffman-La Roche, and American Home Products subsidiary Ayerst, McKenna and Harrison all closed Quebec operations, employment suddenly became an important component of the drug patent debate.<sup>300</sup> There were predictions that "Canada could lose as much as \$75 million/year (Canadian) that is invested in pharmaceutical research and development."<sup>301</sup> Gilbert Paquette, Quebec's Minister for Science and Technology, in a letter to Andre Ouellet, Canada's Minister of Consumer and Corporate Affairs and the person responsible for proposing any modifications in the patent law, called for the repeal of compulsory licensing.<sup>302</sup> Paquette argued in the letter that "since 1969, when Section 41 of the patent act was amended, industry and pharmaceutical research in Quebec [has] been heavily penalized. Their survival is in danger."<sup>303</sup>

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<sup>297</sup> CAMPBELL & PAL, *supra* note 6, at 34.

<sup>298</sup> *Id.*

<sup>299</sup> *Id.*

<sup>300</sup> See David Oxtoby, *Drug Industry Awaits Compulsory Licensing Verdict*, FIN. POST, Mar. 9, 1985, § 3, at 11; see also John Sawatsky & Harvey Cashore, *Inside Dope: The Multi-Million Dollar Sellout of Canada's Generic Drug Industry*, 20 THIS MAGAZINE § 3, at 8 (1986).

<sup>301</sup> *Canada May Water Down Its Law on Drug Licensing*, CHEM. WK., May 18, 1983, at 45.

<sup>302</sup> *Id.*

<sup>303</sup> *Id.*; see also *Mediating a Drug-Patent Hassle*, CHEM. WK., June 15, 1983, at 15.

Ouellet [offered] three possible courses that [were] designed mainly to make research and development activity in Canada more attractive to multinational pharmaceutical producers. One course would retain the compulsory licensing system now in effect, but would change the standard 4% royalty rate, pegging the amount to reward R&D investment by the patent holder. A second proposal is for a "mini-patent" system for pharmaceutical products that would provide protection between the void in current legislation and the 17 years for other inventions. The third idea: Eliminate compulsory licenses when companies agree to certain price levels and R&D investment.



In response to pressure from both proponents and opponents of compulsory licensing, Judy Erola, Ouellet's replacement as Minister of Science and Technology, appointed a Royal Commission of Inquiry on the Pharmaceutical Industry.<sup>304</sup> The Commission, which became known as the Eastman Commission after its chairman, University of Toronto economist Harry Eastman, released its report in May 1985.<sup>305</sup> The report concluded that the Canadian research pharmaceutical industry was not adversely affected by compulsory licensing, that Canadian consumers had saved \$211 million in 1983, and that patent policy in Canada had little or no effect on the research and development investment decisions of multinationals.<sup>306</sup> "The report suggested giving new drugs four years of protection and creating a royalty fund to reward firms doing their R&D in Canada."<sup>307</sup>

Between the appointment of the Eastman commission and the release of its conclusions, Canada held a federal election. Conservative candidate Brian Mulroney won the election in a landslide. Just as the outgoing Liberals had, Mulroney's Conservatives drew a disproportionate number of its Parliamentarians from Quebec.<sup>308</sup> Unlike the Liberals, Mulroney's Conservatives had no historical affection for compulsory licensing.

### *B. Canada: The Canada-U.S. Trade Agreement and Bill C-22*

U.S. President Reagan and Canadian Prime Minister Mulroney met in March 1985 in Quebec City at what came to be called the Shamrock Summit.<sup>309</sup> Canada's compulsory licensing system was item number three on Reagan's agenda.<sup>310</sup> At the conclusion of the

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*Id.*

<sup>304</sup> CAMPBELL & PAL, *supra* note 6, at 37 (calling Erola's commissioning of a study "a quintessential Canadian move").

<sup>305</sup> David Oxtoby, *supra* note 300.

<sup>306</sup> See McDONALD, *supra* note 18, at 207.

<sup>307</sup> CAMPBELL & PAL, *supra* note 6, at 38.

<sup>308</sup> Sawatsky & Cashore, *supra* note 300, at 10.

<sup>309</sup> Lexchin, *supra* note 272, at 151.

<sup>310</sup> Gord Crann, *Patent Act Could Be Mulroney's Undoing*, TORONTO STAR, Nov. 30, 1986, at F3 (reporting that President Reagan raised the matter of Canadian drug patent laws with Mulroney as item number three at the first Shamrock Summit in Quebec city on Mar. 17, 1985).

meeting, Reagan and Mulroney issued a communiqué directing U.S. Trade Representative William Brock and Canadian Trade Minister James Kelleher to resolve some eight "specific impediments to trade."<sup>311</sup> One of the eight specific impediments identified in the communiqué was "abuses of copyright and patent law."<sup>312</sup> "The communiqué also talked of developing 'common standards and understandings regarding patents . . .'"<sup>313</sup>

On September 26, 1985, Mulroney announced that he would propose to "negotiate the broadest possible package of mutually-beneficial reductions in tariff and nontariff barriers" between Canada and the U.S.<sup>314</sup>

The United States was interested in, among other things, revamping the Canadian compulsory licensing system.<sup>315</sup> In October 1985, the annual report of the U.S. Trade Representative complained that Canada's compulsory licensing policy was costing U.S. companies "hundreds of millions of dollars."<sup>316</sup> The report stressed that the United States had "repeatedly raised the issue of patent protection for pharmaceuticals and the compulsory licensing provisions of Canada's patent law in trade discussions, usually in connection with compulsory licensing."<sup>317</sup>

During hearings over fast-track trade negotiation authorization, the U.S. Trade Representative told a Senate Finance Committee that intellectual property was among the areas that had been identified and would be pursued during any trade negotiations.<sup>318</sup>

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<sup>311</sup> Crane, *supra* note 291, at B1.

<sup>312</sup> *Id.* (noting that the patent law dispute had to do with Canada's pharmaceutical legislation).

<sup>313</sup> *Id.*

<sup>314</sup> Prime Minister Brian Mulroney, Statement to the House of Commons (Sept. 26, 1985), reprinted in Shelly Battram, *Canada-United States Trade Negotiations: Continental Accord or a Continent Apart?*, 22 INT'L LAW. 345 (1988).

<sup>315</sup> See Giles Gherson, *Free Trade Flashpoints: Lumber, Drugs, Publishing Are Prickly Issues*, FIN. POST, Dec. 21, 1985, at 1 ("Big U.S. drug companies are lobbying furiously against what they consider inadequate pharmaceutical patent protection in Canada, and they want relief—fast. The focus of their ire: laws in force since 1969 that permit generic drug companies to swiftly copy new products developed by the giant multinationals.").

<sup>316</sup> Crane, *supra* note 291, at B1.

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

<sup>318</sup> Battram, *supra* note 314, at 366-67.

The Committee was told that “[t]he American business community [was] concerned about the protection of intellectual property in Canada. . . . [They] felt that Canada does not accord adequate protection to American ownership of pharmaceuticals.”<sup>319</sup>

President Reagan promised Senators that any free trade agreement between the U.S. and Canada would provide for “comparable treatment for America and Canada in investment and intellectual property rights in both countries . . . while involving outstanding trade disputes.”<sup>320</sup>

Prime Minister Mulroney seemed to be agreeing with Reagan when he conceded that the country had acted “as a scavenger in the area of intellectual property.”<sup>321</sup> Consumer and Corporate Affairs Minister Harvie Andre was even more blunt, referring to the 1969 bill granting compulsory licensing as legalized theft.<sup>322</sup> Andre argued that with the repeal of compulsory licensing, Canada “will no longer be taking a free ride at the expense of the rest of the world.”<sup>323</sup>

Negotiations commenced in Ottawa on May 21, 1986, with Ambassador Peter Murphy from the United States Trade Representative’s office and Ambassador Simon Reisman as the Canadian negotiator.<sup>324</sup> According to McDonald, however, U.S. Trade Representative Peter Murphy entered the free trade negotiations with little direction from the Reagan administration.<sup>325</sup> Instead, Reagan chose to delegate most of the management authority to the Advisory Committee on Trade Negotiations (ACTN).<sup>326</sup>

<sup>319</sup> *Id.* at 367.

<sup>320</sup> *Id.*; see also Crane, *supra* note 291, at B1 (noting that Senator Dole introduced a resolution stating that “no trade agreement with Canada should be submitted for review . . . until such agreement” could satisfy Congress on the “full and effective protection for intellectual property rights in Canada comparable to the protection afforded such rights in the United States”).

<sup>321</sup> MCDONALD, *supra* note 18, at 211.

<sup>322</sup> Alan Story, *Drug Wars: Does anyone really know the price tag? Ottawa says its plan to change law won’t raise prices. Others disagree*, TORONTO STAR, Dec. 20, 1986, at B1.

<sup>323</sup> *Id.*

<sup>324</sup> MCDONALD, *supra* note 18, at 200-01.

<sup>325</sup> *Id.* at 206.

<sup>326</sup> *Id.*

The chairman of the ACTN was Edmund Pratt, Chief Executive Officer of Pfizer Inc., and president of the Pharmaceutical Manufacturers Association.<sup>327</sup> According to a profile in the *National Journal*, "many Washington observers think that [Pratt] is the corporate executive with the most influence on trade issues, influence that he has used to further his company's goals as well as the nation's."<sup>328</sup> "After a talk with Pratt, Peter Murphy had no doubt about his marching orders on the pharmaceutical question: his job was to wangle an intellectual property clause encompassing patent protection in the free trade negotiations."<sup>329</sup>

"Then suddenly, without warning in early 1986, [U.S. Trade Representative Peter Murphy] was told not to bother [pursuing patent protection for pharmaceuticals in trade negotiations]: the drug-makers were doing a side deal with the Canadian government at the highest level."<sup>330</sup>

[According to] Bill Merkin, the U.S. deputy chief negotiator in the free-trade talks, . . . "Ottawa didn't want [intellectual property] to be in the free trade negotiations. They didn't want to appear to be negotiating that away as part of the free trade agreement. Whatever changes they were going to make, they wanted them to be viewed as . . . 'in Canada's interest.'"<sup>331</sup>

On June 27, 1986 Mulroney's government attempted to introduce Bill C-22.<sup>332</sup> "Bill C-22 propose[d] . . . to grant manufacturers of new drugs ten years of market exclusivity."<sup>333</sup>

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<sup>327</sup> *Id.*

<sup>328</sup> Crane, *supra* note 291, at B1.

<sup>329</sup> MCDONALD, *supra* note 18, at 208.

<sup>330</sup> *Id.* at 208-09 ("In Ottawa, federal bureaucrats soon got the same message: the government immediately moved to bring in a new pharmaceutical bill to undo Trudeau's.").

<sup>331</sup> Lexchin, *supra* note 272, at 151.

<sup>332</sup> Sawatsky & Cashore, *supra* note 300, at 12 (Michael Côté, Minister of Consumer and Corporate Affairs, submitted Bill C-22 hours before Parliament's summer recess. Having been delivered to Parliament Hall by courier, the bill sat on the desk of a security guard. When House Speaker John Bosley called for bills, "Côté had no bill to present." Because it was the last day before Parliament's recess, Bill C-22 would not be introduced until the Fall term.).

<sup>333</sup> David Owen, *Ottawa's Unusual Drug Patent Bill*, *FIN. TIMES*, Oct. 22, 1987, at 9.

“Generic manufacturers [could] reduce [that] exclusivity period to seven years if they agree[d] to source the drug’s active ingredients domestically.”<sup>334</sup> The Canadian equivalent of the Drug Price Competition and Patent Term Restoration Act compromise, Bill C-22 sought to keep drug prices under control during the monopoly period by establishing a Patented Medicines Price Review Board, which was to be empowered to award compulsory licensing for “any drug it found to be overpriced.”<sup>335</sup> Though not part of the legislation, the research pharmaceutical industry promised to invest \$1.4 billion in Canada.<sup>336</sup>

While the trade issues were being negotiated, Bill C-22 languished in Parliament. Mulroney’s Conservatives had a majority in the House but the Senate was dominated by opposition Liberals. The Liberal-dominated Senate, which like the British House of Lords is unelected, had traditionally rubber-stamped legislation approved in the House.<sup>337</sup> This fact, however, may have had more to do with the Liberals’ historic hold on the House than on any predilection for House measures on the part of the Senators.<sup>338</sup> The resurgent Senate Liberals, for the first time in Canadian history, refused to sign a bill passed by the House of Commons on two occasions, forcing the House to pass C-22 three

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<sup>334</sup> *Id.*

<sup>335</sup> *Id.*

<sup>336</sup> *Id.*; see also Bernard Simon, *Multinationals Offer Deal On Canadian Drug Rule*, FIN. TIMES, Sept. 26, 1986, at 6 (citing an announcement by Miles Laboratories, Beecham Laboratories, and Glaxo Canada of “substantial new investments in Canada on condition that the Federal Government presses ahead with controversial legislation to tighten patent protection on brand-name medicines”).

<sup>337</sup> *Senate Finally Passes Patent Act Amendment Ending Compulsory Pharmaceutical Licensing*, 4 INT’L TRADE REP. (BNA) 1492 (Dec. 2, 1987) (“The Canadian Senate, whose members are appointed, usually does little more than rubber-stamp government legislation from the elected House of Commons.”); David Hatter, *Drug Bill Struggle Poses Question on Senate Role*, FIN. POST, Nov. 2, 1987, at 6 (“In practice, senators have usually acted with restraint due to their nonelected status.”).

<sup>338</sup> See *Senate Finally Passes Patent Act Amendment Ending Compulsory Pharmaceutical Licensing*, *supra* note 337, at 1492.

The Senate . . . has all the same powers as the House of Commons, with three exceptions. On paper, the only limitations to the Senate’s powers are: it cannot hold a vote of confidence on the government; it cannot originate money bills; and on a constitutional amendment, it cannot veto what the Commons has passed, only delay it for 180 days.

Hatter, *supra* note 337, at 6.

times.<sup>339</sup>

Opponents of C-22 continued to focus on allegations that drug prices would rise and that the entire debate was fueled by the free trade talk with the U.S.<sup>340</sup> Opposition leader John Turner questioned why the Mulroney government was using "the sick and the elderly as a pawn in the free trade negotiations."<sup>341</sup> Turner characterized as "obscene [the] desire of the government of Canada to bow to American pressure to amend our drug patent legislation and dramatically increase prices in order to maintain the free trade negotiations."<sup>342</sup> In somewhat hyperbolic fashion, Jack Kay, Chairman of the Canadian Drug Manufacturer's Association (CDMA), compared Bill C-22 to "economic rape."<sup>343</sup>

During the free trade negotiations, Canada was confronted with another issue of national political importance: Quebec.<sup>344</sup> In the early 1980s, Canadian Prime Minister Pierre Trudeau made constitutional reform a centerpiece of his administration.<sup>345</sup> The result of Trudeau's efforts, the Constitutional Act of 1982, included increased protection for individual and minority rights.<sup>346</sup> However, those in the Quebec nationalist movement were displeased that the Act failed to grant any special status to Quebec.<sup>347</sup>

Prime Minister Mulroney, whose Conservative Party drew a

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<sup>339</sup> Kenneth Freed, *Canada on Brink of Constitutional Crisis; Proposed Drug Bill Sparks Critical Parliamentary Confrontation*, L.A. TIMES, Aug. 30, 1987, at 6.

<sup>340</sup> Alan Story, *supra* note 322, at B1 (citing claims that the proposed patent law changes contained in Bill C-22 could cost Canadian consumers \$4 billion in higher prescription drug prices over the next ten years).

<sup>341</sup> CAMPBELL & PAL, *supra* note 6, at 40.

<sup>342</sup> *Id.* at 43.

<sup>343</sup> William Walker, *Consumers Will Be Hurt, Panel Told Free Trade and Drug Bill Called "Economic Rape,"* TORONTO STAR., Oct. 27, 1987, at A2.

<sup>344</sup> See generally Elizabeth L. Wiltanger, *Sound the Trumpets! Quebec is Shouting, "Victory!" Despite the Canadian Supreme Court's Denial of Unilateral Secession*, 17 DICK. J. INT'L L. 505 (1999); Kevin Sneesby, *National Separation: Canada in Context—A Legal Perspective*, 53 LA. L. REV. 1357 (1993).

<sup>345</sup> Wiltanger, *supra* note 344, at 507.

<sup>346</sup> *Id.*

<sup>347</sup> *Id.* Only the federal government and nine predominantly English-speaking provinces agreed on the Constitutional Act of 1982, with Quebec obviously not among them. *Id.* at 507.

disproportionate number of seats from the Quebec caucus, was keen on satisfying Quebec's demands.<sup>348</sup> The Meech Lake Accords of April 1987 were the product of Mulroney's desire to have Quebec ratify a new Canadian constitution.<sup>349</sup> The Meech Lake Accord integrated five of Quebec's demands.<sup>350</sup> "The first was 'a constitutional recognition of Quebec's status as a distinct society.'<sup>351</sup> The second was a constitutional provision giving Quebec preeminent control over immigration to the province.<sup>352</sup> "The third addressed 'restrictions on federal spending in areas of provincial jurisdiction.'<sup>353</sup> The fourth demand was that Quebec be given a "veto over constitutional amendments involving changes to federal institutions, and an extension of Quebec's right to opt out with compensation from amendments transferring jurisdiction from the provinces to Ottawa."<sup>354</sup> "The final claim sought [increased] 'participation in [the] naming [of] some Supreme Court . . . judges.'<sup>355</sup>

With the support of Prime Minister Mulroney, all of the provincial premiers, and the leaders of the federal opposition parties, the Meech Lake Accord appeared likely to be ratified.<sup>356</sup> However, when "Manitoba did not assent [and] New Brunswick withdrew its ratification, . . . the Meech Lake Accord . . . failed."<sup>357</sup>

The significance of the Meech Lake Accord and Bill C-22 is the special role that Quebec played in the caucuses of both the Conservatives and Liberals. Both parties drew a disproportionate number of MPs from Quebec. Montreal, Quebec was the center of the research pharmaceutical industry in Canada. At a time when secessionist pressures within Quebec were growing and negotiations were underway to pacify Quebec nationalists at Meech Lake, opposition to Bill C-22 began to be framed as anti-

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<sup>348</sup> Sneesby, *supra* note 344, at 1364.

<sup>349</sup> *Id.* at 1363.

<sup>350</sup> Wiltanger, *supra* note 344, at 508.

<sup>351</sup> *Id.* (quoting R. KENT WEAVER, *THE COLLAPSE OF CANADA* 57, 60 (1982)).

<sup>352</sup> *Id.* at 508.

<sup>353</sup> *Id.* (quoting WEAVER, *supra* note 351, at 60).

<sup>354</sup> *Id.* (quoting WEAVER, *supra* note 351, at 61).

<sup>355</sup> *Id.* (quoting WEAVER, *supra* note 351, at 61).

<sup>356</sup> Wiltanger, *supra* note 344, at 509.

<sup>357</sup> Sneesby, *supra* note 344, at 1364.

Quebec.

Prime Minister Mulroney acted as heresthetician, adding a new dimension into the debate about compulsory licensing. Mulroney accused opponents of C-22 of "choking off \$700 million of investment going right into the province of Quebec and 1300 jobs in science and technology and . . . inflicting irreparable damage to the scientific well-being of Quebec."<sup>358</sup> Mulroney was joined by Quebec Liberal Senator Pierre de Bane and Liberal MP J.C. Malepart, among others, who "broke ranks with the Liberal party under pressure from constituents."<sup>359</sup> In essence, Bill C-22 became "the latest symbol . . . of the economic tug-of-war between Quebec and Ontario, Montreal and Toronto."<sup>360</sup>

As the free trade negotiations with Canada dragged on, "the White House threatened to throw the whole thing overboard unless Ottawa rammed through the pharmaceutical bill."<sup>361</sup> The compulsory licensing issue continued to play a central role in the negotiations of a broader U.S.-Canada trade deal. "For the Reagan administration, any backing away . . . by Prime Minister Brian Mulroney from [Bill C-22] . . . because of protests by Canadians would be seen as a clear sign that [his] government, when put to the test, lacks the political spine to make the concessions the U.S. expects."<sup>362</sup> No matter how much the Conservatives tried to distance Bill C-22 from the free trade talks, the connection between the two was inescapable.<sup>363</sup>

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<sup>358</sup> CAMPBELL & PAL, *supra* note 6, at 43.

<sup>359</sup> *Id.*; see also Bill Fox, *Quebec Liberals Tiptoe Around Patent Drug Issue*, TORONTO STAR, Aug. 23, 1987, at B3 ("Quebec is expected to see some \$800 million of the promised new investment and 1,300 of the new jobs. Quebec's Liberal Premier Robert Bourassa stands foresquare behind the Mulroney government's legislation; Malepart and company, aware of the bill's popularity in their own electoral backyards, are tiptoeing around.").

<sup>360</sup> Robert McKenzie, *Quebecers Like Tory Drug Bill*, TORONTO STAR, Nov. 5, 1987, at A30 (noting that "[t]he two biggest generic drug manufacturers in Canada, Novapharm and Apotex, are in (Metro) Toronto and . . . have lobbied ferociously (against Bill C-22)").

<sup>361</sup> McDONALD, *supra* note 18, at 213.

<sup>362</sup> David Crane, *If Patent Drug Bill Is Approved a Free Trade Deal May Be Next*, TORONTO STAR, Dec. 13, 1986, at B2 ("Should Mulroney give in to pressures from ordinary Canadians worried about the effect the legislation will have on drug prices, the Americans would probably abandon their interest in comprehensive free trade talks.").

<sup>363</sup> See *House of Commons Rejects Senate Changes, Fails to Amend Pharmaceutical*



Trade Minister Pat Carney protested that “[a]t no time did negotiators agree to the inclusion of a commitment with respect to Bill C-22 as part of the Canada-U.S. free trade agreement.”<sup>364</sup> Michael Wilson, Canada’s Finance Minister, insisted that Bill C-22 “was not and is not related to the free trade agreement.”<sup>365</sup> Even while part of the Canadian government was denying any connection, however, Senate Government Leader Lowell Murray was warning Liberal senators who threatened to block C-22 that to defeat the drug bill could kill the free trade deal. “If the [Canadian] Senate were to defeat Bill C-22, I believe that many congressmen and senators in the United States would think twice about their support for the free trade agreement.”<sup>366</sup>

In the end, it appears obvious that Bill C-22 and the Free Trade Agreement were conjoined in the negotiators’ minds. “In their initial October 4, 1987, summary of the [free trade] deal for Reagan’s cabinet, [Trade Representative Clayton Yeutter’s office] acknowledged an agreement for the ‘effective protection of pharmaceuticals in Canada by liberalizing compulsory licensing provisions.’”<sup>367</sup> “By the time an updated version of the text was released to the press days later, that admission had disappeared.”<sup>368</sup>

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*Patent Act*, 4 INT’L TRADE REP. (BNA) 1387 (1987) (quoting Jack Kay, chairman of the Canadian Drug Manufacturers’ Association, as telling a “parliamentary committee studying the free trade agreement with the United States” that “[i]t is unconscionable that a foreign power, under the guise of negotiating a free trade agreement, could actually dictate a major change in domestic economic and social policy”).

<sup>364</sup> Joe O’Donnell, *Ottawa Denies Link to Drug Bill*, TORONTO STAR, Oct. 10, 1987, at A4.

<sup>365</sup> Owen, *supra* note 333, at 9.

<sup>366</sup> O’Donnell, *supra* note 364, at A4.

<sup>367</sup> McDONALD, *supra* note 18, at 213; *see also* Ed Broadbent, *U.S. Comes Out a Clear Winner*, FIN. POST, Oct. 19, 1987, at 14 (citing “U.S. government briefing notes on the trade deal prepared for Treasury Secretary James Baker . . . [claiming] under the heading ‘What the U.S. got,’ that: ‘Canada will enact pending amendments in Bill C-22, and Parliament will review within 10 years the further protection for pharmaceutical inventions.’”).

<sup>368</sup> McDONALD, *supra* note 18, at 213; *see* Stuart Auerbach, *U.S. Bowed to Canadian Demands to Change Pact*, WASH. POST, Oct. 17, 1987, at G1 (noting that:

Canadian negotiators [had] demanded the removal of a section pledging Canada to change its drug patent laws [and that] to Reagan administration officials, headed by Treasury Secretary James A. Baker III and U.S. Trade Representative Clayton K. Yeutter, bowed to the Canadian demand and allowed the section on the drug patents to be removed.

However, the proverbial cat was already out of the bag. In fact, "both [U.S. Trade Representative Peter] Murphy and [deputy Canadian trade negotiator Bill] Merkin confirm[ed] the link."<sup>369</sup> Still, the Free Trade Agreement was an enormous achievement. "U.S. Trade Representative Clayton Yeutter compared 'the historic significance of the [CFTA], in the economic sphere, . . . to the historic significance of the U.S.-Soviet arms control treaty in the national security arena.'"<sup>370</sup>

### *C. Canada: The NAFTA and Bill C-91*

The battles over Bill C-22 and the Canada-U.S. Free Trade Agreement began a decade-long process of regional and international integration. During the next ten years, the U.S. and Canada would add Mexico in a North America Free Trade Agreement and complete an historic round of negotiations under the General Agreements on Tariffs and Trade. Again, intellectual property rights would play an important role in both talks. And again, the United States research pharmaceutical industry would direct the U.S. effort to increase international intellectual property standards.<sup>371</sup>

This time, Canada's domestic reaction to U.S. pressure was Bill C-91.<sup>372</sup> Bill C-91 would further amend Canada's patent law, making two fundamental changes.<sup>373</sup> First, Bill C-91 would eliminate compulsory licensing of pharmaceuticals altogether.<sup>374</sup>

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<sup>369</sup> MCDONALD, *supra* note 18, at 213.

<sup>370</sup> Judith H. Bello & Alan F. Holmer, *The NAFTA: Its Overarching Implications*, 27 INT'L LAW. 589, 590 (1993).

<sup>371</sup> See Linda Diebel, *How U.S. Drug Lobby Put New Patent Law atop Canada's Agenda*, TORONTO STAR, Dec. 6, 1992, at A1.

The U.S. pharmaceutical industry, one of the richest and most powerful sectors in America, has been fighting for [elimination of compulsory licensing] since Canada brought in consumer-friendly drug legislation in 1969. Finally, in [the NAFTA negotiations], they won virtually every demand they made of Trade Minister Michael Wilson in the free trade negotiations.

*Id.*

<sup>372</sup> Silbermann, *supra* note 20, at 622 (arguing that Canada's maintenance of its limited compulsory licensing scheme promoted the U.S. to place it on the Special 301 Watch List in 1989, 1990, and 1991).

<sup>373</sup> CAMPBELL & PAL, *supra* note 6, at 50.

<sup>374</sup> *Id.*

The patent term for pharmaceuticals would be extended to the international standard twenty years, including ten years of market exclusivity.<sup>375</sup> Second, the Patent Medicines Prices Review Board (PMPRB) would be given additional powers to monitor and enforce drug prices.<sup>376</sup> The PMPRB would have the power, equal to that of the Federal Court, “to order price decreases, take back super-profits, and impose penalties, [both] fines and imprisonment.”<sup>377</sup>

On June 23, 1992, Bill C-91 was introduced in the House of Commons.<sup>378</sup> The reaction was immediate and predictable. The opponents of Bill C-22, galvanized from their previous fight over patent reform, immediately mobilized. The Canadian Drug Manufacturers Association commissioned a study by Dr. Stephen Schondelmeyer, University of Minnesota professor of pharmaceutical economics.<sup>379</sup> Dr. Schondelmeyer estimated that Bill C-91 would cost Canadian consumers between \$4 and \$7 billion over a fifteen- to twenty-year period.<sup>380</sup> This figure compared to only \$500 million in increased research and development spending in Canada.<sup>381</sup>

In stark contrast to the government’s handling of Bill C-22, “it unabashedly linked Bill C-91 with the GATT agreements and the North American Free Trade Agreement.”<sup>382</sup> Minister for International Trade Michael Wilson, who as Finance Minister had declared that Bill C-22 “was not and is not related to the [Canada-

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<sup>375</sup> *Id.*

<sup>376</sup> *Id.*; see also G. Alexander Macklin & Emma A.C. Grell, *Recent Amendments Aid Rightholders, but Create Procedural Uncertainties*, IP WORLDWIDE, Jan.-Feb. (1996) (describing how Bill C-22 created the Patented Medicines Prices Review Board (PMPRB)). This board was empowered to review the price of any medicine that was the subject matter of a Canadian patent to determine whether the medicine was being sold at an excessive price. *Id.* If the PMPRB so determined, it could order the patentee to reduce its price, or it could remove the patentee’s exclusivity periods for the excessively priced medicine and/or one other medicine of the patentee protected by a Canadian patent. *Id.*

<sup>377</sup> CAMPBELL & PAL, *supra* note 6, at 50.

<sup>378</sup> *Id.*

<sup>379</sup> *Bill C-91 to Cost Canada up to \$7 Billion by 2010, U.S. Health Care Economist Predicts*, CANADA NEWS WIRE, Dec. 1, 1992.

<sup>380</sup> *Id.*

<sup>381</sup> *Id.*

<sup>382</sup> CAMPBELL & PAL, *supra* note 6, at 52.

U.S.] free trade agreement," now argued that Bill C-91 was required if Canada was to meet its intellectual property rights obligations under the GATT and NAFTA.<sup>383</sup>

From the U.S. research pharmaceutical industry's perspective, Bill C-91 was a watershed moment. With two international negotiations occurring concomitantly, the research industry was aware that an agreement on intellectual property within NAFTA that allowed for Canada to continue to provide compulsory licenses for pharmaceuticals would end any chance of achieving an acceptable comprehensive international minimum standard with the GATT.<sup>384</sup>

However, if the U.S. research industry was afraid that other countries might follow Canada's lead and grant compulsory licenses, it was terrified that its own government might do the same. Canadian MP Jim Karpoff put it bluntly: "[The U.S. research pharmaceutical industry is] deathly afraid that [Clinton] would take a second look at drug prices in the United States and decide that the only possible way to control drug prices would be to adopt the Canadian system of compulsory license[s]."<sup>385</sup> "It was in the multinationals' interest to have Bill C-91 passed before President Clinton began to take compulsory licensing seriously for the United States."<sup>386</sup>

Unlike the negotiations over Bill C-22 and the Canada-U.S. Free Trade Agreement, when the research pharmaceutical industry

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<sup>383</sup> Rob McKensie, *A Hard Pill to Swallow*, CAN. BUS., Feb., 1994, at 44.

<sup>384</sup> Ross Duncan & Dave Blaker, *Trends in the Pharmaceutical Industry in Canada in the Post 1987 Environment*, (Ottawa: Interdepartmental Working Group, Intellectual Property Research Branch, Department of Consumer and Corporate Affairs, unpublished and undated) ("Perhaps the most significant effects of the Canadian patent policies such as . . . compulsory licensing . . . is its role as 'model law' and the potential adoption . . . by many other countries without a significant domestic innovative pharmaceutical sector.") (cited in CAMPBELL & PAL, *supra* note 6, at 53).

<sup>385</sup> CAMPBELL & PAL, *supra* note 6, at 53; see also *Intellectual Property Enforcement Issues to Play Major Role in NAFTA Talks*, 8 INT'L TRADE REP. (BNA) 1554 (Oct. 23, 1991) (quoting Morris Rosenberg, assistant deputy minister for corporate affairs and legislative policy at Consumer and Corporate Affairs Canada, citing "[a] recent report by the U.S. Senate Special Committee on Aging [that] . . . points to high pharmaceutical prices as a major problem for the U.S. health care system, and refers favorably to the balance Canada's legislation has created between the interests of pharmaceutical makers and consumers").

<sup>386</sup> CAMPBELL & PAL, *supra* note 6, at 64.

had a staunch ally in the White House, President Clinton entered office with a decidedly anti-pharmaceutical industry position. In speeches the President had characterized the industry's practices as "unconscionable" and accused it of pursuing "profits at the expense of our children."<sup>387</sup> Clinton had warned the industry that "he would 'stop drug price gouging.'"<sup>388</sup> In what was to be the Clinton Administration's biggest first term policy objective, national healthcare, the President, in "a prelude to introducing his health care reform plan," singled out drug prices as "one example of why the health care system doesn't work."<sup>389</sup>

What was similar to the debate surrounding Bill C-22 was the influence of Quebec on Canadian politics.<sup>390</sup> First, the Conservatives still held a majority in Parliament while Bill C-91 was being debated. The Conservatives' maintained their strong ties to the Canadian research pharmaceutical industry, based primarily in Quebec. Second, the Liberals, led now by Jean Chrétien, continued to be divided on the issue of pharmaceutical patents. Ideologically, compulsory licensing was a Liberal policy, begun under the Liberal Trudeau government in 1967. However, the Liberals continued to draw support from Quebec, with its strong research pharmaceutical presence.<sup>391</sup> Attacking Bill C-91 was again viewed, as when Bill C-22 was center stage, as being anti-Quebec, and ultimately, as being anti-business.<sup>392</sup> Neither

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<sup>387</sup> Linda Diebel, *Clinton Delivers Blistering Attack on Big Drug Firms*, TORONTO STAR, Feb. 13, 1993, at A1.

<sup>388</sup> Robert Pear, *Clinton Team to Tackle Drug Pricing*, N.Y. TIMES, Dec. 15, 1992, at B12.

<sup>389</sup> Sarah Fritz, *Clinton's Jawboning May Win Drug Firm Price Cuts*, L.A. TIMES, Mar. 7, 1993, A1.

<sup>390</sup> See CAMPBELL & PAL, *supra* note 6, at 54 (noting that because the issue of pharmaceuticals was very important for Quebec and less important for all the other provinces, Ontario never "raised the issues of Bill C-91's relationship to NAFTA and the fact that Quebec's job gains were often Ontario's job losses"); see also Shawn McCarthy, *Metro MP Fears for Fate of Generic Drug Review*, TORONTO STAR, June 6, 1994, at A13 (describing Liberal MP Dan McTeague as "worried that political upheaval in Quebec has derailed the government's plans to revisit patent legislation that is keeping lower-cost generic pharmaceuticals off the market").

<sup>391</sup> See Shawn McCarthy, *Liberals at Odds over Drug Patent Bill*, TORONTO STAR, Sept. 17, 1992, at A16 (quoting from a letter circulated by Liberal MP David Berger (Saint-Henri-Westmount) arguing that opposition to Bill C-91 "would be a serious mistake").

<sup>392</sup> Phillip Authier, *Drug Law Plans Creating Instability: Tremblay; Industry*

moniker played well in Canadian politics. As Montreal MP David Berger told the Quebec caucus, "[i]n order to maintain existing jobs and obtain additional investment in today's global market we need to provide patent protection comparable to that which exists in other industrialized countries."<sup>393</sup>

With the Liberals divided and the Conservatives now in control of the Senate, passage of Bill C-91 was inevitable.<sup>394</sup> Unlike the Bill C-22 debacle in the Senate, the Conservatives were able to use a series of parliamentary tactics to limit debate and ensure that C-91 passed quickly and quietly.<sup>395</sup> Bill C-91 became law on February 4, 1993.

What makes the passage of Bill C-91 ironic is that despite all the government protests to the contrary, Canada was then under no obligation to amend its patent system.<sup>396</sup> The GATT negotiations were still ongoing, and in fact would last more than two years. The U.S. Congress had not approved the NAFTA implementing

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*Minister Furious with Ottawa over Decision to Amend Patent Act*, THE GAZETTE (Montreal), Apr. 28, 1994, at A7 (quoting Industry and Commerce Minister Gerald Tremblay as criticizing the Canadian government for suggesting that the issue of compulsory licensing could be reviewed). "Stating that law C-91 could be reopened creates instability and when you create instability it gives negative results." *Id.*

<sup>393</sup> McCarthy, *supra* note 391, at A16.

<sup>394</sup> CAMPBELL & PAL, *supra* note 6, at 61. The Canadian Drug Manufacturers Association (CDMA), which represents the interests of generic producers, filed suit enjoining the enforcement of Bill C-91. *Id.* The CDMA "argued that the government was . . . required by § 39.26 of the Patent Act to . . . review . . . Bill C-22 in 1996." *Id.* It argued, therefore, that Bill C-91 was beyond Parliament's power to amend the Patent Act before the review. *Id.*

<sup>395</sup> CAMPBELL & PAL, *supra* note 6, at 59 (describing the Liberal and New Democratic Parties' efforts to hold hearings on Bill C-91 and the ruling Conservative government's ultimatum: "agree to limit the committee stage to a certain number of hours" or "the government would move to return the legislation to the House of Commons without committee hearings at all").

<sup>396</sup> *American Pressure Killed Compulsory Licensing not NAFTA*, CDMA Asserts, CANADA NEWSWIRE, June 2, 1993, quoting Professor of International Business Law at Osgoode Hall Law School, Jean-Gabriel Castel:

I am of the opinion that in view of article 30 of the Dunkel (GATT) document and article 1709(6) of the NAFTA, Canada was not obliged to eliminate compulsory pharmaceutical patent licensing. . . . As was the case with the FTA, Canada has now passed Bill C-91 which removes compulsory licensing of pharmaceutical patents in order to accommodate U.S. concerns using the pretext that the Dunkel Document and the NAFTA required such a course of action.

*Id.*

legislation, and, as Congressional Democrats raised concern over jobs and the environment, looked less likely to do so with each passing day.<sup>397</sup> The Canadian government, which had so vehemently denied the obvious linkage between Bill C-22 and the Canada-U.S. Free Trade Agreement, now argued that an as-yet nonexistent free trade agreement compelled them to pass Bill C-91. Ultimately, of course, both the GATT and NAFTA would come into effect. At the time the Canadian Parliament passed Bill C-91, however, there was no international mandate for it to do so.

## VI. Conclusion

The passage of Bill C-22 provides an excellent example of how the distribution of benefits obtained from an international agreement among domestic constituents may impact the decision of national leaders so as to make voluntary Pareto-inferior international agreements a possibility.

Regardless of the protests to the contrary, both the treaty negotiators and the Canadian public viewed Bill C-22 as part of the Canada-U.S. trade talks.<sup>398</sup> Just as clearly, the passage of Bill C-22 made Canadian consumers worse off (at least in the near term).<sup>399</sup> While additional research and development investments might lead to the discovery of new medicines, such discoveries were some time off in the future. Similarly, it is unclear what percentage of future medicines, whether discovered in Canada or elsewhere, would not have been introduced into the Canadian market had Bill C-22 not been passed.

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<sup>397</sup> E.g., J. Jennings Moss, *NAFTA's Backers Fear Ruin in Defeat; Gore Sees Clinton Hobbled if It Dies*, WASH. TIMES, Nov. 15, 1993, at A1 (detailing the debate in Congress over NAFTA); Meg Vaillancourt, *Labor's Call: Defeat, Defeat, Defeat*, BOSTON GLOBE, Sept. 23, 1993, at 43 (describing labor union leaders' opposition to NAFTA); Richard Wolf, *Opposition Building to Free Trade Agreement*, USA TODAY, Sept. 3, 1993, at 8A (describing the Clinton administration's attempt to attain passage of NAFTA as "an uphill battle").

<sup>398</sup> However, it is interesting to note that the strategy of delinkage places the passage of Bill C-22 clearly outside the theoretical bounds outlined in Michael P. Ryan, *The Function-Specific and Linkage-Bargain Diplomacy of International Intellectual Property Lawmaking*, *supra* note 103.

<sup>399</sup> Toronto economist Harry Eastman, who headed a royal commission that studied the impact of compulsory licensing on consumer prescription drug prices, found that Canadian consumers were paying as much as \$300 million more each year for their prescriptions as a result of the passage of Bill C-22. Crane, *supra* 269, at C9.

The explanation for the passage of Bill C-22, therefore, lies in the search for regulation (in this case patents) by an industry that relies heavily on government-mandated barriers to entry (i.e., patents). The willingness of the Canadian government to accede to the wishes of this industry, even without popular support, can be explained by the distribution of benefits derived from providing the research pharmaceutical industry with its preferred policy. That is to say, because the Liberal Party drew a disproportionate amount of support from the Montreal area of Quebec, which, coincidentally, was the center of the Canadian research pharmaceutical industry, its historical preference for compulsory licensing was muted by internal party politics. The importance of Quebec, especially during the secessionist tumult of the 1980s, made opposition to Bill C-22 politically risky.

The theory presented herein provides a parsimonious explanation to the passage of Bill C-22 and the Canada-U.S. trade agreement. The U.S. research pharmaceutical industry, facing repeated political defeats within the U.S. domestic political system, sought to transfer policy decision-making to an institution more favorable to their interests. By utilizing heresthetics, the industry was able to change the relevant policy space of U.S. policymakers and focus the debate about intellectual property rights on "piracy." Once intellectual property rights became an important trade issue for U.S. policy makers, domestic opposition to the research pharmaceutical industry's preferred policy was muted because the locus of policymaking shifted from the floors of Congress to the U.S. Trade Representative's Office. In essence, the research pharmaceutical industry was able to change the institution in which decisions affecting its interests were made from one in which it was not achieving its goals (i.e., Congress) into one in which its goals could be obtained (i.e., the U.S.T.R.).

In Canada, the decision about whether to enact legislation similar to Bill C-22 was impacted by the distributional consequences of repealing compulsory licensing as outlined above. Because the Canadian government insisted that Bill C-22 was not a quid pro quo for any U.S. policy reversals negotiated within the framework of the trade agreement, one cannot persuasively argue that the Mulroney administration tied or linked this costly policy (the repeal of compulsory licensing) to any tangible benefit (such as easier access to the U.S. agricultural



market). Even though the evidence is clear and convincing that Bill C-22 was indeed part of the trade talks (or, at least, that without repeal of compulsory licensing the United States appeared unwilling to enter into any trade agreement with Canada), the government's insistence that it was not is puzzling under existing theory. Such insistence is puzzling because theories of bargaining usually stress the importance of linking costly policy reversals to beneficial policy initiatives; otherwise, domestic opposition to the resultant international agreement will prevent its enactment.

However, the theory presented herein provides a consistent explanation that does not rely on trade-offs and issue linkage bargaining. Rather, one can explain Canada's repeal of compulsory licensing as a function of domestic politics and the consequences of the distribution of benefits arising from an international agreement. That is to say, one need only look at who the winners and losers would be under a proposed international agreement to understand whether there exists a domestic coalition capable of securing passage. In this case, because of the unique influence of the province of Quebec, both in terms of national unity and party loyalties, the research pharmaceutical industry was able to form a winning coalition among Canadian parliamentarians.

The theory presented herein and the example of the passage of Bill C-22 suggests that industries that seek to change the national policies of governments through international negotiation should look at the distribution of benefits to be derived from the enactment of the desired change rather than at what other industries could be included in the negotiations to provide issue linkage. In other words, the distribution of benefits among domestic constituencies may be more important in determining the results of international negotiations than the trade-offs that negotiators are able to obtain. The conclusion, then, is that Pareto-inferior international agreements are possible when the distribution of benefits from such an agreement flow to a winning domestic political coalition.

On the other hand, the passage of Bill C-91 can best be explained by Subramanian's status quo reciprocity.<sup>400</sup> The U.S. first used as leverage the provisions of Special 301 and later the

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<sup>400</sup> See Subramanian, *TRIPs and the Paradigm of the GATT*, *supra* note 101, at 520.

implicit threat that Canada would be left on the outside of a U.S.-Mexico trade deal.<sup>401</sup> In both cases, the status quo as it existed before negotiations began was removed, by the United States, from the possibilities of outcomes should negotiations between the U.S. and Canada fail to end in agreement. In other words, the conditions as they existed under the Canada-U.S. Free Trade Agreement were not going to remain regardless of Canada's decision regarding Bill C-91.

The theory presented herein and the examples of the passage of Bill C-91 suggest that industries that seek to change the national policies of governments through international negotiation are aided when the host-government has the power to manipulate, through its market power for instance, the choice set facing its negotiating partners. In other words, when the status quo ante is removed from the set of choices available to negotiators, the resultant agreement need not reside along the Pareto-frontier. Rather, it is entirely possible to achieve a voluntary Pareto-inferior international agreement because the relevant choice is not between the status quo and the agreement, but between the agreement and some even worse alternative.

CHRISTOPHER SCOTT HARRISON

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<sup>401</sup> See Bello & Holmer, *supra* note 370, at 589.

Canada's government officials faced continuing criticism from opponents of the CFTA, which was blamed for virtually every economic difficulty facing the country. At least in the United States, Canada's participation in the NAFTA negotiations appeared to be largely a defensive maneuver to ensure that the NAFTA did not dilute the Canadian benefits of the CFTA. If Canada had remained on the sidelines and an U.S.-Mexico bilateral FTA had been consummated, the result would have been only one North American country with duty-free access to all of North America—the United States. Canada had no desire to be a mere spoke on a wheel with the United States as the hub. Canada concluded that it could benefit from better access to the Mexican market, while preserving its access to the United States, far and away its largest trading partner. *Id.* at 590-91.