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DRUG PRICE REGULATION AND COMPULSORY LICENSING FOR PHARMACEUTICAL PATENTS: THE NEW ZEALAND CONNECTION

John M. Wechkin

Abstract: This Comment addresses effects of the 1992 rescission of compulsory licensing laws for pharmaceutical patents in New Zealand. The Comment summarizes the history behind the change in law, the effect the change has had, projections for future effects, and the degree to which the change brings New Zealand law into compliance with proposed General Agreement on Trade and Tariffs ("GATT") provisions. The effects of the repeal on drug prices appear to be masked by changes in New Zealand's pharmaceutical price support system. Both changes are illustrative of the continuing conflict over technology protection in the marketplace, a conflict which is particularly acute in the area of pharmaceuticals. The change is significant because it may indicate a shift from intellectual property laws to price regulation as a means by which governments control the price and availability of pharmaceuticals.

I. INTRODUCTION

The worldwide development of intellectual property protection has been characterized by a tension between the desire to provide protections and incentives for inventors, and the desire to disseminate useful information and inventions. This tension is particularly acute in the pharmaceutical industry. Drug manufacturers seek to maximize the return on large research and development investments by means of patent protection for their products. Opponents claim that the monopoly power granted by patents results in high prices and reduced availability of essential pharmaceutical products.¹

Compulsory licensing is one mechanism by which a government may curb the monopoly power of a patent. The effect of a compulsory license is to force the patent holder to license the invention to others in return for a royalty set by the government.² A second mechanism by which to control

¹ "No other major industry approaches pharmaceuticals in its degree of attachment to patent protection; in no other field have critics of patent monopolies been so severe." C.T. TAYLOR & Z.A. SILBERSTON, *THE ECONOMIC IMPACT OF THE PATENT SYSTEM* 231 (1973).

² Gianna Julian-Arnold, *International Compulsory Licensing: The Rationales and the Reality*, 33 J. L. & TECH. 349 (1993) (quoting P. GORECKI, *REGULATING THE PRICE OF PRESCRIPTION DRUGS IN CANADA: COMPULSORY LICENSING, PRODUCT SELECTION, AND GOVERNMENT REIMBURSEMENT PROGRAMMES* (ECONOMIC COUNCIL OF CANADA 1981)).

the price of pharmaceuticals is the use of direct government price regulation.

Recently, the trend worldwide has been to restrict the use of compulsory licensing provisions. Two reasons account for this trend: pressure from pharmaceutical manufacturers and the desire to unify disparate international intellectual property laws under the General Agreement on Trade and Tariffs ("GATT").³ The long-term effect of this trend may be to shift the disparities in the treatment of pharmaceuticals from the intellectual property arena to the price regulation arena. Although there may be no direct causal link between New Zealand's abandonment of pharmaceutical compulsory licensing and changes to drug pricing policy, it is clear that in the absence of compulsory licensing,⁴ increased reliance has been placed upon price regulation as a means for controlling drug prices.

This Comment analyzes the combined effects resulting from New Zealand's repeal of its pharmaceutical compulsory licensing laws and modification of its drug pricing regulations. After a general overview of compulsory licensing, the New Zealand provision and the events leading up to its repeal are analyzed. The Comment then assesses the effects of the change in New Zealand, and compliance of the patent law changes with new GATT provisions. The change in law in New Zealand and the GATT position on compulsory licensing together have implications for such provisions in other countries, which are next assessed. Finally, the applicability of the changes to the U.S. health care system is analyzed.

II. COMPULSORY LICENSING

A. Overview

A patent generally grants the holder the exclusive right to make, use and sell a useful invention for a limited period of time.⁵ The purpose of the

³ Under the current text, member countries are permitted to provide "limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent . . . taking account of the legitimate interests of third parties." *General Agreement on Tariffs and Trade (Uruguay Round), Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods*, 33 I.L.M. 95, art. 30. (Geneva, Switz., Dec. 15, 1993) [hereinafter *TRIPS Agreement*]. See GATT provisions, *infra* part III.C.2.

⁴ New Zealand repealed its compulsory licensing provisions for pharmaceuticals in 1992. Patent Act, No. 64, § 51, (1953) (N.Z.) repealed by New Zealand Amendment 1992 No. 81.

⁵ In New Zealand, the specific language is "make, use, exercise and vend the said invention within New Zealand." Third Schedule, Patent Regulations, 1954. The patent term in 1992 was sixteen years in

patent is to "foster human creativity without unduly restricting dissemination of its fruits."⁶ Patent protection grants the inventor an opportunity to exploit potential profits from the invention, thereby recouping investment costs associated with its creation.⁷ The patent protection is designed to prevent "free riders" from copying the invention without having invested time and money in the prerequisite research and development.⁸

Patent rights are limited to the jurisdiction granting them.⁹ Thus, the holder of a U.S. patent can successfully bring suit for infringement of the patent only if the infringement occurs within the United States and the infringer is within the reach of U.S. courts. A foreign infringer beyond the reach of U.S. courts is not bound by U.S. patent laws. An international business will naturally seek the greatest protection possible under the laws of each nation in which it sells patented goods. However, the level of patent protection available varies greatly from country to country, leaving technology exposed to possible infringement in countries with weak or nonexistent patent protection.¹⁰

Patent rights may be voluntarily licensed or assigned by the patent holder.¹¹ A compulsory license, however, is an involuntary contract between an unwilling patent holder and a willing licensee, imposed and enforced by the state.¹² Compulsory licensing is intended to make the patented product more readily available by permitting licensees, as well as the patent holder, to produce the patented invention. Such licenses are also used to reduce the price of the invention. By compelling technology licensing, a government can increase the number of producers in the marketplace,

New Zealand. 1953 Patent Act, No. 64, § 30 (1953) (N.Z.) The patent term has been extended twenty years to maintain compliance with the General Agreement on Trade and Tariffs ("GATT") Trade Related Aspects of Intellectual Property ("TRIPS") provisions. Patents Amendment Act 1994, No. 122, art. 18.

⁶ DONALD A. CHISUM & MICHAEL A. JACOBS, UNDERSTANDING INTELLECTUAL PROPERTY LAW 1-2 (1992).

⁷ See J.H. Reichman, *Beyond the Historical Lines of Demarcation: Competition Law, Intellectual Property Rights, and International Trade After the GATT's Uruguay Round*, 20 BROOKLYN J. INT'L L. 81 (1993).

⁸ See *id.*

⁹ For example, under New Zealand law, the patentee has the exclusive right to "make, use, exercise and vend the said invention *within New Zealand*." Third Schedule, Patent Regulations, 1954, *supra* note 5 (emphasis added). Under U.S. law, the patent holder has the right to exclude others from "making, using or selling the inventions *throughout the United States*." 35 U.S.C. § 154 (1980) (emphasis added).

¹⁰ For a recent listing of countries retaining compulsory licensing provisions, see *supra* note 2, at app. A.

¹¹ DONALD A. CHISUM & MICHAEL A. JACOBS, UNDERSTANDING INTELLECTUAL PROPERTY LAW § 2A, at 2-9 (1992).

¹² Julian-Arnold, *supra* note 2, at 349.

increasing the level of competition between producers, and decreasing the price of the product.

Compulsory licenses have typically been granted more readily for pharmaceuticals than for other inventions.¹³ Many justifications have been offered to account for this practice. Compulsory licenses can be used to stimulate a country's economy by several mechanisms, and are often of particular interest to developing countries.¹⁴ Such licenses permit local manufacture of drugs, thus reducing imports. Since the cost of developing pharmaceuticals may be prohibitive for developing countries, compulsory licensing provides a means by which to start a high technology pharmaceutical manufacturing industry without investing in research and development capability.¹⁵ The increased manufacturing capacity attracts doctors, chemists, and other high technology professionals, further stimulating the economy.¹⁶ Since the drugs are produced by local factories, with local labor, they can be sold at prices commensurate with the local earning power.¹⁷

Additionally, the use of compulsory licenses may have political justifications. Their use permits maintenance of a stable, local source for pharmaceuticals in the event that an international disturbance makes importation of pharmaceuticals nonviable.¹⁸

Compulsory licenses have application in developed economies as well, when used to curb the dominant market power created by a patent. Economists argue that excessive patent protection is antithetical to a free marketplace and that true competition and optimum pricing are realized only without the artifice of a patent.¹⁹ The responsibility on the part of the State to maintain public health, combined with the desire to minimize the cost of so doing, make compulsory licensing for pharmaceuticals particularly attractive.

Finally, compulsory licensing may have technological benefits. Economists are typically unwilling to accept the claim by pharmaceutical

¹³ A 1993 survey of intellectual property law indicates that the most prevalent applications of compulsory licenses occur when a dependent patent is being blocked, when a patent is not being worked, or when an invention related to food or medicine. Julian-Arnold, *supra* note 2.

¹⁴ *Id.* at 354.

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ See generally STUDY OF THE SUBCOMMITTEE ON PATENTS, COPYRIGHTS AND TRADEMARKS OF THE COMMITTEE ON THE JUDICIARY, S. RES. 236 STUDY NO. 15, 85th Cong., 2d Sess. (1958).

manufacturers that the large research and development investments required by the industry justify maximizing patent protection.²⁰ Instead, economists have characterized the efforts of drug manufacturers as generally causing only incremental changes in drug effectiveness, rather than the large breakthroughs that might justify large capital expenditures.²¹ In fact, the presence of patent protection may provide an incentive to develop drugs which simply escape patent infringement, rather than drugs which are truly innovative.²²

On the other hand, compulsory licensing measures have been criticized on several grounds.²³ Foreign firms may be dissuaded from supplying their wares to markets governed by patent laws containing liberal compulsory licensing provisions. Such provisions clearly weaken the patent protection available to the manufacturers. As a result, manufacturers have less incentive to develop drugs tailored for countries with weak patent protection. Developing countries in particular, which may have unique pharmaceutical requirements, will not attract significant research and development activity if they also have weak patent laws.²⁴

Pharmaceuticals, compared with other products, are particularly easy to copy because "reverse engineering" methods can be used to determine the constituent components of the drug and its method of manufacture.²⁵ It is therefore argued that stronger rather than weaker patent protection should be extended to pharmaceuticals.²⁶

The cost of developing drugs is often extremely high,²⁷ due not only to the expenses associated with developing and testing the drug, and

²⁰ An early study on the subject determined the percentage of the product selling price due to research and development costs for a variety of products: pharmaceuticals (11.5%), ranked high in comparison to plastics (2%), mechanical products (3%), and telecommunications products (5.5%). But pharmaceuticals ranked lower than electronics (13.5%). TAYLOR & SILBERSTON, *supra* note 1, at 145. This would indicate that pharmaceuticals should be treated as any other product, and compulsory licenses should not be easier nor more difficult to obtain for pharmaceuticals than for other products.

²¹ Telephone interview with Dr. Reinhard Pauls, Manager of Research and Analysis at Pharmaceutical Management Agency Ltd. (Pharmac) (Nov. 28, 1994) [hereinafter Pauls Interview].

²² *Id.*

²³ See generally RICHARD T. RAPP & RICHARD P. ROZEK, NATIONAL ECONOMIC RESEARCH ASSOCIATES INC. ("NERA"), BENEFITS AND COSTS OF INTELLECTUAL PROPERTY PROTECTION IN DEVELOPING COUNTRIES (June 1990); Richard P. Rozek, *The Consequences of Pharmaceutical Product Patenting: A Critique*, 16 WORLD COMPETITION (March 1993), at 91.

²⁴ RAPP & ROZEK, *supra* note 23, at 32.

²⁵ *Id.* at 7. See also Thomas G. Field Jr., *Pharmaceuticals and Intellectual Property: Meeting Needs Throughout the World*, J. L. & TECH. 3, 9 (1983).

²⁶ RAPP & ROZEK, *supra* note 23, at 91.

²⁷ The cost has been estimated at U.S.\$231 million in 1987 dollars. Rozek, *supra* note, 23 at 99 n.23.

obtaining government approval and bringing the drug to market, but also due to the development costs associated with drugs that ultimately prove unmarketable.²⁸ A manufacturer with a patented product has a limited time (the duration of the patent)²⁹ to charge prices reflective of the research and development investment which resulted in the patent. A compulsory license cuts short this period of time. With a compulsory license in hand, a generic manufacturer has access to the patented technology without having spent resources on research and development,³⁰ and is therefore able to charge a lower price than that charged by the brand-name manufacturer. The brand-name manufacturer may respond by lowering its price below that which properly accounts for its research and development expenditure. To recoup that expenditure, the brand-name manufacturer may increase prices in markets which have fewer generic manufacturers, particularly those markets which do not permit compulsory licensing.³¹

The company obtaining a compulsory license has a double advantage. As discussed above, the selling price of the licensee's drug does not need to reflect research and development costs. In addition, the profit margin on the licensee's drugs is reduced. Since the risk associated with investment in ventures which merely manufacture pharmaceuticals is less than that associated with ventures which actually perform research and development, those investing in manufacturing ventures expect a lower return on their investment.³² A lower return on investment implies a lower profit margin which in turn means that the licensee can charge lower prices in the marketplace.

A final argument for abandoning compulsory licensing is that the widespread repeal of such measures will bring international uniformity to the field of patent law and should therefore improve the overall efficiency of the patent system.³³ As patent laws around the world are made more uniform, the risk associated with the uncertainties of international transactions

²⁸ One study has indicated that of 4,000 drugs which started development, only five actually made it to market. Alan M. Fisch, *Compulsory Licensing of Pharmaceutical Patents: An Unreasonable Solution to an Unfortunate Problem*, 34 JURIMETRICS, Spring 1994, at 303.

²⁹ Patent terms vary from country to country. The current GATT agreement calls for 20-year patent terms. *Trips Agreement*, *supra* note 3, art. 33 at 96. New Zealand has recently adopted the 20-year term. Patent Act, No. 64, § 30, (1953) (N.Z.), as amended by New Zealand Amendment 1994, No. 122. The United States has adopted the 20-year term as well. Uruguay Round Agreements Act, Pub. L. No. 103-465, § 532, 108 Stat. 4809 (1994) (amending 35 U.S.C. § 154 (1988)).

³⁰ TAYLOR & SILBERSTON, *supra* note 1, at 249.

³¹ Field, *supra* note 25, at 4.

³² TAYLOR & SILBERSTON, *supra* note 1, at 249.

³³ Field, *supra* note 25, at 22, n.86 (1983).

is reduced. Lower risk on the part of the seller should imply lower prices, as well as increased distribution.

Prior to 1992, New Zealand patent laws contained provisions specifically intended to permit minimally restricted compulsory licensing for pharmaceutical patents. Major pharmaceutical manufacturers, backed by the United States, strongly oppose compulsory licensing.³⁴ By means of threatened trade sanctions, the United States exerted pressure on New Zealand, and as a direct result, New Zealand repealed its liberal compulsory licensing provisions for pharmaceuticals.³⁵

B. *Compulsory Licensing of Pharmaceutical Patents in New Zealand*

In 1953, New Zealand passed the Patent Act,³⁶ which contained provisions explicitly permitting compulsory licensing of pharmaceuticals and food products.³⁷ Section 51 of the Act required the Patents Commissioner, upon application by any interested party, to compel a pharmaceutical patent owner to grant the applicant a license to use the patent on terms specified by the Commissioner.³⁸ The Commissioner was to ensure that such products were made available to the public at the lowest possible price, consistent with the patentees' deriving a "reasonable" profit from their patent rights.³⁹ Thus, foreign manufacturers seeking patent protection for their products sold in New Zealand were subject to the possibility of a compulsory license.

Until 1992, cases brought under section 51 rarely resulted in the grant of a compulsory license.⁴⁰ This does not necessarily imply that section 51 had no effect. Rather, the limited use of section 51 may simply have been

³⁴ See generally RAPP & ROZEK, *supra* note 23, at 91.

³⁵ See *infra* note 54 and accompanying text.

³⁶ Patent Act, No. 64 (1953) (N.Z.).

³⁷ Patent Act, No. 64, § 51, (1953) (N.Z.). The compulsory license measure was based upon similar English legislation, which was put into effect after World War I in reaction to perceived dominance by the German pharmaceutical manufacturers. *New Zealand: How USA's Heavy Hand Forced Drug Rethink*, NAT'L BUS. REV., June 19, 1992, at 26 available in WESTLAW, INT-NEWS database [hereinafter *NBR*].

³⁸ Section 51 applies to food, medicine, or surgical or curative device patents. Patent Act, § 51 (1953).

³⁹ Patent Act, No. 64, § 51, (1953) (N.Z.).

⁴⁰ Prior to 1992, only three compulsory licenses were actually granted under section 51, and none of these were ever put to practical use because the patent holder was able to control the price of active ingredients. An additional application submitted in 1991 was withdrawn. *NBR*, *supra* note 37, at 26.

an indication of its dormant power to urge successful negotiations between potential licensees and licensors.⁴¹

In 1990, the dormant power was revived. Pacific Pharmaceuticals, a generic drug manufacturer, applied to the Patent Commissioner for a compulsory license from Glaxo, one of the world's largest brand-name drug companies.⁴² In a brief statement, the Commissioner noted that the application presented a *prima facie* case for a compulsory license under section 51, and granted the license.⁴³ Glaxo appealed the decision, which was upheld by the Court of Appeal Wellington.⁴⁴ The court held that Glaxo was unable to overcome a presumption in favor of the grant of a license and that the Patent Commissioner was therefore justified in granting the license on the basis of anticipated increased competition.⁴⁵ The presumption in favor of the grant was an indication of the ease with which a *prima facie* case could be made out. The court expressly noted that "New Zealand may be moving into an era in which applications for compulsory licenses for drug patents become more common."⁴⁶

The court's prediction was not in fact realized. The grant of a compulsory license to Pacific Pharmaceuticals exacerbated a legislative erosion of patent protection for pharmaceuticals in New Zealand.⁴⁷ Despite generally strong patent protection for other products,⁴⁸ amendments to the New Zealand Medicines Act in 1989 compromised the rights of pharmaceutical patent holders⁴⁹ by permitting parallel trade of pharmaceuticals.⁵⁰ Although the Medicines Act was watered down in 1990, the United States was not

⁴¹ See Julian-Arnold, *supra* note 10 at 364.

⁴² Glaxo Group Ltd. v. Commissioner of Patents, 3 N.Z.L.R. 179, 180 (C.A. 1991).

⁴³ *Id.*

⁴⁴ The court held that by showing that it could produce Ranitidine (an anti-ulcerant) at prices equal to or below those charged by Glaxo, Pacific pharmaceuticals had made out a *prima facie* case for a compulsory license. *Id.* at 184. Since no apparent "good reason" for refusing the application was supplied, the Commissioner's decision was permitted to stand. *Id.*

⁴⁵ *Id.* at 183.

⁴⁶ *Id.* at 184.

⁴⁷ *NBR*, *supra* note 37, at 26.

⁴⁸ The United Nations Conference on Trade and Development ("UNCTAD") rated New Zealand patent laws a "four" on a scale of zero to five, with five representing protection fully consistent with U.S. Chamber of Commerce minimum standards. RAPP & ROZEK, *supra* note 23, at A-3.

⁴⁹ *USTR Releases Annual Trade Report on Restrictions Around the World*, PAT. TRADEMARK & COPYRIGHT DAILY (BNA) May 22, 1991, available in LEXIS, PATENT Library, BNAPTD File

⁵⁰ Parallel trade occurs when a foreign manufacturer arranges with an exclusive distributor for the importation of a patented product into a target country, and a third party buys the product in the country of manufacture and imports it without authorization. Kaoru Takamatsu, *Parallel Importation of Trademarked Goods: A Comparative Analysis*, 57 WASH. L. REV. 433 (1982).

entirely mollified.⁵¹ As a result of the general treatment of pharmaceutical patents, and specifically the presence of section 51, New Zealand was put on the U.S. Trade Representative's "watch list" in 1990.⁵² The watch list represents the first step taken by the U.S. Trade Representative toward imposing trade sanctions under "Special 301"⁵³ of the 1988 Trade Act.

In response to the mounting pressure, the New Zealand legislature repealed section 51 of the Patent Act in August 1992,⁵⁴ thereby deleting the provision specifically aimed at compulsory licensing for pharmaceuticals. New Zealand was removed from the watch list in October 1992.⁵⁵

Several factors contributed to the repeal of section 51. Perhaps most obviously, the provision was anachronistic, based as it was on post-World War I British legislation which had outlived its original purpose.⁵⁶ In addition, compulsory licensing is often perceived as particularly beneficial to developing countries, since developing economies may have the greatest difficulty supporting the high cost of drug development.⁵⁷ New Zealand, however, is considered a developed capitalist country,⁵⁸ with a gross

⁵¹ *USTR Releases Annual Trade Report on Restrictions Around the World*, PAT. TRADEMARK & COPYRIGHT DAILY (BNA) May 22, 1991, available in LEXIS, PATENT Library, BNAPTD File.

⁵² *NBR*, *supra* note 37, at 26.

⁵³ Trade Act of 1974, Pub. L. No. 93-618, Jan. 3, 1975, 88 Stat. 1978, as amended by 19 U.S.C. §§ 2101-2495 (1988). The 1988 Trade Act permits the U.S. Trade Representative to designate countries with inadequate protection for intellectual property. 19 U.S.C. § 2242(a)(1)(A), as amended by Pub. L. No. 103-82, 107 Stat. 2156, Dec. 8 1993; Pub. L. No. 103-465, 108 Stat. 4938. Dec. 8, 1994. Such countries are designated "priority foreign countries." 19 U.S.C. § 2242(a)(2) as amended by Pub. L. No. 103-82, 107 Stat. 2156, Dec. 8 1993; Pub. L. No. 103-465, 108 Stat. 4938. Dec. 8, 1994. Designation as a priority foreign country represents the last step before trade sanctions may be imposed, provided the inadequacies cannot be resolved via negotiations or dispute settlement. 19 U.S.C. § 2415(a)(1) (1988). Official notice in the Federal Register is provided for priority foreign country listings, indicating the reasons for the designation. 19 U.S.C. § 2411(d)(3)(C)(ii) as amended by Pub. L. No. 103-465, 108 Stat. 4938. Dec. 8, 1994. The U.S. Trade Representative may identify countries with less inadequate protection for intellectual property by placing such countries on a "watch list" or "priority watch list." Telephone interview with Joseph Papovich, Deputy Assistant U.S. Trade Representative for Intellectual Property (November 16, 1994). No official notice is given for countries with watch list or priority watch list designations, nor does the U.S. Trade Representative's office keep any public records on file for watch list countries. *Id.*

⁵⁴ Patent Act, No. 64, § 51 (1953) (N.Z.), as amended by New Zealand Amendment 1992, No. 81.

⁵⁵ *New Zealand Removed From Intellectual Property List*, INT'L TRADE DAILY (BNA) Oct. 13, 1992, available in WESTLAW, BNA-BTD database.

⁵⁶ The initial purpose of the English legislation which New Zealand adopted was to prevent adverse effects on the English pharmaceutical industry due to perceived dominance by German pharmaceutical manufacturers. *NBR*, *supra* note 37, at 26.

⁵⁷ See discussion *supra* part II.A.

⁵⁸ CHARLES S. RHYNE ET AL., LAW-MAKING ACTIVITIES OF THE UNITED NATIONS CONFERENCE ON TRADE AND DEVELOPMENT 119 (1976).

national product commensurate with that of Western European nations.⁵⁹ In 1992, Canada was the only other industrialized nation with broad-based compulsory licensing laws, and was on the verge of repealing those provisions.⁶⁰ Thus, section 51 may not have been appropriate for New Zealand as a developed nation.

On the other hand, proponents of compulsory licensing argue that benefits exist even for a developed country such as New Zealand. The New Zealand Public Health Association ("PHA") cited the lack of competition created by patent protection as a factor leading to increased prices. Although the U.S. drug manufacturers typically respond to such charges by pointing to the flourishing generic market in the United States,⁶¹ the PHA indicated that New Zealand's small market makes it difficult to obtain good prices from large manufacturers and noted that brand-name manufacturers are buying up generic manufacturers in order to retain control over prices once the patent expires.⁶² Finally, while section 51 was not used extensively, it presented the silent threat of a compulsory license, and as the *Glaxo* court noted, that threat was likely to become more potent after Pacific Pharmaceuticals' victory was upheld.⁶³

External forces with significant domestic effects in New Zealand ultimately appeared to force repeal of section 51. New Zealand wished to expand its agricultural exports,⁶⁴ particularly to the United States, but was in no position to do so as a result of the watch list designation by the U.S. Trade Representative. Glaxo put additional pressure on the legislature by threatening to withdraw plans for a multi-million dollar pharmaceutical plant.⁶⁵ These external pressures were considered to outweigh the potential benefits associated with retention of section 51.

⁵⁹ New Zealand's 1985 per capita GNP of U.S. \$7,290 ranks between that of Italy (U.S. \$6,500) and the United Kingdom (U.S. \$8,380). RAPP & ROZEK, *supra* note 23, at A-11.

⁶⁰ NBR, *supra* note 37, at 26. Canada has since amended its patent laws. *Canada Approves Changes to Drug Patent Legislation*, REUTERS CAN. FIN. REP., Feb. 4, 1993, available in LEXIS, NEWS Library, CURNEWS File. The change included a repeal of pharmaceutical compulsory licensing measures. *American Pressure Killed Compulsory Licensing Not NAFTA*, CDMA Asserts, Canada Newswire, June 2, 1993, available in LEXIS, NEWS Library, CURNEWS File.

⁶¹ RAPP & ROZEK, *supra* note 23, at 98. In the absence of compulsory licensing measures, generic manufacturers obtain access to patent rights either by obtaining voluntary licenses from patent holders or by delaying manufacture until after the patent term has expired.

⁶² NBR, *supra* note 37, at 26.

⁶³ *Glaxo Group Ltd. v. Commissioner of Patents*, 3 N.Z.L.R. 179, 184 (C.A. 1991).

⁶⁴ Mark Magnier, *New Zealand Skirts Nuclear Debate to Get U.S. Support on Farm Trade*, J. COM., July 1, 1991, at 1A, available in WESTLAW, IOC database.

⁶⁵ *New Zealand: Legal Victory Proves Pyrrhic for Generic Drug Maker*, NAT'L BUS. REV., June 26, 1992, at 6, available in WESTLAW, INT-NEWS database.

C. *Pharmaceutical Price Regulation in New Zealand*

Shortly after the repeal of section 51, New Zealand's health care system underwent significant changes. Prior to 1993, the New Zealand government provided price subsidies for prescription drugs on the basis of chemical composition.⁶⁶ Under that program, doctors generally were not informed of drug prices and pharmacists did not have the power to substitute one drug for another.⁶⁷

Under the current regulations, doctors are informed of drug prices, and Regional Health Authorities ("RHAs"), which provide the drug subsidies, are given an annual budget.⁶⁸ Thus, an incentive now exists to prescribe the lowest priced drugs, and the information required to make the proper decision is in the hands of the prescriber. Furthermore, the regulating authority, Pharmaceutical Management Agency Ltd. ("Pharmac"), has adopted a reference pricing scheme.⁶⁹ Under this system, drugs are classified into therapeutic groups, consisting of drugs which are used to treat the same or similar conditions. Therapeutic groups are further divided into subgroups, consisting of drugs which produce similar therapeutic effects while treating similar conditions.⁷⁰ The subsidy price is established by the lowest priced drug within a subgroup.⁷¹ If a manufacturer charges more than the subsidy price, the purchaser must pay the difference.⁷²

The changes in the drug price regulation scheme were clear attempts to improve the efficiency of the health care system.⁷³ By making information available to those in decision-making positions, the use of less expensive treatments is encouraged. By establishing a subsidy price equal to the lowest priced drug within a therapeutic subgroup, manufacturers are encouraged to charge low prices but need not give up patent protection. The combined effects of these changes and the repeal of section 51 are analyzed in the following section.

⁶⁶ Pauls Interview, *supra* note 21.

⁶⁷ *Id.*

⁶⁸ *Id.*

⁶⁹ PHARMACEUTICAL MANAGEMENT AGENCY, LTD., OPERATING POLICIES AND PROCEDURES OF PHARMACEUTICAL MANAGEMENT AGENCY LIMITED, July 1993 at 8 [hereinafter OPERATING POLICIES].

⁷⁰ *Id.*

⁷¹ *Id.*

⁷² Pauls Interview, *supra* note 21.

⁷³ *Id.*

III. THE EFFECTS OF THE RESCISSION OF SECTION 51

Since the repeal of section 51 and the changes in drug price regulations, the following results have occurred. Drug prices in New Zealand have been stable and the number of generic manufacturers has increased,⁷⁴ indicating that price regulations have been effective despite the loss of compulsory licensing. Compulsory licensing measures not specific to pharmaceuticals have been amended,⁷⁵ making frequent use of such provisions unlikely for any product, including pharmaceuticals. The reforms of these measures bring them into compliance with recent GATT provisions.⁷⁶ The combination of the new GATT provisions and U.S. policy on compulsory licensing, suggests that continued pressure will be brought to bear on countries retaining liberal compulsory licensing measures. Finally, the worldwide shift from compulsory licensing to price regulation may eventually force the United States to adopt such regulations, in which case the New Zealand approach provides a reasonable template on which to base new legislation. Therefore, understanding the effects of price regulation in New Zealand is important for U.S. pharmaceutical manufacturers and regulatory bodies.

A. *Effects on the New Zealand Marketplace*

The countervailing effect of pharmaceutical pricing reforms appears to be responsible for the fact that, despite the repeal of section 51, drug prices in New Zealand have remained stable,⁷⁷ and the number of generic manufacturers in the marketplace has actually increased.⁷⁸ The indirect method of obtaining price controls by curbing intellectual property rights has been effectively replaced by increased direct regulation of prices. The question presented then is whether on balance increased reliance on price regulation, and in particular the type of reference pricing adopted by New Zealand, represents an improvement over reliance on compulsory licensing.

⁷⁴ *Id.*

⁷⁵ Patents Amendment Act No. 64, § 46(2) (1953) (N.Z.). See *infra* notes 91-93 and accompanying text.

⁷⁶ The recent GATT provisions are contained in the *TRIPS Agreement*, *supra* note 3. For further discussion, see *infra* part III.C.2.

⁷⁷ Pauls Interview, *supra* note 21.

⁷⁸ *Id.*

There is a clear benefit to drug manufacturers as a result of the reduced threat presented by compulsory licensing.⁷⁹ Manufacturers are free to enter and exit the market without fear of losing patent protection. As a direct result of increased patent protection, plans for a New Zealand manufacturing facility, which were shelved by Glaxo during the debates over the repeal of section 51, have since been approved.⁸⁰

The effects of reference pricing are a bit less clear. Reference pricing in general has been criticized on several grounds. First, by charging the purchaser for any difference between the established subsidy price and the price desired by the manufacturer, manufacturers are forced to match the subsidy price because purchasers will not choose to pay anything if they have the option to pay nothing.⁸¹ While the strategy may result in short-term price reductions, the long-term effects are less certain.⁸² Long-term effects may include an eventual reduction in research and development efforts due to reduced revenues from drug sales.⁸³

A second criticism is that price regulation schemes focus narrowly on drug prices and not on overall expenditures.⁸⁴ This criticism appears to be met by New Zealand's implementation method. Under the New Zealand system, the RHAs operate a budget which includes pharmaceuticals as part of a larger health care package. Thus, if a more expensive drug treatment saves money in the long run by reducing the need for more costly procedures, the RHAs have the ability to make the long-term cost-effective choice.⁸⁵

The reference pricing system provides some of the same consumer benefits that compulsory licensing would. It provides incentives for manufacturers to produce drugs within a therapeutic subgroup at the lowest possible cost. This will tend to encourage generic manufacturers to enter the market. The system also provides incentives for manufacturers to

⁷⁹ The threat has not been completely eliminated. Compulsory license measures do still exist in New Zealand in only a general sense. These measures are not applied specifically to pharmaceuticals. The general provision makes the grant of a compulsory license more restrictive than section 51. See discussion in Section III.

⁸⁰ 1992 NATIONAL TRADE DATA BANK MARKET REPORTS, Nov. 13, 1992, available in LEXIS, ASIAPC Library, NZEAL File.

⁸¹ HEINZ REDWOOD, PRICE REGULATION AND PHARMACEUTICAL RESEARCH—THE LIMITS OF COEXISTANCE 40 (1993).

⁸² Long-term results for countries with reference pricing systems have been described as "disappointing." *Id.* at 41.

⁸³ This possible effect is discussed in greater detail *infra* part III. D.

⁸⁴ REDWOOD, *supra* note 81, at 59.

⁸⁵ Pauls Interview, *supra* note 21.

develop truly innovative drugs because such drugs may be placed in a separate subgroup, and thus remain immune from direct price competition until similar drugs are independently developed.⁸⁶

The trouble is that treating New Zealand as a closed system may tend to exaggerate the potential benefits of price regulation. With price regulations in place, New Zealand consumers can benefit from the research and development efforts of brand-name manufacturers while paying the lower prices charged by generic manufacturers. Brand-name manufacturers must recoup their investment in unregulated markets, where they can charge prices representative of their research and development expenditures. The United States is an obvious example of such a market. Thus, while cost savings can result in the short term and perhaps even in the long term in New Zealand, the reason may simply be that the true cost of research and development is being borne by consumers in unregulated markets, such as the United States.⁸⁷

In sum, intellectual property rights have been strengthened by the repeal of section 51, and drug prices in the short term have remained stable. More time is required to assess the long-term effects on drug prices and, just as importantly, time is required to determine the effect of increased price regulation on research and development.

B. Alternative Compulsory Licensing Measures

The repeal of section 51 did not expunge compulsory licensing measures from the New Zealand Statutes. Section 51 dealt with compulsory licensing for foods, medicines, and surgical devices,⁸⁸ but a manufacturer seeking a compulsory license might instead apply under sections 46-50 of the Patent Act. These sections permit compulsory licensing of any patentable invention, although under more severe restrictions than were required under section 51. Under section 51, a compulsory license could be granted upon application by any interested person, with no additional restrictions beyond the Commissioner's approval.⁸⁹ Under sections 46-50, compulsory

⁸⁶ OPERATING POLICIES, *supra* note 69.

⁸⁷ *Industry Issue Brief—International Price Comparisons*, PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA, 1994, at 7.6 [hereinafter PHRMA].

⁸⁸ Patent Act No. 64, § 51 (1953) (N.Z.).

⁸⁹ *Id.*

licenses can be granted only under particular conditions, such as inadequate working.⁹⁰

However, even the general compulsory licensing measures were recently made more restrictive in order to comply with GATT intellectual property measures. On January 1, 1995, New Zealand passed additional reforms of the Patent Act, among them modifications to section 46. The changes limit compulsory licenses for domestic markets,⁹¹ eliminate the availability of compulsory licenses for junior patents,⁹² and require that licensing negotiations be attempted with the patent holder prior to the grant of a compulsory license.⁹³ These changes bring the New Zealand compulsory licensing measures into compliance with GATT provisions.

The section 46 applicant has a difficult task ahead. Successful use of section 46 prior to 1992 was nonexistent,⁹⁴ and with additional restrictions imposed as of 1995, it is possible that compulsory licensing in New Zealand has truly been limited.⁹⁵ Particularly in the area of pharmaceuticals, the

⁹⁰ Under the Patent Act No. 64 (1953) (N.Z.), a compulsory license will be granted if the patent is not being worked to the fullest extent capable in New Zealand (§ 46(2)(a)), if importation of the patented article hinders commercial working of the patent in New Zealand (§ 46(2)(c)), if by refusal of the patentee to grant a license, an export market is not being supplied (§ 46(2)(d)), or if the working of another patent (junior patent) is hindered by the patentee's refusal to grant a license (§ 46(2)(d)). Non-working of a patent occurs when the patent owner does not exploit the patent. Compulsory licensing is one solution to the problem, since it permits others to produce the patented article. PAUL GOLDSTEIN, COPYRIGHT, PATENT, TRADEMARK AND RELATED STATE DOCTRINES 497 (1993). Non-working is of particular concern where public health or safety is at issue.

⁹¹ "The grounds upon which a license may be granted under this section are that a market for the patented invention is not being supplied, or is not being supplied on reasonable terms, in New Zealand." Patents Amendment Act No. 64, § 46(2) (1953) (N.Z.), as amended by New Zealand Amendment 1994, No. 122.

⁹² The Patent Act originally permitted compulsory licenses in cases, where by the refusal of the patentee to grant a license, the working or efficient working of any other patented invention was hindered. Patent Act No. 64, § 46(2)(d)(ii) (1953) (N.Z.). This language was deleted in the 1994 Amendments. Patents Amendment Act 1994, § 46 (N.Z.).

⁹³ "No license shall be granted under this section unless the person applying for the license, having taken all reasonable steps to do so, has been unable to obtain a license, or to obtain a license on reasonable terms, from the patentee." Patents Amendment Act 1994, § 46(7) (N.Z.).

⁹⁴ It should be noted that as of 1992, no licenses have been granted under the current provisions. *New Zealand Joins PCT; Compulsory License Provisions are Abolished*, PAT., TRADEMARK & COPYRIGHT DAILY, (BNA) (Nov. 6, 1992), available in LEXIS, PATENT Library, BNAPTD File. This may be an indication that no compulsory licenses were sought or, perhaps more likely, that the threat of compulsory licenses provided the incentive for successful negotiations. If the latter is the case, then mandating attempted negotiations prior to the grant of a compulsory license should not have a significant effect on current business practices.

⁹⁵ On the other hand, it is not clear exactly why the use of § 46 has been limited. It is possible that the threat of a compulsory license forced successful negotiations. See *supra* note 41. It is also possible that pharmaceutical applications which would have gone through section 51 will now simply be redirected

continued threat of trade sanctions by the United States may well discourage the Commissioner from granting compulsory licenses under section 46.

The changes in New Zealand's compulsory licensing laws were brought about through the use of two separate means. Section 51 was repealed as a result of bilateral negotiations with, and unilateral trade sanction threats by, the United States. The modifications to section 46 were brought about as a result of New Zealand's status as a signatory to the multilateral GATT agreement. The GATT position on compulsory licensing is important, both for its effect on New Zealand law and its effect on the laws of all member nations. The GATT position is reflective of both the trend away from compulsory licensing and the reluctance of member nations to abandon compulsory licensing as quickly as the United States might wish.

C. *Compliance with GATT*

The General Agreement on Trade and Tariffs ("GATT") is a multilateral trading agreement which has focused on the elimination of non-tariff trade barriers among member nations.⁹⁶ The most recent round of GATT negotiations, the Uruguay round, included considerable treatment of intellectual property issues collectively known as Trade Related Aspects of Intellectual Property, or TRIPS. Compulsory licensing received special consideration in the GATT TRIPS,⁹⁷ and the evolution of the current agreement is indicative of both the disparity between developed and developing countries and the continued unease associated with patent rights for pharmaceuticals. The pressure brought to bear on New Zealand in a bilateral setting was present in a multilateral setting throughout the GATT treaty negotiations.

1. *Pre-Uruguay Round Intellectual Property Agreements*

Prior to the formulation of the TRIPS language during the Uruguay round of GATT, the Paris Convention and Patent Cooperation Treaty

through section 46. However, it is indisputable that obtaining such a license under section 46 will be more difficult, due to the requirement for domestic use and proof of attempted negotiations.

⁹⁶ RALPH H. FOLSOM ET AL., INTERNATIONAL BUSINESS TRANSACTIONS 19 (1991).

⁹⁷ See *TRIPS Agreement*, *supra* note 3, at 95 (discussing "limited exceptions to the exclusive rights" granted by a patent).

provided the bases for international protection of intellectual property.⁹⁸ Under article 5 of the Convention, compulsory licenses could be granted against the patentee for "abuses" of rights under the patent.⁹⁹ Compulsory licenses could also be granted for failure to work or insufficient working of the patent.¹⁰⁰ These provisions have been interpreted as permitting compulsory licenses to be used liberally when local working of the patent is considered insufficient.¹⁰¹

2. *GATT Compulsory Licensing Provisions*

In 1988, the European, Japanese, and United States business communities proposed GATT provisions prohibiting the discrimination against particular classes of subject matter when granting compulsory licenses.¹⁰² The language was specifically directed at countries which maintained provisions permitting easy compulsory licensing for food and medicine.¹⁰³ The current GATT text does not contain the suggested prohibition on discrimination. This is an indication of the international resistance to U.S. efforts to curb the use of compulsory licensing.

Under the current text, member countries are permitted to provide "limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent . . . taking account of the legitimate interests of third parties."¹⁰⁴ The exception is subject to two restrictions. First, the individual must have made efforts to obtain authorization from the rights holder on

⁹⁸ Under the Paris Convention, foreign holders of local patents are to be treated no differently than local holders. FOLSOM ET AL., *supra* note 96, at 615, citing Paris Convention for the Protection of Industrial Property of March 20, 1883, as revised at Brussels on December 14, 1900, as revised at Washington on June 2, 1941, as revised at The Hague on Nov. 6, 1925, as revised at London on June 2, 1934, as revised at Lisbon on October 31, 1958, as revised at Stockholm on July 14, 1967, art. 2, 21 U.S.T. 1631 [hereinafter Paris Convention.] The Patent Cooperation Treaty provides for uniform patent search and filing procedures. *Id.* at 615, citing Patent Cooperation Treaty, June 19, 1970, entered into force January 24, 1978, 28 U.S.T. 7645. However, neither treaty provides for international uniformity of patent protection.

⁹⁹ Paris Convention, *supra* note 98, art. 5, § 2, 21 U.S.T. 1636.

¹⁰⁰ Under the Convention, compulsory licenses could be granted for failure to work or insufficient working four years after the date of filing or three years after the date of patent grant, whichever occurred later. Paris Convention, *supra* note 98, art. 5, § 4, 21 U.S.T. 1637.

¹⁰¹ Reichman, *supra* note 7, at 101.

¹⁰² 11 IIC STUDIES, GATT OR WIPO? NEW WAYS IN THE INTERNATIONAL PROTECTION OF INTELLECTUAL PROPERTY 372 (Friedrich-Karl Beier & Gerhard Schricher eds., 1989).

¹⁰³ *Id.* at 374.

¹⁰⁴ TRIPS Agreement, *supra* note 3, art. 30, at 95. "Third parties" include consumers, other manufacturers, and governments.

reasonable commercial terms.¹⁰⁵ Second, use of the patent is predominantly for the supply of the domestic market of the member country authorizing such use.¹⁰⁶ The requirement for authorization efforts will be waived in the event of a national emergency,¹⁰⁷ and both requirements will be waived if the use of the patent is a remedy for anti-competitive practices.¹⁰⁸ Remuneration shall be paid to the patent holder to account for the economic value of the authorization.¹⁰⁹ Any doubt that this language leaves the door open to compulsory licensing of pharmaceuticals is dispelled by comparing similar TRIPS language in article 21 dealing with the compulsory licensing of trademarks, which states flatly that "compulsory licensing of trademarks shall not be permitted."¹¹⁰

The net effect of the GATT provisions is that compulsory licenses cannot generally be granted unless prior negotiations have failed to yield a satisfactory solution. Beyond this requirement, considerable flexibility is given to national governments to develop their own methods for promoting internal development.¹¹¹ The revised text does not prevent special treatment for food and pharmaceuticals, as did the 1988 text. In fact article 8, which contains basic principles of the TRIPS provisions, allows member nations to revise national laws as necessary to protect public health and nutrition.¹¹²

Nevertheless, the new GATT measures represent a restriction on compulsory licensing when compared to the Paris Convention provisions. It also seems likely that within the GATT framework, the trend toward reducing the use of compulsory licensing measures will be amplified in bilateral negotiations between countries which maintain liberal compulsory licensing measures and those which seek to have such measures

¹⁰⁵ *Id.* art. 31(b), at 95.

¹⁰⁶ *Id.* art. 31(f), at 95.

¹⁰⁷ *Id.* art. 31(b), at 95.

¹⁰⁸ *Id.* art. 31(k), at 96.

¹⁰⁹ *Id.* art. 31(h), at 95.

¹¹⁰ *Id.* art. 21, at 90.

¹¹¹ Reichman, *supra* note 7, at 104.

¹¹² Article 8.1 states that "Members may, in formulating or amending their national laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital interest to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement." *TRIPS Agreement*, *supra* note 3, art. 8.1, at 87. Article 8.2 provides: "Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology . . ." *TRIPS Agreement*, *supra* note 3, art. 8.2, at 87.

removed.¹¹³ Technically, New Zealand was not required by GATT to repeal section 51. However, the gradually decreasing tolerance of compulsory licensing by the GATT members makes bilateral and unilateral actions by the United States, such as those engaged in with New Zealand, more consistent with GATT mainstream policies. The GATT position, while reflective of the controversy surrounding compulsory licensing, is indicative of the trend away from such laws as a means to control pharmaceutical prices.

D. Effects Beyond New Zealand's Borders

1. Implications for Compulsory Licensing Worldwide

The change in patent law in New Zealand has implications for the United States and its trading partners. U.S. Trade Representative Carla Hills cited New Zealand's action as one which ought to be followed by other countries.¹¹⁴ At the time the legislation was passed, thirty-four countries were on the "Special 301" list.¹¹⁵ The fact that a significant effort was expended by the United States and drug manufacturers to reform a relatively small market¹¹⁶ may be another indication that the reforms were intended as much to set an example as to protect holders of New Zealand patents. The United States was no doubt concerned that if a developed nation such as New Zealand were unwilling to repeal compulsory licensing provisions, developing countries, which risk a greater potential for loss by rescinding compulsory licensing measures, would be even less likely to enact such reforms.¹¹⁷

Canada presents an example of another nation which came under attack by the United States for maintaining liberal pharmaceutical compul-

¹¹³ It should be noted that the passage of GATT has not affected the use of Special 301, under which the United States can impose trade sanctions (as it threatened to do in the case of New Zealand's section 51) against countries seen as maintaining lax intellectual property standards. For a brief description of Special 301, see *supra* note 53.

¹¹⁴ Following the repeal, U.S. Trade Representative Carla Hills was reportedly "pleased that the issue was resolved" and stated that she hoped "other trading partners will follow the lead of New Zealand by modernizing their patent laws consistent with evolving international trends." *New Zealand Removed From Intellectual Property List*, INT'L TRADE DAILY (BNA) (Oct. 13, 1992).

¹¹⁵ *US Cites India, Taiwan, Thailand for Worst Records on Intellectual Property, PAT., TRADEMARK & COPYRIGHT DAILY* (BNA) (May 1, 1992), available in WESTLAW BNA-BTD database. The list is updated annually and in 1994, 27 countries were represented. It remains to be seen whether subsequent lists will include countries which have adopted the GATT TRIPS provisions.

¹¹⁶ The population of New Zealand was 3.5 million in 1991. Magnier, *supra* note 64.

¹¹⁷ For a recent listing of countries retaining compulsory licensing provisions, see Julian-Arnold, *supra* note 2.

sory licensing laws. The Canadian experience is important for two reasons. First, Canada, like New Zealand, was under direct pressure from the United States to modify its compulsory licensing measures.¹¹⁸ Such pressure was at least partially responsible for the eventual repeal of Canadian compulsory licensing measures for pharmaceuticals.¹¹⁹ The Canadian experience thus provides an additional example of U.S. zeal to go beyond GATT in securing strong patent protection for pharmaceuticals, and bring the laws of its trading partners into compliance with those of the United States.¹²⁰ Second, the Canadian law repealing compulsory licensing provisions included measures strengthening drug price controls.¹²¹ This action is another indication of the shift toward direct price control brought about by the repeal of compulsory licensing measures.

The long-term effects of changes in both Canada and New Zealand should be closely followed to determine whether the shift in price control mechanisms results in a net increase in benefits to patent holders and consumers over the long term.

2. *Implications for U.S. Pharmaceutical Price Regulation*

As other countries turn to price regulation and drug prices are forced below their market values, the result may be that international pharmaceutical companies charge higher prices in the United States to make up for the

¹¹⁸ In February 1993, Canada passed Bill C-91, which reformed drug patent laws. *Canada Approves Change to Drug Patent Legislation*, REUTERS CAN. FIN. REP., Feb. 3, 1993, available in LEXIS, NEWS Library, CURNWS File. The reform included the repeal of compulsory licensing for pharmaceuticals. *American Pressure Killed Compulsory Licensing, Not NAFTA, CDMA Asserts*, CAN. NEWSWIRE LTD., June 2, 1993, available in LEXIS, NEWS Library, CURNWS File. The Canadian Drug Manufacturers Association ("CDMA") asserted that the measure was not repealed in order to comply with either GATT or NAFTA. *Id.* Indeed, NAFTA art. 1709(6) contains language nearly identical to that in GATT art. 31, which, as discussed in part III.C., does not prohibit compulsory licensing.

¹¹⁹ *American Pressure Killed Compulsory Licensing, Not NAFTA, CDMA Asserts*, CAN. NEWSWIRE LTD., June 2, 1993, available in LEXIS, NEWS Library, CURNWS File.

¹²⁰ The United States maintains extremely limited compulsory licensing measures in the areas of environmental technology, e.g., Clean Air Act, 42 U.S.C. § 1875(h)(6); and nuclear energy, e.g. Atomic Energy Act, 42 U.S.C. § 2183(g). CHISUM & JACOBS, *supra* note 6, at 2-309, n.19 (1992).

¹²¹ According to the Pharmaceutical Manufacturer's Association, Canada ("PMAC") the legislation grants the Patented Medicine Prices Review Board ("PMPRB") increased powers to order price rollbacks and reimbursement of excess revenues from patented pharmaceuticals. *Debate Rages in Parliament Over Drug-Patent Legislation* PAT., TRADEMARK & COPYRIGHT DAILY (BNA) (Jan. 6, 1993), available in LEXIS, BNA Library, BNAPTD File. Included in the measure is language permitting the provincial governments to consider reference pricing as a means to control drug costs. *Year of "Unprecedented Turmoil" in Canada*, MARKETLETTTER (PUBLICATIONS) LTD., June 20, 1994, available in LEXIS, NEWS Library, CURNWS File.

shortfall. The net effect may be similar to that under a liberal compulsory licensing regime, namely that U.S. consumers provide a disproportionate amount of the support required to develop new pharmaceuticals. U.S. consumers may end up subsidizing consumers in countries with strong price regulations, just as they previously subsidized consumers in countries with weak patent protection.

The United States need not give up its own strong patent laws to establish equity with other members of the international marketplace. One option the United States has is to attempt to reduce the use of drug price regulations worldwide. This approach has been advocated by major drug manufacturers.¹²² However, such an approach is bound to be fraught with difficulties. Foreign nations are by nature reluctant to change purely internal policies, particularly those concerned with public health, at the behest of the United States. In addition, the sheer number of developed as well as developing countries which maintain some form of drug price control system¹²³ provides worldwide resistance to changes in regulatory schemes.

A second option is for the United States to implement a price regulation scheme of its own in order to place U.S. consumers on an equal footing with international consumers. Such measures have been considered as part of the recent health care proposals now before Congress.¹²⁴ As might be expected, price regulation schemes have not been met with approval from drug manufacturers. Manufacturers point out that countries which have pricing freedom for pharmaceutical products are correlated with countries which generate significant contributions to pharmaceutical research and development.¹²⁵ However, correlations do not necessarily imply causation. Drug manufacturers also point out that price regulation systems tend to be more concerned with low drug prices than with low expenditures. They contend that lower prices may result in excessive consumption and an ultimate rise in per capita pharmaceutical expenditures.¹²⁶ In this regard, the New Zealand system appears to balance the maintenance of a competitive drug industry with the desire to keep prices low.¹²⁷ If the benefits brought

¹²² PHRMA, *supra* note 87.

¹²³ REDWOOD, *supra* note 81, at 39.

¹²⁴ One such plan to enforce price regulation for new breakthrough drugs was defeated in 1994. *Dingell Will Kill Drug Review Council Plan*, MARKETLETTER, May 2, 1994, available in LEXIS, NEWS Library, CURNWS File.

¹²⁵ REDWOOD, *supra* note 81, at 3.

¹²⁶ *Id.* at 59.

¹²⁷ See OPERATING POLICIES, *supra* note 86 and accompanying text.

about by the New Zealand system are long-lived, such a system can provide a template for institution of drug price control in the United States.

An additional difficulty with price regulation in the United States is that research and development may be further discouraged, since drug manufacturers will have no other markets available in which to charge prices reflective of their research and development expenditures. One solution to this difficulty is to increase the research and development subsidies already made available to the industry through the National Institutes of Health ("NIH").¹²⁸

Ironically then, each increase in government participation in the marketplace leads to the need for additional participation. Patent protection resulted in the need for price regulation, which in turn may result in the need for increased research and development subsidies. The inevitable conclusion is that, particularly in the area of pharmaceuticals, where public health and safety are at issue, some form of government participation is necessary. As the United States and the world become increasingly committed to strong patent protection, governments will naturally tend to seek supplementary schemes such as price regulation and research subsidies by which to balance low prices and availability with incentives for continued development.

IV. CONCLUSIONS

The effect of the repeal of New Zealand's pharmaceutical compulsory licensing laws was to exceed the requirements currently mandated by GATT. Remaining compulsory licensing measures have been modified to be compliant with GATT. Any tendency for prices to increase as a result of the repeal of New Zealand's compulsory licensing provisions were overshadowed by updates to New Zealand's price regulation plan for pharmaceuticals. This indicates that as compulsory licensing is restricted, price regulation may play a greater role in establishing pharmaceutical price levels.

If past trends are any indication, the United States will continue to advocate the reduced use of compulsory licensing for pharmaceuticals worldwide, despite the fact that GATT, which restricts compulsory licensing, does not prohibit such measures. By so doing, U.S. and foreign

¹²⁸ *Statement Calls for Attention to Medical Research in Reform Debate*, HEALTH CARE POL'Y REP. (BNA) (May 9, 1994), available in LEXIS, BNA Library, BNAHCP File.

inventors can obtain patent rights abroad which at least approach those granted by a U.S. patent. This is a positive step, in that it increases patent uniformity and allows patent holders to enter foreign markets without the threat of compulsory licensing. However, as the use of compulsory licensing is diminished, price regulation will increasingly be relied upon as a means for ensuring low drug prices. The likely result is that U.S. consumers, operating in a relatively unregulated market, may subsidize consumers elsewhere.

By adopting a price regulation system of its own, the United States may both ensure lower drug prices and put U.S. consumers on an even footing with those in the rest of the world. The New Zealand system may serve as a useful model—one that balances price regulation with price competition and research incentives.

