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Argentina's Emerging Standard of Intellectual Property Protection: A Case Study of the Underlying Conflicts between Developing Countries, TRIPS Standards, and the United States

Kimberly A. Czub

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ARGENTINA'S EMERGING STANDARD OF INTELLECTUAL PROPERTY PROTECTION: A CASE STUDY OF THE UNDERLYING CONFLICTS BETWEEN DEVELOPING COUNTRIES, TRIPS STANDARDS, AND THE UNITED STATES

Kimberly A. Czub[*]

INTRODUCTION

In 1994, members of the World Trade Organization (WTO) signed the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) that provides minimum standards for national legislation regarding intellectual property rights.[1] The TRIPS Agreement is significant because it establishes intellectual property (IP) standards far above the national laws of many developing countries. Since many countries did not have an existing system to protect IP rights[2], developing countries were given extra time to establish laws reflecting the standards of the TRIPS Agreement.[3]

The first deadline for developing countries to implement national legislation was January 1, 2000[4] and there is significant controversy surrounding the efforts of many developing countries to implement TRIPS standards. One of the most controversial areas of IP protection involves pharmaceutical patents, an area in which the United States has had considerable difficulty with its trading partners.[5]

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* B.A., (Economics), American University, 1995; J.D., Case Western University School of Law, 2001. Executive Topic Development Editor, *Case Western Reserve Journal of International Law.* The author would like to thank her parents and Garrett Nagle for their love, support and encouragement during the student note process and throughout law school.

[1] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Annex 1C, LEGAL INSTRUMENTS-RESULTS OF THE URUGUAY ROUND vol. 31; 33 I.L.M. 81 (1994) [hereinafter TRIPS Agreement].

[2] *See* CARLOS M. CORREA, INTELLECTUAL PROPERTY RIGHTS, THE WTO AND DEVELOPING COUNTRIES: THE TRIPS AGREEMENT AND POLICY OPTIONS 107 (2000).

[3] TRIPS Agreement, *supra* note 1, at art. 65.

[4] An additional five years was granted with respect to pharmaceutical patents. *See id.*

[5] TRIPS patent disputes initiated by the United States have resulted in two DSU decisions and numerous consultations in the WTO. *See Snapshot of WTO Cases Involving the United States* (last modified Feb. 8, 2001), *at* http://www.ustr.gov/enforcement/snapshot.html. The issue of pharmaceutical patent protection has been especially contentious between the United States and Argentina. *See* Travis Lea, *Argentina and the United States Clash Over Drug Sales at the WTO* (Jan. 8, 2001) (noting "Pharmaceutical patent protection has been one of the most important trade issues of the past

Argentina is an important country to study pharmaceutical patent enforcement because Argentine manufacturers copy about $500 million annually from multinational companies[6] and because Argentina is one of the few countries to have consistently resisted U.S. pressure to reform its pharmaceutical patent laws. Although Argentina's resistance may provide examples to other developing countries, the greatest impact of the feud over patent protection will be found in regional trade agreements.[7] Since the formation of the TRIPS Agreement, the United States has sought to increase patent protection in the Northern and Southern Hemispheres through other agreements such as the North American Free Trade Agreement (NAFTA) and the Free Trade Agreement of the Americas (FTAA).[8] Argentina's resistance may have a negative effect on other

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decade between the United States and Argentina."), *at* http://www.inthesetimes.com/web2503/lea2503.html. The tension between the United States and Argentina has been fueled by the United States pharmaceutical industry which has labeled Argentina as a "stand out in [its]refusal to adopt adequate and effective patent protection for pharmaceutical products". Glenn Hess, *PhRMA Calls for Tougher Enforcement of Trade Regulations*, CHEMICAL MARKETING REPORTER, Mar. 6, 2000, *available at* Westlaw, 2000 WL 9382329.

[6] *See* Craig Torres, *Argentina Is Tricky Ground for U.S. Drug Makers: Lax Enforcement of Treaty Causes a Loss of Sales*, WALL ST. J., Dec. 3, 1999, at A13.

[7] The United States pharmaceutical industry was never entirely satisfied with the level of protection TRIPS provided. Consequently, the United States has sought to increase IP standards beyond TRIPS in regional trade agreements. The Pharmaceutical Manufacturers Association stated that "it is our understanding that the United States will continue to use strong bilateral negotiations to achieve NAFTA standards of protection." *See Drug Firms Back GATT Accord Provided the United States Pursue Further Bilateral Negotiations*, PAT. TRADEMARK & COPYRIGHT L. DAILY (BNA), (Jan. 25, 1994), *available in* LEXIS, Patent Law Treatises & Analytical Materials file. NAFTA is regarded as having some of the strongest IP protections in the world. *See* Robert M. Sherwood, *Intellectual Property Systems and Investment Stimulation: The Rating of Systems in Eighteen Developing Countries*, 37 IDEA 261, 343-44 (1997). The Free Trade Agreement of the Americas is not yet complete but the United States is pressing for standards of IP protection beyond those found in the TRIPS Agreement. *See US Firms to Push for More IP Rights Protection in WTO, FTAA Talks*, AM. TRADE, Aug. 6, 1998, at 24 (stating the United States wants to strengthen TRIPS provisions in the FTAA negotiations to achieve a WTO plus level of protection).

[8] One way the US would like to strengthen intellectual property standards in the Americas is through the FTAA. *See FTAA Negotiating Group on Intellectual Property: Public Summary of US Position* (visited Jan. 20, 2001), http://www.USTR.gov/regions/whemisphere/intel.html. Thus far, Argentina and other Latin American Countries have resisted increased regional standards of protection. *See Papovich: IP Rights Provisions in FTAA Should Not Be Limited to TRIPS*, AM. TRADE, July 23, 1998, at 5 (noting that Joseph Papovich, the Assistant US Trade Representative for Services and Intellectual Property, said "demands by some Latin American countries that the FTAA should not go beyond the TRIPS Agreement are a 'waste of time.'").

signatories to these agreements and other Latin American trade agreements such as Mercosur.[9]

A case study of Argentina's patent problems reveals many of the variables that comprise effective enforcement of the TRIPS Agreement. First, this Note will explain the history of the current dispute and the U.S. attempts to compel patent protection. Next, an assessment of the benefits and harms of strengthening IP rights to the levels favored by the United States will be examined. Finally, the effect of external and internal impediments to strengthening IP rights in Argentina and prospects for change in the future will be assessed.

I. BACKGROUND

A. The Path to the WTO Dispute Settlement Body

1. Pre-TRIPS Negotiations

The current patent rights dispute in Argentina is over fifteen years old and the WTO consultations are the latest attempt of the United States Trade Representative (USTR) to strengthen IP protection in Argentina. While the WTO consultations between the United States and Argentina progress, it is easy to forget that the current controversy is not limited to global intellectual property rights, but to domestic international trade concerns as well. The 1974 Trade Act included a provision under Section 301 by which private parties may obtain the intervention of the United States against foreign trade practices that unfairly limit US commerce.[10] Remedies for infractions are not limited to a particular trade agreement;[11] rather, the USTR has broad discretion to impose a range of remedies including trade sanctions.[12] Two mechanisms, Special 301 and Super 301, list procedures identifying countries with unfair trade practices.[13] The first step in a Super 301 investigation is the preparation of a National Trade Estimate Report.[14] During 1985-1987, the USTR published several

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[9] The Mercosur Agreement was supposed to lead to coordination of IP rights in South America by December of 1994, but no new provisions regarding such protection have been added to the agreement as of this date. *See Mercosur Agreement Should Lead to Harmonized Industrial Property Laws*, PAT. TRADEMARK & COPYRIGHT L. DAILY (BNA), (Sept. 16, 1991), *available in* LEXIS, Patent Law Treatises & Analytical Materials file.

[10] Trade Act of 1974 §§ 301, 182, *as amended by* 19 U.S.C. §§ 2412(a)(1), 2242(a)(1)(B).

[11] *See* EDWARD SLAVKO YAMBRUSIC, TRADE BASED APPROACHES TO THE PROTECTION OF INTELLECTUAL PROPERTY 29 (1992).

[12] *See id.* at 30.

[13] *See id.* at 189.

[14] *See id.*

National Trade Estimate Reports that examined Argentina's 1864 Patent Law and the country's IP rights structure.[15] The chief problem with the 1864 law was that it excluded pharmaceuticals from patent protection.[16] Argentina was not the only country targeted for IP reforms; the United States also criticized the patent laws of countries all over the world.[17] On September 27, 1988, the United States launched a Section 301 investigation of Argentine patent protection and consultations with the Argentine government followed.[18]

Serious change within Argentina's IP regime did not occur until 1989 when Carlos Saul Menem came to power and pledged to reform Argentina's patent laws.[19] President Menem promised to send legislation to the Argentine Congress to provide patent protection of pharmaceuticals, but legislation was not presented to the Argentine Congress until 1991.[20] The original bill provided for patent pipeline protection and severely restricted compulsory licensing provisions. These provisions have been consistently and strongly endorsed by the United States in negotiations with developing countries throughout the world.[21] The bill was not passed immediately and lost most of its momentum in March of 1993 when the House Committee on Industry decided not to debate the patent bill until the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) negotiations was concluded.[22] While the bill was stalled, Carlos Menem still signed

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[15] *See The Path to Patent Law As Taken by Argentina*, MARKETLETTER, Jan. 29, 1996, *available at* Westlaw, 1996 WL 8314654 [hereinafter *The Path to Patent Law*].

[16] *See id.*

[17] *See id.*

[18] *See* Initiation of Section 301 Investigation: Argentina's Failure to Provide Adequate and Effective Intellectual Property Protection for Pharmaceuticals, 53 Fed. Reg. 37,668 (Sept. 27, 1988). The investigation was launched in response to a petition by the Pharmaceutical Manufacturers Association (PMA) on August 10, 1988, citing Argentina's lax IP protection. *See id.*

[19] *See The Path to Patent Law, supra* note 15.

[20] The PMA withdrew its request for an investigation before consultations with Argentina regarding pharmaceutical patent protection. *See USTR, Citing Argentina's 'Progress,' Announces Withdrawal of PMA Petition*, PAT. TRADEMARK & COPYRIGHT L. DAILY (BNA), (Oct. 18, 1989), *available in* LEXIS, Patent Law Treatises & Analytical Materials file.

[21] *See* Antonio Mill & Estudio Mill, *Patent Law Would Be Modernized by Draft Bills Now Before Congress*, PAT. TRADEMARK & COPYRIGHT L. DAILY (BNA), (May 19, 1992), *available in* LEXIS, Patent Law Treatises & Analytical Materials file.

[22] *See Analysts Debate Intention of New Pharmaceutical Decree*, PAT. TRADEMARK & COPYRIGHT L. DAILY (BNA), (May 27, 1993), *available in* LEXIS, Patent Law Treatises & Analytical Materials file [hereinafter *Analysts Debate*]. *See also Opposition Keeps Patent Law on Hold Until Conclusion of Uruguay Round*, PAT. TRADEMARK & COPYRIGHT L. DAILY (BNA), (Aug. 7, 1992), *available in* LEXIS, Patent Law Treatises & Analytical Materials file, (noting that the draft legislation under debate contains several provisions,

Executive Decree 177 amending various aspects of the existing patent law.[23] The decree was viewed in Argentina as a compromise, but the contents of the decree did not enact significant pharmaceutical patent protection. Instead, the decree addressed labeling of pharmaceuticals and importation of pharmaceutical products.[24] The United States was not pleased with the delay and placed Argentina on the Special 301 Priority watch list in April of 1993.[25] The patent bill finally made it to the Senate in May, and in December the GATT negotiations were continued.[26] On June 30, 1994, Argentina was on the watch list again.[27]

2. Post-TRIPS Negotiations

On November 17, 1994, the Senate finally passed a patent protection bill that was a mixture of approaches from various political parties. Unfortunately, the protections contained in the original bill were not provided for in this new bill.[28] In December of 1994, the Senate proposed amendments to the original bill and did not include pipeline protection or compulsory licensing.[29] The United States felt the provisions were not up to par with TRIPS or GATT.[30] In January of 1995, Law 24,425 was published which ratified the WTO and TRIPS.[31] After the treaties were ratified, President Menem clarified that any inconsistencies in the pending

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including compulsory licensing that may be illegal if certain proposals in the Uruguay round are successful). Compulsory licensing was later incorporated into TRIPS. *See* TRIPS Agreement, *supra* note 1, at art. 31.

[23] *See Analysts Debate, supra* note 22.

[24] *See id.*

[25] *See USTR Names Brazil, India, Thailand "Special 301" Priority Countries*, PAT. TRADEMARK & COPYRIGHT L. DAILY (BNA), (May 11, 1993), *available in* LEXIS, Patent Law Treatises & Analytical Materials file.

[26] *See Argentine Senate Approves Patent Protection Bill*, PAT. TRADEMARK & COPYRIGHT L. DAILY (BNA), (Nov. 29, 1994), *available in* LEXIS, Patent Law Treatises & Analytical Materials file [hereinafter *Argentine Senate*].

[27] *See* USTR Notice, *Identification of Foreign Countries That Deny Adequate and Effective Intellectual Property Protection or Market Access to Persons That Rely on Intellectual Property Protection*, 59 Fed. Reg. 26341 (1994).

[28] *See Argentine Senate, supra* note 26.

[29] *See GATT Treaty Would Have Precedence Over Argentine Patent Law, DiTella Says*, PAT. TRADEMARK & COPYRIGHT L. DAILY (BNA), (Mar. 23, 1995), *available in* LEXIS, Patent Law Treatises & Analytical Materials file.

[30] *See Menem to Modify Argentine Patent Bill in Wake of United States and European Criticism*, PAT. TRADEMARK & COPYRIGHT L. DAILY (BNA), (Apr. 21, 1995), *available in* LEXIS, Patent Law Treatises & Analytical Materials file.

[31] *See id.*

legislation would be decided in favor of the TRIPS provisions.[32] In March of 1995, the Argentine House passed Law 24,481 that called for an eight-year transition for pharmaceutical protection.[33] President Menem vetoed this bill and introduced the provisions of GATT (Decree 548/95).[34] Later, Article 50 of Law 24,572 was modified in December of 1995 to make it easier to keep compulsory licenses.[35]

In 1995, President Menem issued regulatory decree 621/95 on the application of international treaties.[36] Pharmaceutical patent protection would be granted as of January 1, 1996, and the form of patent revalidation was included. However, most of the provisions of the presidential decree were overturned and Law 24,481 was passed.[37] The patent law is in force, but the corrective measures have made some of the provisions unclear.[38] On March 22, 1996 Menem signed legislation that provided for a five-year transition period for patent protection and established a framework for compulsory licensing.[39] Concurrent with the legislation, the Executive Branch also issued Decree 260/96, replacing Decree 590/5 that had been overturned earlier by Congress. The decree contained a number of clarifications and interpretations about the evolving patent act. The new law was not entirely satisfactory to the United States and they urged Menem to reopen debate on such issues as data secrecy and compulsory licensing.[40] Negotiations continued and by December a supplementary law was issued. On December 18, 1996, the Argentine Congress passed Law 24,766 that "mirrors" TRIPS and permits innovator's competitors to use the innovator's test data already in the public domain, and eliminated a clause that did not protect information for entities not previously registered in

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[32] *See id.*

[33] *See id.*

[34] *See New Argentine Patent Regime Still Judged Subpar, US Executive Says*, PAT. TRADEMARK & COPYRIGHT L. DAILY (BNA), (Apr. 4, 1996), *available in* LEXIS, Patent Law Treatises & Analytical Materials file [hereinafter *Argentine Patent Regime*].

[35] *See id.*

[36] *See id. See also Cavallo Says Executive Decree Will Implement GATT, TRIPS Requirements*, PAT. TRADEMARK & COPYRIGHT L. DAILY (BNA), (Apr. 24, 1995), *available in* LEXIS, Patent Law Treatises & Analytical Materials file.

[37] *See Argentine Patent Regime, supra* note 34.

[38] *See Patent Law Enters Into Force; Corrective Measure's Status Remains Unclear*, PAT. TRADEMARK & COPYRIGHT L. DAILY (BNA), (Nov. 2, 1995), *available in* LEXIS, Patent Law Treatises & Analytical Materials file.

[39] *See Argentine Patent Regime, supra* note 34.

[40] *See Menem Says He'll Try to Reopen Discussions On New Patent Law*, PAT. TRADEMARK & COPYRIGHT L. DAILY (BNA), (June 18, 1996), *available in* LEXIS, Patent Law Treatises & Analytical Materials file.

Argentina.[41] In addition to pressing for concessions above the standards of the TRIPS Agreement, the USTR threatened that if the law was not passed by December 20, sanctions against Argentina would be enforced. Even though the TRIPS Agreement protects new patent registrations, the United States wanted protection for all products already within the Argentine market.

3. Trade Retaliation by the United States

Regardless of Argentina's efforts during the transitional period, the United States still brought trade sanctions against Argentina. In 1997, The United States revoked GSP status for Argentine exports due to Argentina's failure to enact stronger patent legislation[42] within Law 24,766.[43] While U.S. sanctions have been successful with Argentina's largest trading partner Brazil,[44] Argentina's economic and political structure is less supportive of a strong IP rights regime.

In response to the trade sanctions, Argentine legislators threatened a counterstroke that would extend its transition period under the TRIPS Agreement for pharmaceutical products. Argentina originally volunteered to comply within five years.[45] The U.S. trade sanctions did not produce any meaningful changes to Argentina's patent laws and Argentina remained on the USTR watch list for 1997-1999.[46]

Efforts by the United States to ascertain and promote TRIPS compliance after the sanctions were initiated in the WTO during 1998 and 1999. For example, the United States requested that Argentina submit answers to a WTO questionnaire regarding the implementation of Articles

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[41] *See Lower House Approves Provision on Pharmaceutical Trade Secrets*, PAT. TRADEMARK & COPYRIGHT L. DAILY (BNA), (Nov. 29, 1994), *available in* LEXIS, Patent Law Treatises & Analytical Materials file.

[42] *See* USTR Notice, *Generalized System of Preferences; Intellectual Property Rights; Request for Public Comment on Products Affected by Partial Withdrawal of Argentina's Benefits*, 62 Fed. Reg. 3072-07 (Jan. 21, 1997) [hereinafter USTR Sanction Notice]. The United States revoked GSP for 118 tariff lines or about half of the trade for which Argentina has GSP Status. *See US Listing of Goods to Lose GSP Benefits Spurs Anger in Argentina*, INSIDE NAFTA, Apr. 17, 1997, at 1, 30.

[43] *See USTR-Designate Barshefsky Announces GSP Sanctions Against Argentina for Continuing IP Rights Problems*, USTR Press Release, Jan. 15, 1997, *available in* LEXIS, News Library, News file.

[44] *See The Path to Patent Law, supra* note 15.

[45] Kevin G. Hall, *Tension Mounts in US- Argentine Spat Over Drug Patents*, J. COMMERCE, Dec. 10, 1997, at 1A.

[46] *See, e.g.*, USTR Sanction Notice, *supra* note 42.

70.8 and 70.9 of the TRIPS Agreement.[47] Argentina complied with the request and submitted answers on February 17, 1999.[48] With the 2000 TRIPS deadlines looming, the United States turned to the WTO dispute body to press its positions.

B. WTO Dispute Proceedings

1. The 1999 Consultations

The United States has initiated two sets of consultations with Argentina in the WTO. Concurrent with the USTR Special 301 proceedings in 1999, the USTR filed its first set of consultations with the WTO regarding Argentina's protection of patent rights.[49] The first set of consultations addressed Argentina's enforcement of restrictions on the marketing of pharmaceuticals and protection of proprietary data for agrochemicals.[50] Switzerland petitioned to be added to the consultations later in the month.[51] Although the WTO consultations are not a formal suit, the United States has hinted that Argentina will be one of the first countries to be subject to patent litigation under TRIPS after 2000.[52]

The two issues raised in the Complaint deal with the enforcement and interpretation of Articles 70.9 and 39.3 of TRIPS. According to Article 70.9, Argentina is required to provide exclusive marketing rights (EMRs)

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[47] *See Implementation of Articles 70.8 and 70.9: Responses by Argentina at Meeting of Council for TRIPS held Mar. 12, 1999*, (Document No. IP/C/W/135) (visited Mar. 1, 2001), *at* http://www.wto.org [hereinafter *Argentine Response*].

[48] *See id.* Many other developing countries were asked to comply with these requests. Unfortunately, the United States was not pleased with the progress and refused to identify the steps it was taking to ensure the transfer of technology to developing countries as required by TRIPS. *See* Daniel Pruzin, *US and Developing Countries Feud Over Intellectual Property Provisions*, INT'L TRADE DAILY (BNA), (Dec. 8, 1998), *available in* LEXIS, News Library, BNA file.

[49] *See* USTR Notice, *Identification of Countries That Deny Adequate Protection or Market Access for Intellectual Property Rights Under Section 182 of the Trade Act of 1974*, 64 Fed. Reg. 24438 (May 6, 1999).

[50] *See Argentina-Patent Protection for Pharmaceuticals and Test Data Protection for Agricultural Chemicals*, Request for Consultations by the United States, (May 10, 1999), *at* http://www.wto.org [hereinafter U.S. 1999 Consultations].

[51] *See Argentina-Patent Protection for Pharmaceuticals and Test Data Protection for Agricultural Chemicals*, Request to Join Consultations by Switzerland, (May 26, 1999), *at* http://www.wto.org [hereinafter Switzerland 1999 Consultations].

[52] *See* Corbett B. Daly, *United States Threatens Argentina with Suit Under the TRIPS Agreement*, INT'L TRADE DAILY (BNA), (Oct. 18, 1999), *available in* LEXIS, News Library, BNA file. *See also* Daniel Pruzin, *WTO Postpones Seattle Post-Mortem*, PAT. TRADEMARK & COPYRIGHT L. DAILY (BNA), (DEC. 20, 1999), *available in* LEXIS, News Library, BNA file.

for pharmaceuticals since it does not have to provide patent protection until 2000.[53] However, the United States has complained that this provision is not enforced in Argentine courts.[54] Secondly, the United States contends that Argentina's practices violate Article 39.3 of TRIPS by enacting legislation that fails to protect confidential test data for agricultural chemical products for U.S. companies seeking patents.[55] The consultations were held on June 15, 1999 and July 27, 1999, but the countries have not resolved their differences.[56]

2. The 2000 Consultations

The 2000 consultations expanded the list of grievances against Argentina and reflect the United States' displeasure with Argentine patent administration and judicial enforcement. The expanded list of grievances included complaints regarding: (1) improperly excluded subject matter from patent protection; (2) lack of safeguards used to grant compulsory licenses; (3) failure to provide preliminary injunctions to prevent patent infringements; (4) improper limits of judicial authority to shift the burden of proof in civil cases involving infringement of patent processes; (5) impermissible limits on certain transitional patents to limit the exclusive rights granted by these patents; and (6) lack of patentee rights to amend their patent applications to claim the enhanced protections of TRIPS.[57] Consultations were held on July 17, 2000 and November 29, 2000, but they did not lead to any significant changes in Argentina's patent laws.[58]

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[53] *See* TRIPS Agreement, *supra* note 1, at art. 70.9.

[54] *See* specific examples of the U.S. charge that Argentine courts do not enforce EMRs *infra* Section IV.

[55] *See* TRIPS Agreement, *supra* note 1, at art. 39.3.

[56] *See* Office of the USTR, *Dispute Settlement Update,* (last modified Feb. 9, 2001), *at* http://www.ustr.gov/enforcement/high.html [hereinafter *Dispute Settlement Update*].

[57] *See* WTO Consultations Regarding Argentina—Patent and Test Data Protection, 65 Fed. Reg. 36497 (June 8, 2000); *See also Certain Measures on the Protection of Patents and Test Data,* Request for Consultations by the United States, (June 6, 2000), *at* http://docsonline.wto.org/DDFDocuments/t/IP/d/22.DOC [hereinafter U.S. 2000 Consultations]. The European Union and Switzerland later requested to join the consultations initiated by the United States. *See Request to Join Consultations: Communications from the European Communities, Argentina—Certain Measures on the Protection of Patents and Test Data,* (visited June 20, 2000), *at* http://docsonline.wto.org/DDFDocuments/t/WT/DS/196-2.DOC; *See also* Switzerland 1999 Consultations, *supra* note 51.

[58] *See Dispute Settlement Update, supra* note 56.

3. Effect of the Consultations On Argentina's IP Laws

The request for consultations by the United States has been viewed as an excuse by the Argentine legislature to further curtail patent protection.[59] After the announcement of the first set of consultations two bills were introduced in the Argentine legislature; one seeking to extend the patent transition period another five years and the other seeking to change the existing patent law and require local production in exchange for a patent.[60] Neither measure is particularly novel or harsh, but the U.S. pharmaceutical industry is alarmed because neither action is viewed as a step forward. Argentina's actions have aggravated a contentious issue.[61] However, Argentina does have the option of extending its transition period under TRIPS Article 65.[62] Moreover, the requirement of local production is also not prohibited by TRIPS, and Argentina's main trading partner, Brazil, has the same requirement in its patent law.[63] Despite these facts, the USTR has warned that further consultations with the USTR would result if either law were passed.[64] Contrary to U.S. accusations of retaliation, several Argentine legislators have asserted that the IP legislation was introduced to protest agricultural subsidies.[65]

The consultations between the United States, Switzerland, the European Union, and Argentina are just the latest chapter in a highly polarized debate about IP protection in developing countries. While industrialized nations counsel patience to developing countries and emphasize the long term benefits of a strong IP regime, they often forget that the benefits to their industries will surface in the long run as well due to the changes developing countries must undergo to support strong IP rights. However, just as the U.S. trade sanctions were merely a paper victory,[66] it is

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[59] *See Argentine Congress Holds Back On WTO Patent Compliance Delay,* AM. TRADE, June 17, 1999, at 3 [hereinafter *Argentine Congress Holds Back*].

[60] *See id.*

[61] *See US Attacks Argentine Proposal to Delay WTO Patent Compliance,* AM. TRADE, June 3, 1999, at 3-5 [hereinafter *WTO Patent Compliance*].

[62] *See The Path to Patent Law, supra* note 15.

[63] *See* ECONOMIST INTELLIGENCE UNIT: *Investing, Licensing and Trading in Argentina* 19 (1999).

[64] *See id.*

[65] *See WTO Patent Compliance, supra* note 61.

[66] While US sanctions enacted in response to Argentina's inadequate patent laws may have hurt Argentina economically, both the sanctions and the threat of sanctions created a political backlash that made the legislature more hostile to immediate patent reform. *See Argentine Government Said Working on Compromise Patent Legislation,* PAT. TRADEMARK & COPYRIGHT L. DAILY (BNA) (Jan. 17, 1996), *available in* LEXIS, News Library, BNA file, (noting threat of sanctions had opposite effect of "giving rise to nationalist arguments in certain sectors"); *See also Latin American Firms Condemn US Pressure,* MARKETLETTER,

likely that a decision by the WTO in favor of the United States will have limited short-term results as well.

II. ISSUES SURROUNDING THE IP PROTECTION DEBATE

A. Consumer Drug Prices

One of the largest concerns of developing countries is the effect of a patent system on pharmaceutical prices. Many developing countries feel that the exclusive rights conferred by a patent will lead to higher prices for consumers. Such a fear is especially relevant to the Argentine market for medicines. On a per capita basis, Argentina's consumer spending on pharmaceuticals rose from $113 to $191 between 1991 and 1995 as compared to Brazil's increase during the same period from $33 to $62. This is a significant difference given the respective population differences of 34 million and 159 million.[67]

Consumer prices for medicines have always been a large concern with the TRIPS Agreement; several studies were done in Argentina that showed significant price increases (71%) and decline in consumption (50%) when a monopoly follows a competitive situation.[68] Price increases were predicted in India and other developing countries in the Far East as well.[69]

The charge that consumer prices will increase has been one of the more appealing defenses of the Argentine pharmaceutical companies, but other developing countries have been equally concerned with price increases.[70] The World Health Organization (WHO) has also published a report, widely criticized by the pharmaceutical industry, arguing that patent rights should be balanced with affordable access to pharmaceuticals in developing countries.[71] Still there is a perception among Argentine citizens that the socioeconomic costs of IP rights would be too great.[72] One study claimed that the average price charged to consumers by Latin American pharmaceuticals for pirated products is 56% lower than the price charged

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Aug. 3, 1998, (stating "while the Latin American drug industry is perfectly prepared to pay royalties to multinationals to market their medicines, it is not prepared to meet all the prerequisites that are being laid down by the 'all powerful North'), *available in* WL, Gale-News database, ISSN: 0951-3175.

[67] *See Mercosur and the Pharmaceutical Industry-Waiting for a Common Patent Regime*, LATIN AM. L. AND BUS. REP., Apr. 30, 1997, at 23, 25 [hereinafter *Common Patent Regime*].

[68] *See United Nations Conference on Trade & Development: The TRIPS Agreement and Developing Countries*, Annex 1, at 62, UNCTAD/ITE/1 (1996).

[69] *See Common Patent Regime, supra* note 67.

[70] *Id.*

[71] *See Id.*

[72] *See Id.*

for the patented product in the United States.[73] Before the TRIPS Agreement was even signed, the Argentine pharmaceutical industry ran a full-page advertisement in *The New York Times* comparing drug prices in the United States and Argentina.[74] The advertisement claimed, for example, that a popular anti-ulcer drug patented in the United States cost $55.15 while the price in Argentina was $19.63. A larger gap occurred in the price of an anti-arthritis drug where the price in the United States was $169.84 compared to $35.08 in Argentina.[75]

Of course, there have been differing views about the problem of price increases in industrialized countries. Several studies conducted by the U.S. pharmaceutical industry have shown that consumers in Argentina actually pay more in relative dollars for their medicines without strong patent protection, while the Argentine pharmaceutical industry becomes richer and richer. Despite these charges regarding the Argentine pharmaceutical industry and other local industries, there is still a perception that they are the best equipped to meet the health demands of their countries and will get the products that consumers need quicker and cheaper than the western countries. The entire process becomes a vicious cycle because, while the Argentine labs procure the medicines the market needs, there is little incentive for countries like the United States to introduce their latest technology into Argentina, which in turn inspires more copies of products that are not available in the Argentine market.

B. Foreign Investment

Stringent IP laws are viewed as a magnet for foreign investment and increased foreign investment has been used as an incentive for developing countries to strengthen their laws. A comparison of Brazil and Argentina illustrates this phenomenon. Brazil passed its industrial property law on May 14, 1996; the law went into effect in 1997.[76] The new law is being hailed as a magnet for foreign investment. For example, a US pharmaceutical manufacturer claims that Brazil and Mexico received over $2 billion dollars in new investment by pharmaceutical companies within the first 18 months of enacting US supported patent laws.[77]

Foreign investment is crucial to long-term economic growth. Whether such investment in competitor nations is hurting Argentina is

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[73] *Id.*

[74] *See Drug Makers, PMA Trade Jabs Over Pharmaceutical Patent Protection*, PAT. TRADEMARK & COPYRIGHT L. DAILY (BNA), (Dec. 10, 1990), *available in* LEXIS, News Library, BNA file.

[75] *See id.*

[76] *See Latin America: Brazil Is Booming, Argentina and the Rest Lag Behind*, MED AD NEWS, May 1997, at 4 [hereinafter *Brazil Is Booming*].

[77] *See* Hall, *supra* note 45.

subject to debate. An Argentine official notes that Argentina has seen the return of ten multinational pharmaceutical companies and has attracted $1.5 million in investment during the time other countries were strengthening their patent laws. Prior to TRIPS, the U.S. share of the pharmaceutical industry fell in Argentina from 25% in 1984 to 14% in 1985 in part due to piracy.[78] Many of the companies that have returned to Argentina use it as an export base for the rest of the Mercosur trading bloc that includes Brazil.[79] While these gains may be attributed to the promise of patent protection, certainly no companies have left Argentina because of the current events and there is evidence that more investment is pouring in despite the lack of "TRIPS-plus" or U.S. levels of protection.[80]

Furthermore, although the promise of foreign investment is used as a "lure" to increase IP rights, the siphoned investment that is now going to Brazil or Mexico is not necessarily connected to the strength of those laws. For example, Brazil's patent law contains a provision that requires domestic production of pharmaceutical products. Argentina's response to the foreign investment flowing into Brazil was to draft similar legislation requiring home production rather than revising their IP law in its entirety.

As stated earlier, the strength of IP rights in Latin American is linked to the amount and type of technology that is transferred by U.S. firms to the region. Hence, even though countries may draw foreign investment through home production requirements, the best type of investment will occur with strong IP rights. Sixty-two percent of American chemical and pharmaceutical firms felt that Argentina's IP laws were too weak to allow the transfer of the latest and best technologies of those companies.[81] The United States is the primary force for lobbying for IP rights in South America because they have the most to lose even if their best and latest technology is not transferred to South America. Foreign pharmaceutical firms have been aggressively buying local firms since the implementation of TRIPS.[82] Argentina has the 11th largest pharmaceutical market in the world with over $3 billion in annual revenue.[83] Because of the influx of foreign buyouts the pharmaceutical sector is now highly concentrated with the top ten pharmaceutical firms controlling 35% of the

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[78] *See* Glenn Hess, *Administration Threatens to Punish Argentina for Intellectual Pirating; Trade Sanctions Planned to Protest Pharmaceutical Piracy,* CHEMICAL MARKET REP., Jan. 27, 1997.

[79] *See id.*

[80] *See id.*

[81] Edwin Mansfield, *Intellectual Property Protection, Direct Investment, and Technology Transfer: Germany, Japan, and the United States,* 10 International Finance Corporation Discussion Paper 27 (World Bank, 1995).

[82] *See* ECONOMIST INTELLIGENCE UNIT, *supra* note 63, at 18-19.

[83] *Id.*

market's revenues.[84] Still, despite the threat of less investment, it is not entirely clear that Argentina is lacking the latest pharmaceutical advances. As stated above, Argentine firms have been known to enter medicines, patented in the United States, into their market even though the United States had no plans to market that product in Argentina.[85]

III. ARGENTINEAN PATENT PROTECTION WILL REMAIN WEAK IN THE IMMEDIATE FUTURE

It has been recognized that one of the stumbling blocks to IP harmonization in developing countries is their historical conception and use of IP rights.[86] Although this fact is not particularly tangible or measurable, it still is a characteristic of many developing countries and pervades the judicial, political, and economic systems of many developing countries. While this section explores the factual evidence of patent protection in Argentina, it is important to remember that underlying conceptions or knowledge about IP rights have a profound influence on many of the actions of developing countries subsequent to the TRIPS Agreement implementation deadlines of 2000.

The dispute between Argentina and the United States regarding pharmaceutical patent protection illustrates that the TRIPS Agreement is only a starting point for ensuring IP protection abroad.[87] While the TRIPS Agreement is an important step in the harmonization of IP laws,

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[84] *Id.*

[85] *See* Torres, *supra* note 6 (noting that Merck's hypertension drug Rentic was launched by a local pharmaceutical firm Roemmers SA before Merck could market the original version in Argentina).

[86] *See* CORREA, *supra* note 2, at 102 (noting differences between Western and South American conception of IP Rights); *See also* Ruth Gana, *Prospects for Developing Countries Under the TRIPS Agreement*, 29 VAND. J. TRANSNAT'L L. 735, 747 (1996) ("[D]eveloping countries' refusal to adhere to higher standards of intellectual property protection cannot therefore, as is often the case, simply be explained as 'ignorant', 'backward' or conscious decisions to exploit the system....refusals often represented conscious policies to use the system to serve national interests, however those interests may have been defined.").

[87] TRIPS was not solely designed to protect the rights of patent holders. Carlos Correa remarks, "The TRIPS Agreement has not adopted an 'absolutist' model of intellectual property, but rather aims at balancing the various interests at stake. The purpose of the TRIPS Agreement is not merely to confer strong protection to title-holders. It contains pro-competitive rules...thus striking a proper balance between...interests." *See* Carlos M. Correa, *Harmonization of Intellectual Property Rights In Latin America: Is There Still Room for Differentiation?* 29 N.Y.U. J. INT'L L. & POL. 109, 122-23 (1997).

significantly for the holders of patents in the pharmaceutical sector,[88] the treaty only imposes minimum IP standards.[89] Since many of the developing nations did not have IP regimes in place or had narrow IP laws in place when TRIPS went into effect, there are large gaps in the level of protection between nations despite the minimum standards required by TRIPS.[90] Gaps in IP protection between industrialized nations such as the United States and developing countries such as Argentina have shaped the controversy regarding pharmaceutical patent protection.[91] Since the gaps between TRIPS standards and U.S. IP laws have worked to the disadvantage of the American pharmaceutical industry, the USTR has made strong initiatives to increase the level of IP protection in developing countries with well-established local industries.

TRIPS does not prohibit countries from legislating IP standards beyond the provisions of the treaty. Countries may also elect to enter into regional trade agreements requiring higher levels of IP protection.[92] However, under Article 1, more extensive IP protection cannot be forced upon member countries.[93] It is not likely that these countries will increase IP protection beyond TRIPS. According to Carlos Correa, TRIPS "has been regarded by many developing countries as representing both the minimum and the maximum limit of protection to be granted...[t]hey consider that the agreement also sets forth the upper limit of protection they should confer in order to ensure a right balance between the producers and

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[88] TRIPS patent obligations are numerous and detailed, and grant rights to patent holders that did not exist in many countries before the Uruguay Round. *See* CORREA, *supra* note 2, at 120.

[89] *See* J.H. Reichman, *Enforcing the Enforcement Procedures of the TRIPS Agreement*, 37 VA. J. INT'L L. 335, 336-37 (1997) (cautioning dispute resolution panels of the WTO to remember that TRIPS standards are "minimum standards").

[90] *See* Correa, *supra* note 86, at 109-110. TRIPS eliminated the division between countries which grant patents to the pharmaceutical industry and those that do not. *See id.* Before TRIPS, fifty countries did not have laws extending patent protection to pharmaceutical products. *See id.* at 117. *See generally,* Sherwood, *supra* note 7, (noting the differences in the level of protection in relation to direct investment between the TRIPS standards, United States standards, and NAFTA standards).

[91] *See* J.H. Reichman, *From Free Riders to Fair Followers: Global Competition Under the TRIPS Agreement*, 29 N.Y.U. J. INT'L L. & POL'Y 11 (1997).

[92] TRIPS Agreement, *supra* note 1, at art. 1. The provision explicitly states, "Members may, but shall not be obliged to, implement their own domestic laws more extensive than the protection required by this Agreement, provided that such protection does not contravene the provisions of this agreement."

[93] *Id.*

users of technology."[94] Higher levels of IP protection will only occur if certain external and internal forces are present in Argentina.[95]

This section will first examine the limits of the TRIPS Agreement to increase the level of patent protection in Argentina and Argentina's compliance with the TRIPS Agreement itself. Next, the effectiveness of external and internal mechanisms to increase intellectual property protection in Argentina will be reviewed and compared to other developing countries and other types of IP protection in Argentina. Finally, with the advent of the year 2000 TRIPS compliance deadline, this section will examine the options for both the United States and Argentina in the future.

A. Limitations of the TRIPS Agreement

The TRIPS Agreement contains many provisions that may encourage developing nations to diverge from the enhanced TRIPS levels of IP protection supported by the United States.[96] These provisions are the cornerstone of the controversy between many developed and less developed nations over TRIPS patent standards: the developing countries seek to use the technology transfer provisions in TRIPS to support their own local industries, while the developed countries focus upon IP rights protection to protect their industries. Viewed within this context, developing countries will not necessarily seek to violate TRIPS, but have little incentive to increase patent protection beyond TRIPS either.[97] There are several reasons why developing countries will not increase existing TRIPS patent protections. These include "economic start-up costs, the reluctance to grant monopoly rights to foreign companies instead of local industries and increases in consumer prices."[98]

Certainly there are many other reasons why developing countries may not have incentives to go beyond the TRIPS provisions, but the chief opposition to increasing TRIPS protection in Argentina has been the local pharmaceutical industry.[99] Countries with strong domestic pharmaceutical industries perceive an unbalanced economic playing field between themselves and the United States and have enacted or proposed legislation within the parameters of the TRIPS Agreement to counter such an

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[94] CORREA, *supra* note 2, at 102.

[95] *See id.*

[96] See Correa, *supra* note 86, at 122-23 ("[I]nfluenced by the underlying [pro-competitive] philosophy of TRIPS, many countries have followed this path in their recent reforms.").

[97] *See* J.H. Reichman, *The TRIPS Agreement Comes of Age: Conflict or Cooperation With the Developing Countries?*, 32 CASE W. RES. J. INT'L L. 441, 450-51 (2000).

[98] *See* Correa, *supra* note 86, at 119.

[99] *See id.*

imbalance.[100] It is not clear if several provisions of the Argentine patent legislation are legal under TRIPS since parts of the legislation are currently being challenged in the WTO dispute process.[101] However, even if the WTO does not find any of the recently enacted legislation actionable, there is still an underlying tension between what TRIPS requires and what the United States wants.[102]

The next few sections will compare and contrast the several key provisions of the TRIPS Agreement and the implementing Argentine legislation. Except for the provisions of the legislation currently subject to WTO consultations, the legislation largely mirrors the requirements of TRIPS and is subject to the same ambiguities and interpretation problems. Although the USTR frequently cites Argentina as a violator of the TRIPS Agreement, the real issue with Argentina's patent legislation is not its compliance with TRIPS but its reluctance to legislate beyond the TRIPS treaty.

1. TRIPS Article 65: Transnational Arrangements for Developing Countries

A concession to developing countries without prior pharmaceutical patent protection came in the form of a ten-year delay in the implementation of patents for pharmaceuticals and chemical products.[103] Since Argentina did not allow pharmaceutical products to be patented before the TRIPS Agreement, it could elect to use the ten-year transition period to enact and enforce the legislation complying with TRIPS.[104] Argentina elected to reduce the transition period for pharmaceutical patents to five years in Article 100 of Law 24,481 on Patents and Utility Models.[105] The transition period is subject to two requirements: (1) developing countries must provide exclusive marketing rights to the holder of patents

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[100] *Id.*

[101] *See* U.S. 1999 Consultations, *supra* note 50; *see also* U.S. 2000 Consultations, *supra* note 57.

[102] *See generally* CORREA, *supra* note 2, at 49-98 (noting gaps that encourage nations to formulate their own local policies).

[103] *See* TRIPS Agreement, *supra* note 1, at art. 65. The General Provisions and Basic Principles of the TRIPS Agreement note that the socialized need of developing countries need to be recognized in the creation of maximum flexibility in domestic implementation of laws and regulations.

[104] *See id.* at art. 38 (excluding pharmaceutical products from patent protection for 10 years).

[105] *See* Law No. 24,481, on Patents and Utility Models, tit. VIII, art. 100 (1995) (Arg.) ("Inventions relating to pharmaceutical products shall not be patentable until five years have elapsed following the publication of this Law in the Official Gazette.") [hereinafter Argentine Patent Law].

filed in other countries; and (2) developing countries may not adopt IP laws lower than the TRIPS standards during the transition period.[106] The transition period provided by TRIPS and followed by Argentina both contain provisions requiring that patents filed during the transitional period must receive protection in the form of exclusive marketing rights.[107]

The question still remains whether Argentina can extend its transition period beyond the five-year period it has publicly committed to. As explained earlier, the Argentine Congress has several pieces of legislation pending since the U.S. request for consultations that would amend the patent law to include a longer transition period.[108] Such a delay may be legal under TRIPS, but it is in direct conflict with U.S. efforts to strengthen IP protection in the Americas by 2005. Furthermore, there are also questions as to what aspects of the transition period apply to disputes between patent holders and third parties. Since many developing countries did not enact domestic legislation concurrent with ratification of the TRIPS Agreement, the question remains as to how and when these provisions will be enforced. Argentina has encountered many interpretation issues and these problems are addressed in a later section. Such problems should be a signal to countries that TRIPS is not the ending point to patent protection – it is only the beginning.

2. TRIPS Article 31: Compulsory Licensing/Home Production Requirements

a. Compulsory Licensing

Like the transition period, compulsory licensing was another concession to developing countries[109] and the TRIPS Agreement does not explicitly prohibit legislation that grants compulsory licenses or that allows for government use of patents.[110] As stated earlier, the compulsory licensing provisions of the TRIPS Agreement were opposed by the United States and have been a frequent point of contention between the US and Argentina. However, with the exception of several provisions in the Argentine patent legislation, the requirements of TRIPS and the patent legislation are the same. Hence, whether the grant of compulsory licenses will result in a lower standard of TRIPS protection will be a matter for local courts and the WTO dispute panel to decide.

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[106] TRIPS Agreement, *supra* note 1, at art. 65.

[107] *Id.* at art. 70.9; Argentine Patent Law, *supra* note 104, at art. 8.

[108] *See Argentine Congress Holds Back, supra* note 59, at 3.

[109] *See* Correa, *supra* note 86, at 120-21.

[110] The language in Article 31 states that "where a law of a member allows for other use" implying the ability of countries to legislate compulsory licensing provisions. *See* TRIPS Agreement, *supra* note 1, at art. 31.

Despite the grant of power to use compulsory licenses, the device is still subject to restrictions that must not undermine the rights of the patent holder.[111] Unfortunately, TRIPS does not give explicit standards or examples of what may undermine the patent holder's rights and countries are free to legislate as long as the level of protection granted does not fall below the minimum standards of TRIPS.[112] As stated above, the Argentine law included a provision that authorizes compulsory licensing within 150 days if reasonable terms and conditions have been offered to an inventor for exploitation and the offers have been rejected and the inventor has not exploited his invention.[113] Exceptions to this rule include *force majeure* and patent registration delays beyond the control of the inventor.[114] Even though the TRIPS Agreement does not prohibit these licensing requirements, the United States opposes this provision on several grounds. First, the provision unduly restricts the patent holders' property right.[115] Second, and more importantly, at the time of the legislation, Argentina was the only country to have enacted such a provision and the United States is worried other developing countries will follow suit. [116]

Even if the patent holder becomes subject to a compulsory license, he is still eligible to receive royalties for his invention under Article 43.[117] The royalty amount will be determined by the circumstances of each case, the economic value of the authorization, and the average rate of royalties payable in the sector concerned under contractual licenses between independent parties.[118] Compulsory licensing can also occur when the holder of the patent engages in anti-competitive practices.[119] Anti-competitive practices include excessive pricing, refusal to supply the market on reasonable terms, and restricting production.[120] A third restriction on the rights of patent holders is federal action to exploit the patent in cases of national emergency or security.[121] Again, the TRIPS

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[111] Argentine Patent Law, *supra* note 104, at art. 47.

[112] *See* CORREA, *supra* note 2, at 89-94.

[113] Argentine Patent Law, *supra* note 104, at art. 43.

[114] *Id.*

[115] *See* 1999 U.S. Consultations, *supra* note 50. *See also* 2000 U.S. Consultations, *supra* note 57.

[116] *See WTO Patent Compliance, supra* note 61, at 3-5.

[117] Argentine Patent Law, *supra* note 104, at art. 43.

[118] *Id.*

[119] *Id.* at art. 44.

[120] *Id.*

[121] *Id.* at art. 45.

Agreement does not prohibit any of these actions but the United States views these provisions as weakening TRIPS standards.[122]

It is debatable whether these provisions regarding the 150 day limit violate TRIPS, but it is important to note that the patent holder is not left without recourse if any of the above occur; compulsory licensing is subject to judicial review in civil and federal courts.[123] Argentine courts have not interpreted these provisions yet, but other countries such as Thailand have had to wrestle with the parameters of compulsory licensing in the TRIPS Agreement for health reasons.[124] The USTR response was to impose heavy diplomatic pressure against such use of the patent despite the fact it was legal under TRIPS.[125]

b. Home Production/Quotas

The United States is opposed to any legislative proposals that require foreign drug manufacturers to produce their products locally.[126] However, other Latin American countries have adopted this position and it is arguable whether such a requirement will be legal under the TRIPS Agreement. Developing countries view home production as a way to counter the negative welfare effects of the initial implementation of strong IP laws. Argentine officials point out that after Chile adopted IP laws favored by the United States, the local pharmaceutical industry disappeared and hope to avoid the same result.

c. Article 39: Undisclosed Information/Test Data

As stated in Section I, the United States initiated consultations in the WTO in May of 1999 regarding a 1996 amendment to Argentina's patent legislation.[127] TRIPS Article 39 unequivocally provides that "test

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[122] *Id.*

[123] *Id.* at art. 48.

[124] The Ministry of Public Health in Thailand recently decided it will not allow for the compulsory licensing of the AIDS drug didanosine due to fear that the United States would retaliate with trade sanctions. Although the USTR indicated that it would not impose trade sanctions if the licensing complies with TRIPS. Internal officials still worried about the repercussions of compulsory licensing because of a perception that the United States does not want the ddI case in Thailand to set a precedent for other countries. *See* Aphaluck Bhatiasevi & Woranuj Maneerungsee, *Compulsory ddI Licensing Seen Unlikely*, BANGKOK POST, Feb. 2, 2000, at 4.

[125] *See* Section I of this Note, *supra*.

[126] *See Argentina Reviews IP Rights Laws; US Commerce Secretary Warns Over Local Production Plans*, MARKETLETTER, Feb. 28, 2000, *available in* 2000 WL 7540747. *See also US Threatens Trade Sanctions if Argentina Extends Patent Law*, AFX NEWS, Feb. 17, 2000, *available in* LEXIS, News File, AFX News.

[127] *See* Section II of this Note, *supra*.

data provided by a company in order to obtain marketing approval for agricultural and chemical products must be protected against unfair commercial use...[and] disclosure."[128] The only exception to this requirement is the "necessary protection of the public."[129] Argentina did not explicitly cite public health concerns as the reason for the amended legislation. Despite the legislation, Article 25 of Patent Law 24,481 still applies and states, "pending patent applications and annexes shall remain confidential until the time of their publication."[130] The problem is that Argentina's law allows publication six months after the time of filing. Since TRIPS did not proscribe specific publication limits, Argentina has specified a time limit in its legislation.

d. Articles 70.8 and 70.9: Exclusive Marketing Rights for Pharmaceutical Products

Argentina's provisions for exclusive marketing rights are the second part of U.S. requests for consultations in the WTO.[131] TRIPS Articles 70.9 and 70.8 state that transitional period countries must grant EMRs to patent holders from other countries who wish to market the product in their country and have not obtained a patent.[132] Argentina grants exclusive marketing rights in Article 101 of Patent Law 24,481.[133] EMRs are valid until the TRIPS transitional period ends (November, 2000 for Argentina) and are subject to an important and controversial exception.[134] Argentina will not enforce EMRs when a "third party or parties making use of the [inventor's] invention without his authorization guarantee that the domestic market will be fully supplied at the same actual prices."[135] If the inventor's product is copied because another person is willing to sell at a lower price, the inventor can collect fair and reasonable remuneration from the third parties and the remuneration is set by the INPI.[136] The legislation specifically stated that such provisions would apply unless the WTO adopted a contrary position into the TRIPS Agreement.[137]

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[128] TRIPS Agreement, *supra* note 1, at art. 39.

[129] *Id.*

[130] Argentine Patent Law, *supra* note 104, at art. 25.

[131] *See* U.S. 1999 Consultations, *supra* note 50. *See also* U.S. 2000 Consultations, *supra* note 57.

[132] TRIPS Agreement, *supra* note 1, at art. 70.8, 70.9.

[133] Argentine Patent Law, *supra* note 104, at art. 101.

[134] *Id.*

[135] *Id.*

[136] *Id.*

[137] *Id.*

Argentina further explained the EMR provisions to the Council for TRIPS on February 17, 1999 when questioned by the United States.[138] Argentina specified that any EMR decisions may be appealed by the patent holder in Argentine national courts[139] and explained that the grant of an EMR is contingent upon the approval of both the INPI and the National Food, Drug and Medical Technology Administration (ANMAT) (under authority of the Ministry of Public Health and Social Action).[140]

B. Internal Impediments to Legislating the TRIPS Treaty

1. The Argentine Pharmaceutical Industry

While TRIPS imposes minimum standards for IP compliance, these standards are not rigid. Article 1(1) of the TRIPS Agreement states, "Members shall be free to determine the appropriate method of implementing the provisions of this agreement within their own legal system and practice."[141] Although developing countries pay lip service to strengthening IP rights, J.R. Reichman notes that "the TRIPS Agreement leaves developing countries ample wiggle room in which to implement national policies favoring the public interest in free competition."[142] Countries may adopt differing interpretations of TRIPS provisions or circumvent provisions entirely by enacting domestic legislation that favors local industry.[143] However, TRIPS states that laws cannot be enacted during the transition period that lower the standards of the TRIPS Agreement.[144] Such is the debate regarding Argentina's TRIPS obligations.[145]

Legislative infighting has led to some confusion about the actual terms of Argentina's patent laws.[146] Unfortunately, due to the U.S. trade sanctions imposed in 1997 and the pending WTO consultations,

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[138] *See Argentine Response*, *supra* note 47.

[139] *See id.*

[140] *See id.*

[141] *See* TRIPS Agreement, *supra* note 1, at art. 1.

[142] *See* Reichman, *supra* note 90, at 28.

[143] *See id.* at 25-6.

[144] *See id.* at 26.

[145] The U.S. Patent Office argued that no other country imposed such a requirement. *See Argentine Labs Would Urge WTO Case vs. Sanctions, Challu Says,* INSIDE NAFTA, Mar. 6, 1996, at 11 [hereinafter *Argentine Labs*].

[146] *See* Correa, *supra* note 86, at 118 ("Argentina's patent system is not completely clear due to legislative turbulence.").

pharmaceutical IP rights are a highly contentious issue in Argentina.[147] Despite the political support and pledges of President Menem,[148] there is strong organized opposition to the U.S. efforts to strengthen patent protection in Argentina.[149] The support is mostly due to the size of the pharmaceutical industry in Argentina.

Supplemental to the problem of political opposition over IP rights is corruption in Argentine politics. The United States asserts that the political will of the legislators has been bought by the Argentine pharmaceutical industry. There is significant evidence that both the Menem administration and its opposition parties are corrupt.[150] For example, Claudio Sebastiani, an Argentine legislator, admitted to receiving large sums of money from Argentine pharmaceutical companies.[151] Again, the United States is hardly blameless either – former Vice President Gore is also noted to have received large contributions from U.S. pharmaceutical interests.[152] It does not appear that a compromise between the pharmaceutical industries of either Argentina or the United States will occur in the near to mid-future. Certainly a supportive legislature is conducive to TRIPS enforcement. While Brazil faced the same interest group opposition before and after the implementation of its patent act, the pharmaceutical industry in Argentina has more to lose. Any change to the status quo will ultimately result from economics rather than politics.

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[147] The U.S. attempt to change Argentina's domestic patent laws has been viewed as economic imperialism. *See Multinational Drug Companies Dictate U.S. Trade Policy,* PR Newswire, Jan. 18, 1997, *available in* LEXIS, General News & Information, PR Newswire (noting that U.S. efforts to change Argentina's patent laws ignores the 'will of the people'.).

[148] Menem has made repeated promises that Argentina will strengthen its patent laws and ensure that the laws are not weakened. *See Menem objetara cambios en la ley de patentas que afecten las inversion* [Menem will object to changes in Patent Law], BUENOS AIRES ECONOMICO, June 17, 1999, translated in WORLD REPORTER.

[149] It has been stated that the pharmaceutical lobby in Argentina is responsible for the current state of affairs. $25 million was allegedly spent by Argentina's pharmaceutical companies as bribes to legislators to hinder stronger IP laws. *See* Martin Edwin Andersen, *Argentina's Corruption Crooks Get Bragging Rights Under Federal Cover*, WASH. TIMES, Oct. 28, 1999, at A23. However, the USTR is equally under the influence of the American drug lobby. *See Blood and Gore: Office of the US Trade Representative Goes Too Far In Promoting Interests of US Drug Companies Abroad*, THE NATION, July, 19 1999, at 16. ("The USTR...has become a virtual appendage of the [U.S.] drug industry."). It has also been acknowledged by the ITC that the U.S. pharmaceutical industry will benefit more than any other sector of the U.S. economy from the TRIPS Agreement. *See USTR Bows to Pressure by Multinational Pharmaceutical Companies*, PR NEWSWIRE, Apr. 22, 1997.

[150] *Id.*

[151] *See The Path to Patent Law, supra* note 15.

[152] *Id.*

2. Argentinean Economic Structure

While IP protection has been linked to economic development, it is also well documented that the adoption of a strong IP regime can produce short-term economic consequences.[153] The problem with the TRIPS approach to dispute resolution is that it focuses on results or sanctions rather than the underlying problem of development thereby aggravating the short-term economic consequences experienced by developing countries adopting stricter IP standards.

The current patent regime has produced economic benefits to Argentina and it has been recognized that lax protection offers economic benefits to other developing nations as well.[154] Currently, Argentina is immersed in a recession that has impeded attempts to legislate IP protection.[155] Since 54% of the industry is domestically owned, the initial impact of strong IP laws can further damage the economy.[156] The pirate pharmaceutical industry is worth $6 billion and supplies the rest of Latin America with pharmaceuticals.[157] Although Brazil has recently enacted strong IP rights protection, the rest of the Mercosur trading bloc has not, so there is less incentive and pressure to strengthen protection.[158] Incentives to increase protection are also linked to future economic returns, but there is mixed evidence regarding the ability of IP rights to increase development in Latin America.[159] Even if IP rights could result in immediate gains for Argentina, several studies have noted that adequate enforcement of pharmaceutical patent laws is many years away.[160]

Latin American countries have traditionally been forced to import information-sensitive goods and services mainly because these countries do

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[153] *See* Keith E. Maskus, *Intellectual Property Rights and Economic Development,* 32 CASE W. RES. J. INT'L L. 471, 489-94 (2000) (noting how the short-term costs of IP rights makes reform difficult).

[154] *See* Tara Kalagher Giunta & Lily H. Shang, *Ownership of Information in a Global Economy,* 27 GEO. WASH. J. INT'L L. & ECON. 327, 331 (1993) ("Because pirates of intellectual property incur minimal production costs and no royalty payments, they are in a better position than legitimate producers to satisfy demands in developing countries.").

[155] In 1995, after the first IP laws were introduced, Argentina GDP decreased by 2.5% and the country suffered from record unemployment. A number of consumers also did not have health insurance making people very conscious about drug prices. The pharmaceutical market also fell by 2%. *See Brazil Is Booming, supra* note 76, at 5.

[156] *See* Lynn Woods, *Free Trade Fears: Intellectual Property Disputes Slow New Pact for the Americas,* CORPORATE LEGAL TIMES, Dec. 1999, at BWB12.

[157] *See id.*

[158] *See* Correa, *supra* note 86, at 119.

[159] *See* CORREA, supra note 2, at 23-30.

[160] *See Argentine Labs, supra* note 144, at 11 (Challu notes that most of the innovation occurs in five developed countries).

not have the infrastructure that supports innovation.[161] Given the lack of infrastructure in Argentina and other Latin American countries, it is not surprising that Latin American nationals generate less than one percent of royalties from IP licenses.[162] Hence, the policies that affect many U.S. pharmaceutical companies have a limited effect on the local IP rights holders. More importantly, there has been research that suggests even with strong patent protection the amount of research and development expended will not significantly increase.[163] Most companies do not have the technology to produce original pharmaceuticals.[164]

In Latin America, technological innovation is focused on the productive capacity of physical capital.[165] Public policy does not support funding for the generation and absorption of applied knowledge.[166] For example, there is a working requirement test for patent protection. If the inventor ceased to use the patented technology for a short period of time or used the technology in a way counter to the wishes of the political system, the patent was revoked and the invention was declared public property.[167] If this is true for most of Latin America, then why have countries like Brazil strengthened their IP rights while countries like Argentina resist? One author points to the failure of import substitution in Brazil. From the 1930s to the 1980s many countries in Latin America believed that amassing physical capital was the key to economic development. Brazil practiced an extreme version of this idea and encouraged investment for domestic manufacturing, suppressed agricultural prices, expanded public sector enterprises and tried to stimulate domestic investment through tax credits.[168]

Unfortunately, other equally important factors of growth, such as human capital and other microeconomic levers, were ignored by policymakers. These import substitutes were still dependent on raw materials and technology, but these materials were hard to acquire because of the protected trade policies that existed. The pharmaceutical industry in Brazil was one of many industries affected by this economic policy.[169] The policy fell out of favor during the international debt crisis in the 1980s and

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[161] *See* EDUARDO BUSCAGLIA & CLARISA LONG, U.S. FOREIGN POLICY AND INTELLECTUAL PROPERTY RIGHTS IN LATIN AMERICA 6 (1997).

[162] *Id.*

[163] *United Nations Conference on Trade & Development: The TRIPS Agreement and Developing Countries*, *supra* note 68.

[164] *See id.*

[165] *See* BUSCAGLIA & LONG, *supra* note 161, at 19.

[166] *Id.*

[167] *See id.*

[168] *See id.*

[169] *See id.*

import competition was increased.[170] Concurrently, there was also a demand for high technology imports that spurred the United States to become more vigilant about IP protection. Because of the effects of the failure of the import substitution program in Brazil, policymakers were more sensitive to other forms of economic growth such as IP rights.[171] As stated earlier, Brazil also has less to lose in the pharmaceutical sector since only 15% of the industry is domestically owned.[172] Argentina never carried out a plan of import substitution to the level of its neighbor Brazil where growth has been focused in other areas such as agricultural and textile exports.

Although many Argentines feel that IP development will lead to growth, it is only one piece of the puzzle; other structures such as funding for human capital must be in place for such a plan to be successful. However, just because Argentina's pharmaceutical industry is focused on copying rather than research and development, there still may be some immediate gains made. Several drug companies in India—another country with a strong domestic industry—have made innovations from existing patents that have profited the inventors. While this technique can help allay some of the short-term economic disincentives for copiers, Argentina will still have to voluntarily decide to increase its IP protection for successful results.

3. Application of TRIPS Provisions by Administrative Agencies And the Judiciary

The U.S. belief that Argentine courts do not enforce Article 70.9 of the TRIPS Agreement illustrates the problem of enforcement in developing countries. Strong laws are meaningless without the structure to enforce them.[173] Structure is not limited to the judiciary—other areas of the government need to coordinate their efforts also. Since the first place a patent applicant will go is the patent office rather than the courts, the existing administrative structure is an indicator of whether IP rights will be

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[170] *See id.* at 17.

[171] *See id.*

[172] *See id.*

[173] Proponents of strong IP rights often neglect this variable in the equation. Many countries that have increased IP rights protection at the urging of the United States have strengthened their laws while neglecting to enforce them. For example, Mexico has a strong record of apprehending pirated products and recently enacted stiffer penalties for copyright violations. However, copyright enforcement is still problematic because "[w]hile Mexico probably seizes more [pirated] product, they never convict anyone." *Mexico Enacts Stricter IP Rights Law, But U.S. Industry Fears Scant Compliance,* AM. TRADE, June 3, 1999, at 1. Furthermore, despite the fact that Brazil has the highest standard of IP protection in Latin America, piracy is still a problem; Brazil is estimated to have one-third of the market for pirated cassette tapes in Latin America. *See* BUSCAGLIA & LONG, supra note 161, at 16.

enforced. For example, the enforcement of exclusive marketing rights for pharmaceuticals is in the hands of two different Argentine agencies, the Economic Ministry and the Ministry of Public Health.[174] An exclusive marketing right provides protections similar to a patent and is a way for companies to protect their pharmaceutical products until patent protection for pharmaceuticals is granted.[175] Unfortunately, the two agencies have ineffectively coordinated their jurisdiction, and it has thus been difficult to adhere to Article 70.9. While the Ministry of Public Health approves all drugs sold in Argentina, the Economic Ministry is charged with protecting exclusive marketing rights.[176] As a result, companies with pirated pharmaceuticals approach the Ministry of Public Health to sell the drugs without consulting the Economic Ministry.[177]

Irregularities have also been reported regarding the EMR application process. In September of 1998, the U.S. drug manufacturer Eli Lilly was granted an EMR for its drug Zyprexa by Norma Felix who was head of the Intellectual Property Institute.[178] After Ms. Felix signed the document, it disappeared from her office but reappeared later with information missing and a recommendation that the EMR be denied.[179] After the incident, Ms. Felix lost her position and was replaced by an advisor to Humberto Ruggerio, a noted supporter of the Argentine pharmaceutical industry.[180] Currently, Eli Lilly cannot enforce its EMR and is involved in litigation with an Argentina lab that markets its drug as "FDA approved."[181] The former advisor to Ruggerio, Horacio Hackenov, had his term extended another four months in June 2000 despite protests from the United States.[182] Other incidents include a fire at the Argentine Patent Office that destroyed many patent applications.[183] This lack of transparency should not be unexpected. Indeed, since these drug manufacturers have brought money into the Argentine economy,[184] it is

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[174] *See* Torres, *supra* note 6.

[175] *See id.*

[176] *See id.*

[177] *See id.*

[178] *See id.*

[179] *See id.*

[180] *See id.*

[181] *Id.*

[182] *See Argentine Patent Regime, supra* note 34.

[183] *Id.*

[184] *See* Helene Cooper, *Argentina Faces Sanctions by US over Drug Patents*, WALL ST. J., Jan. 16, 1997, at A11 (noting that Argentine drug makers also export their products throughout South America).

difficult to see why Argentina would want to enforce laws not favorable to its domestic industry.[185]

The TRIPS Agreement lets countries establish their own structure for administrating and enforcing IP rights; however, it is unrealistic to think that countries without existing or effective IP laws will fulfill their TRIPS obligations immediately. This does not mean that industrialized countries cannot take an active role in assisting developing countries or develop initiatives for compliance. Since trade sanctions, negotiations, and WTO consultations have produced limited results, it may be time for the United States and other countries to change their tactics.[186] As Bruce Lehman said, "there is more to intellectual property recognition than getting other countries to sign the agreement and enact laws...[p]art of the needed follow-up is to...improve judicial systems for the enforcement of new standards."[187] For example, in 1991 Mexico enacted IP legislation that included patent protection for pharmaceutical products.[188] In the first few years of operation the patent office had huge delays, prompting the United States to pledge $250,000 to train patent officers in patent examination and set up an effective administrative system.[189] The program was a success and the backlog was eliminated; supporters of the program cited that small

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[185] *See* Frederick M. Abbott, *The New Global Technology Regime: The WTO TRIPS Agreement and Global Economic Development*, 72 CHI-KENT L. REV. 385, 399 (1996) (finding that developing countries will "continue to resist changes to their [intellectual property rights] laws, and when they do make changes, they will be slow to enforce them in favor of foreign enterprises.").

[186] Although it is easy to pin the current IP problems in Argentina on a greedy pharmaceutical industry, Raul Zavalla Carbo, the director of CIFLA, stated that "Acquiring patents and paying royalties is no problem for us...what we want is the right to compete." *See Pharmaceutical Patents Accepted if Linked to Compulsory Licensing*, PAT. TRADEMARK & COPYRIGHT L. DAILY (BNA), (Nov. 14, 1989), *available in* LEXIS, News Library, BNA file. During the late 1980s, 54 of 88 laboratories were Argentine, 57% of the sales went into the Argentine economy, and 6 of 10 Argentine labs had the highest sales volume in the country in the pharmaceutical industry. There have been some concerns about the increased presence of U.S. firms once Argentina began to reform its patent laws. However, while Argentina's pharmaceutical laws are not up to U.S. standards, the country is gearing up for the 2000 deadline. Two of the largest Argentine pharmaceutical companies are reported not to produce copies anymore and large amounts of money has been devoted to modernizing current plants. *See* ECONOMIST INTELLIGENCE UNIT, *supra* note 63, at 18.

[187] *See Witnesses Urge Use of Foreign Aid to Improve Foreign IP Protection*, PAT. TRADEMARK & COPYRIGHT L. DAILY (BNA), (May 5, 1994), *available in* LEXIS, News Library, BNA file.

[188] *See id.*

[189] *See id.*

amounts of money spent had paid large dividends for the people who were able to register their patents.[190]

4. Judicial Enforcement

The foundation of TRIPS enforcement rests with the judiciary; many of the disputes regarding the TRIPS Agreement will center on how the agreement is enforced domestically.[191] However, the existence of IP laws and a body to enforce the laws are only two pieces of the foundation for a strong IP system. As explained in the following section, the judiciary must have familiarity, technical knowledge, and a historical preference for strong IP rights to truly be successful. Furthermore, judicial enforcement will also be affected by domestic legislation enacted to implement TRIPS obligations. Many authors and officials have noted that the TRIPS enforcement criteria are ambiguous and have predicted enforcement problems.[192]

This section will explain how the above factors have worked together to reduce the effectiveness of the TRIPS Agreement and examine existing Argentine cases interpreting the newly enacted patent legislation. While domestic enforcement is an important part of the TRIPS Agreement, the WTO provides the means for international enforcement as well. Due to the recent interpretation of exclusive marketing rights by the Argentine courts, the United States and Switzerland filed requests for WTO consultations in 1999 and the United States has threatened a WTO suit in 2000. International enforcement of the TRIPS Agreement is limited to the *United States v. India*,[193] which involved different complaints regarding EMRs. Unlike India, Argentina already has functioning EMR laws and an office for administrating the EMRs. Although the decision provided important guidelines for international and domestic enactment of EMRs, the decision did not articulate guidelines for judicial enforcement of the EMR during the transitional period.

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[190] *See id.* The USTR voiced lukewarm support for the bill citing administrative difficulties and the bill, therefore, never became law. *See Administration Offers Cool Response to Intellectual Property Protection Bills*, PAT. TRADEMARK & COPYRIGHT L. DAILY (BNA), (May 5, 1994), *available in* LEXIS, News Library, BNA file.

[191] Disputes are most likely to arise over enforcement issues. *See USTR Official Predicts Difficulty in Forcing Compliance With TRIPS*, AM. TRADE, July 15, 1999, at 1, 11-12. [hereinafter *TRIPS Compliance*].

[192] *See id.*

[193] GATT Dispute Panel Report on EC Complaint Concerning India's Patent Protection for Pharmaceutical and Agricultural Chemical Products, Report of the Panel #98-3091, WT/DS79/R, August 24, 1998, *available at* http://www.wto.org/english/tratop_e/dispu_e/dispu_status_e.htm#1997.

5. Judicial Enforcement of Patent Rights Before TRIPS

A trait shared by many developing countries is a limited or non-existent regard for IP rights. Latin America is no exception to this.[194] IP in Latin America before the TRIPS Agreement was seen as information with commercial value[195] or the heritage of humanity rather than an individual asset.[196] Most of Latin American IP jurisprudence is based on territory and independence that are incompatible with international enforcement required by the TRIPS Agreement.[197] These doctrines had their foundations in the Paris and Berne agreements. The Calvo Doctrine was named for Argentine jurist Carlos Calvo and states that aliens are only entitled to those legal rights and privileges enjoyed by nationals and hence may seek redress for grievances only before local authorities and to the extent permitted by local law.[198] This doctrine, combined with a history of regarding inventions as belonging in the public domain, helps explain much of the resistance to the industrialized nations' pressure to change existing laws. Of course, Argentina's signature on the TRIPS Agreement nullifies this doctrine, but Argentina is still in the developing country transition period with respect to pharmaceuticals and has not enacted laws that correspond with the U.S. interpretation of TRIPS.[199] Hence, it is not surprising that the judiciary still follows the principles of territory and places greater emphasis on national interests rather than U.S. or industrialized nation interests.

Since Argentina does not have a tradition of strong IP protection, it is not surprising that many judges do not have significant amounts of experience deciding IP cases. Robert Sherwood notes that "trademark cases are processed routinely...but patent litigation is almost unknown so judges are unfamiliar with this area of intellectual property law."[200] The problem may start even before the judge sits on the bench; a study on the judiciary found that most Latin American law schools do not offer specialty courses in IP. Furthermore, the tradition of limited IP protection was further shaped by the penalties given to infractions. Infringements were not taken seriously because penalties for patent infringement were nominal or non-existent.[201]

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[194] *See* BUSCAGLIA & LONG, supra note 160, at 4, 12.

[195] *Id.*

[196] *Id.*

[197] *See id.* at 12.

[198] *See id.*

[199] *Id.*

[200] *See* Robert M. Sherwood, *Intellectual Property for Latin America: How Soon Will it Work?*, NAFTA: L. & BUS. REV. AM., Spring 1998, at 77-78.

[201] *See id* at 77. The enforcement provisions of TRIPS may lack bite as well. One USTR official stated, "[t]he enforcement provisions say that countries agree to put into their law provisions for criminal and civil remedies, but then it's up to a judge to implement that on a

When patent cases were decided, they favored copiers of technology. Under the old patent law, the process rather than the final product was the only part of a discovery that could be patented.[202] The law was broadened when the Supreme Court of Argentina found that product patents can only be enforced for those products with different types of chemical production processes.[203] While both the process and final product are now patentable under the Argentine patent law, pre-TRIPS rulings may still have repercussions for pharmaceutical manufacturers. For example, it is unclear whether patents will be refused for processes that cannot be duplicated. The TRIPS Agreement does not provide any explicit guidance on this problem, but several TRIPS sections contain a limited set of criteria by which patent applications could be refused and countries like Argentina may invoke these provisions in future cases based on past principles like the holding in the Supreme Court case mentioned above.

6. Weaknesses in TRIPS Enforcement Procedures

The largest problem with TRIPS enforcement criteria is ambiguity.[204] This ambiguity, coupled with the lack of obligation to devote extra resources to the enforcement of IP rights,[205] will cause many problems for the domestic enforcement of the TRIPS provisions. According to Joseph Papovich, Assistant U.S. Trade Representative for Services, Investment and Intellectual Property, "[T]he enforcement provisions [must have] criminal and civil remedies...[but] it's up to the judge to implement that...and there is concern...that judges might not take seriously these provisions."[206] The TRIPS enforcement procedures are comprised of Articles 42-45 and list different types of damages available to parties and authority for enforcement. Each article states that countries "shall have the authority" to use the procedures in those sections but the article does not state that the procedures "must be followed."[207]

Aside from how to enforce the patent legislation, significant confusion also exists as to when TRIPS or the Argentine patent legislation should be enforced. Argentina's status as a developing country allows it to

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case-by-case basis...there is concern... that judges may not take seriously these provisions, that they might just slap peoples' wrists." *TRIPS Compliance, supra* note 191, at 11.

[202] *See* Gerald J. Mossinghoff, *Research Based Pharmaceutical Companies: The Need for Improved Patent Protection Worldwide*, 2 J.L. & TECH. 307, 312-13 (1987).

[203] *See id.* at 312.

[204] *See TRIPS Compliance, supra* note 191. An official at the USTR has acknowledged problems with TRIPS enforcement procedures and noted that enforcement is often discretionary under Articles 42-45. *See id.* at 11.

[205] *See id.*

[206] *Id.*

[207] TRIPS Agreement, *supra* note 1, at arts. 42-45.

use the transition provisions of Article 65 of the TRIPS Agreement; the provisions state that legislation does not have to be implemented immediately with regard to pharmaceutical patents. Because the enactment of the Argentine patent law was piecemeal, significant confusion exists as to when various provisions had taken effect. There are also problems of consistency in the legislation itself. Robert Sherwood noted that while a new patent law and presidential decree was in place during 1996, subsequent legislation enacted in December of 1996 clashes not only with the prior legislation but with the TRIPS Agreement as well (the 1994 constitution makes international treaties superior to national law).[208] Much of the legislation was also accompanied by executive decrees of President Menem that were used to bypass the opposition of the Argentine Congress. These decrees are often not subject to judicial review but it has been stated that presidential decrees regarding patent laws will not carry the same weight as a measure passed by both houses of the Argentine Congress.[209] Given the above problems and prior history of IP jurisprudence in Argentina, it is no surprise that patent protection has still not progressed in Argentine courts.

7. Litigation After the Adoption of TRIPS and the New Patent Law

The results of the first series of cases interpreting the new patent law have been mostly negative. The newly enacted patent legislation does not allow the holder of an exclusive marketing right to bring a suit against a third party until the TRIPS transition period is over. The only litigated case regarding exclusive marketing rights was decided recently and involved Eli Lilly and a local pharmaceutical company, Laboratorios Gandor SA.[210] Eli Lilly was granted an EMR by the patent office for a pharmaceutical composition.[211] Laboratorios Gador filed a suit against the patent office to have the EMR revoked because they manufactured and marketed the product protected under Eli Lilly's EMR before Eli Lilly's product reached the Argentine market.[212] While the lower court upheld the EMR, it also restricted the enforceability of the EMR when another party was already working the invention. This is a large setback because many products are marketed and used in Argentina before the foreign patent holders can

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[208] *See* Sherwood, *supra* note 198, at 88.

[209] *See* Maria Dakolias, *A Strategy for Judicial Reform: The Experience in Latin America*, 36 VA. J. INT'L L. 167, 175-76 (1995).

[210] *See* Baker & McKenzie, *Patents: Case Law Arisen From the Introduction of the New Patent Law*, 2 LATIN AM. INTELL. PROP. NEWSLETTER 1, 4 (Aug. 1999) [hereinafter Baker & McKenzie].

[211] *See id.*

[212] *See id.*

market their products in Argentina.[213] The case went to the court of appeals and the court partially upheld the primary ruling by restricting Gador's manufacture of the product after 2000.[214] Also as a result of this ruling, the Patent Office has now started to publish EMRs for opposition claim purposes even though this is not mentioned in TRIPS or the new patent law.[215]

8. Confusion Over Patent Term Limits

It is not surprising that some of the early judicial cases interpreting domestic legislation have dealt with the legitimacy of existing and pending patent applications. The United States actively campaigned for an approach that would have retroactively granted patent rights to foreign patent holders to the extent the product had not been introduced into the market ("pipeline protection").[216] Numerous South American countries and the final draft of the TRIPS Agreement did not adopt this approach.[217] Argentine and Brazilian Courts have both wrestled with the effective enforcement dates of patents during the TRIPS transition period.[218] The old Argentine law granted patents for fifteen years from the date of the grant, while Articles 33 and 70 of the TRIPS Agreement set the term at twenty years. Given the piecemeal enactment of the patent law,[219] there exists some confusion as to when the provisions of the TRIPS Agreement became effective in law. Several issues have been litigated and the results are mixed. Two primary issues have surfaced in the existing litigation: (1) is Article 33 of the TRIPS Agreement self-executing; and (2) does Article 65 of the TRIPS Agreement (allowing countries to delay the application for patents) affect the length of patent terms for current applicants.

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[213] *See id.*

[214] *See id.*

[215] *See id.*

[216] *See* Correa, *supra* note 86, at 118.

[217] *See id.*

[218] The Argentine judicial response is discussed later. Brazil's Appellate Courts dealt with this issue in 1999. *See* Otto B. Licks, *Court of Appeals finds TRIPS Self-Executing*, PAT. TRADEMARK & COPYRIGHT L. DAILY (BNA), (Aug. 6, 1999), *available in* LEXIS, News Library, BNA file. Surprisingly, Brazil recently lowered the level of IP protection before its TRIPS deadline. Pipeline protection for pharmaceutical products has been eliminated. *See* Otto B. Licks, *Government Makes Sudden Changes to Newly Enacted Patent Law*, PAT. TRADEMARK & COPYRIGHT L. DAILY (BNA), (Feb. 16, 2000), *available in* LEXIS, News Library, BNA file.

[219] *Id. See also* Baker & McKenzie, *supra* note 210, at 2.

9. Effective Date of the New Patent Law

As stated in Section II, the Argentine patent law evolved through three different pieces of legislation with various provisions amended and revoked during and after each of the three enactments. Hence, the effective date of the new law was one of the primary issues in the early cases. Several courts have established that September 29, 1995, the date Law 24,481 was enacted, is the effective date of the legislation. While these decisions are currently under appeal in the Argentine Supreme Court, it is expected the court will reaffirm the decision of the lower courts.[220]

10. Effective Date of the TRIPS 20-year Patent Term

On August 11, 1998, Chamber 3 of the Court of Appeals in *Industrie Pirelli SpA v. INPI* overturned a lower court ruling and found that TRIPS Article 33 did not apply automatically even though the TRIPS Agreement had been ratified.[221] Hence, even though the TRIPS Agreement had been ratified before the patent expired, Pirelli's patent still expired before the new patent act and the grant of the twenty-year patent term. Pirelli's patent information was considered to be public domain.[222] The court also ruled that in view of the five-year transition period granted to Argentina as a developing country, only patents in force by January 1, 2000 would be entitled to the twenty-year term under TRIPS.[223] The ruling has even greater implications if the Argentine legislature decides to extend the transition period in another five years for pharmaceutical patents, since more patents will expire by that time.

11. Patent Applications Filed Under the Old Law but Granted Under the New Law

Patents filed under the old patent act but granted after the new patent act are treated differently than patents whose terms expired before the enactment of the new patent act. The treatment has been analyzed as more favorable to patent holders, but the case is inconsistent with the above holding in *Industrie Pirelli*. The court found patents granted under the new law are given twenty-year terms regardless of the TRIPS transitional period. There is some inconsistency between the various interpretations of the terms for completed and pending patents. The same court in *Industrie Pirelli* stated in the same opinion that the twenty-year term is applicable for patents pending during the enactment of the patent act effective September

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[220] *See* Baker & McKenzie, *supra* note 210, at 2.

[221] *See id.* at 3.

[222] *See id.*

[223] *See id.*

29, 1995.[224] The inconsistency has carried over into other Courts of Appeal. Two months later, on October 8, 1998, Chamber 2 of the Court of Appeals also found in *BASF AG vs. INPI* that patents filed under the old law but granted under the new law would be granted the twenty year term as provided in the new patent act and TRIPS.[225] The court ruled that patents could be effective under the patent law or TRIPS despite Chamber 2's statement that the provisions of TRIPS regarding patent terms did not apply until 2000.[226]

12. Injunctive Relief and the TRIPS Transition Period

TRIPS Article 44 states that countries have the authority to provide injunctive relief in IP infringement cases[227] but the transition period adopted by Argentina to implement this provision has caused some confusion in the Argentine courts. On June 25, 1998, Chamber 2 of the Federal Court of Appeals issued an order for injunctive relief in *Johnson & Son Inc. c/Clorox Argentina S.A.s/medidades cautelares,* stating that the judiciary can issue injunctive relief in patent infringement cases on the basis of Article 50 of the TRIPS Agreement.[228] However, in *Novartis AG v. Ipsesa SA,* decided February 16, 1999, another court of appeals found that the new patent law effectively delayed the application of the TRIPS provisions. Hence, in the instant patent infringement cases Article 50 could not apply.[229] Consequently, Ipsesa was allowed to continue with its infringement actions.

As demonstrated by the above cases, there is significant confusion and contradiction regarding the application of the TRIPS Agreement in relation to the patent law. Further litigation and clarification is needed before all of the issues regarding Argentina's domestic and international obligations are answered. It is not likely that even with the advent of the 2000 deadline for developing countries that change will suddenly appear. In the short run, patent holders will face significant uncertainty in the Argentine courts.

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[224] *See id.*

[225] *See id.* at 3-4.

[226] *Id.*

[227] *See id.* at 4.

[228] *See id.*

[229] *See id.*

C. External Impediments to Strong IP Rights in Argentina

1. U.S. Trade Policy in Argentina

Although external initiatives to raise the standards of the TRIPS treaty include cooperation, the United States prefers coercion. As Section II explained, the patenting of pharmaceutical products has been a long tug-of-war between the United States and Argentina. Ironically, the net effect of U.S. pressure has been to decrease efforts to legislate additional IP protections.[230] IP is seen as a bargaining chip in the hands of the Argentine government – especially since over half of the country's exports are subjected to U.S. tariffs.[231] The tariffs also include Argentine pharmaceutical and chemical products because of their link to Argentina's patent legislation, thereby making the sanctions even more inflammatory.[232]

While the tariffs are in place largely due to Argentina's treatment of pharmaceuticals, the subject of IP rights enforcement surfaces in other trade disputes as well.[233] By unilaterally imposing tariffs on Argentine exports, many believed that the United States ignored TRIPS and acted outside of international law.[234] There is little political will to enforce the new patent laws because the pressure to enact the legislation was external rather than internal.[235] Part of the anger over the U.S. attempts to enforce greater IP rights is the fact that Argentina became one of the first developing countries to codify the TRIPS Agreement in its national

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[230] *See* Correa, *supra* note 86, at 119 (stating that "direct and open intervention of the US government has served to delay, rather than accelerate changes").

[231] When the Tariffs were announced the government threatened action against a bill pending in Congress aimed at curbing US involvement in government procurement contracts and the current push to extend the transition period may be a result of the tariffs. *See US Listing of Goods to Lose GSP Benefits Spurs Anger in Argentina*, INSIDE NAFTA, Apr. 17, 1997, at 30. Similarly, after the United States brought Argentina to the WTO, several bills were introduced in Argentina to extend the patent transition period. The Argentine government said that these measures were not in response to the consultations but to unfair agricultural subsidies. *See WTO Patent Compliance, supra* note 61, at 3-5.

[232] *Id.*

[233] *See id.*

[234] *See id.*

[235] *See Argentine Congress Holds Back, supra* note 59. *See also* BANKOLE SODIPO, PIRACY AND COUNTERFEITING, GATT, TRIPS AND DEVELOPING COUNTRIES, 269 (1997) (noting that "where laws are passed by national governments solely due to foreign pressure, without any significant advantages for local interests, there may be no political will on the part of the government to enforce the laws...").

legislation.[236] As J.H. Reichman argues, "if the developed countries push too hard and too fast, the developing and least developed countries will also find ways to push back."[237] Legislation was enacted prior to the trade sanctions that curtailed patent protection and several other measures were attempted in response to the USTR's measures.[238] The USTR recognized that the sanctions would have little effect on the Argentine IP rights stance but argued that the move was politically necessary. The Argentine government vocalized its wish for the dispute to be brought before the WTO,[239] but the United States did not press the issue until May 2000, preferring instead to use sanctions.[240] The United States believed the dispute could not be taken to the WTO because Argentina is a developing country under TRIPS and does not have to enforce certain parts of the treaty until 2000, the deadline for developing countries.[241] Arguably, a favorable WTO decision will still not change matters due to enforcement problems.[242]

While the Argentine government favors the dispute mechanisms of the WTO over trade sanctions, Argentine politicians feel they have been pushed too far and are beginning to scale back all of the advances IP rights have made since the TRIPS Agreement through several pieces of legislation.[243] First, a bill was introduced to unilaterally extend patent protection another five years.[244] A second proposal has also been made to require local production as a condition for patent protection. The third proposal would add requirements to the procedure of receiving exclusive marketing rights.[245] As stated earlier, Argentine politicians agreed to forestall any attempts to extend the TRIPS transition period. The issue of

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[236] Other politicians such as Menem and Peronist Presidential candidate Eduardo Duhalde criticized legislation relaxing patent requirements as shortsighted and have refused to accept contributions from the Argentine pharmaceutical industry. *See* Margalit Edelman, *Treading on Toes in US-Argentine Trade Tango*, J. OF COM., June 29, 1999, at 6.

[237] Reichman, *supra* note 88, at 356.

[238] *See generally id.* (describing Argentine patent law development).

[239] *See Argentine Labs, supra* note 144, at 10.

[240] *See id.*

[241] *See* Hess, *supra* note 78. The U.S. action begs the question: How can the United States accuse Argentina of TRIPS violations if Argentina is not under WTO jurisdiction until 2000?

[242] The United States unilaterally believes that transitional periods should end for countries it no longer considers undeveloped. *See id.*

[243] One PhRMA official commented that, "Argentina's IP rights protections have been 'systematically watered down.'" *PhRMA Official Says Many Countries Still Not Complying With TRIPS*, AM. TRADE, Oct. 15, 1998, at 11.

[244] The bill has strong support. *See WTO Patent Compliance, supra* note 61, at 3.

[245] *See id.*

local production still remains and Argentine manufacturers feel some concessions need to be made to preserve the local pharmaceutical industry.

2. The WTO's Section 301 Ruling: Are U.S. Trade Sanctions a Toothless Threat?

As stated in Section II, the USTR's favored method to secure increased IP protection is to impose or threaten trade sanctions. Serious debate has arisen among WTO members whether unilateral trade sanctions to increase TRIPS standards are legal. The complainants were comprised of both industrialized and developing countries indicating a widespread dissatisfaction with the USTR's use of trade sanctions under Section 301. The WTO issued its opinion at the end of last year and imposed several restrictions on the use of unilateral trade sanctions. While the WTO upheld the compatibility of Sections 301-310 of the 1974 U.S. Trade Act with GATT, the ruling panel did specifically state that the statutory language of Sections 301-310 was a violation of WTO rules.[246] Former President Clinton subsequently issued a statement that the United States will avoid unilaterally imposed Section 301 trade sanctions unless the WTO finds a violation has occurred.[247]

The Panel Decision is important to Argentina and other developing countries because the United States must resolve the IP dispute in the WTO before unilaterally imposing sanctions. In a sense, the WTO has found the past unilateral trade sanctions against Argentina and Brazil illegal. As explained below, the WTO decision that the United States must obtain a ruling from the WTO before imposing trade sanctions may help developing countries.

3. WTO Deference to Local Legislation

While the United States has threatened to institute a formal suit against Argentina in the WTO, it is unclear whether the decision making body would necessarily impose sanctions against Argentina or force Argentina to change its current IP laws. The *India* decision emphasized several principals in the TRIPS Agreement deferring to the ability of countries to adopt implementing legislation if "good faith efforts were made."[248] The decision also supports the notion that TRIPS is truly comprised of minimum IP standards and that the Appellate Body will not function as a common law court and fill in any gaps left by the language of

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[246] *See WTO Adopts Panel Findings Upholding Section 301*, USTR Press Release, Jan. 27, 2000, *available at* http://www.ustr.gov/releases/2000/01/00-06.pdf.

[247] White House 201 Decisions Under Attack, Kaye Scholer LLP International Trade Update, February 22, 2000, *available at* http://www.kayescholer.com/podium/articles/2000/White_House_201.html.

[248] *See* Reichman, *supra* note 97, at 450-51.

the treaty.[249] The conjunction of the U.S. promise to refrain from Section 301 sanctions and the WTO position regarding implementing legislation make it imperative for the United States to rethink its foreign policy toward developing countries.

4. Outlook for the Future

Evidence of the benefits of a pro-competitive approach exists in Argentina today. The amount of rhetoric regarding Argentina's treatment of pharmaceutical patents draws attention away from other sectors of the Argentine economy that also have serious IP violations. It is estimated that "80 percent of all [software] programs purchased are illegally copied."[250] Officials admit part of the problem is ignorance; many people don't realize that such piracy is illegal, and as discussed earlier, part of the problem with curbing violations is that Argentina did not extend IP protection for software until the TRIPS Agreement.[251] Realizing that the law alone will not make a significant dent in the levels of piracy, over 300 domestic and foreign companies are supporting a resolution, published in November of 1998, intended to reduce piracy.[252] The strategy involves two steps: education and prosecution.[253] Realistically, the law will not eliminate software piracy; the goal is to keep illegal purchases, which are estimated to be thirty percent even in the United States, at a minimum.[254] Officials expect the law to produce an initial drop in illegal software purchases by fifteen percent, while education and enforcement are expected to lower the piracy rate another ten to fifteen percentage points.[255]

Private companies such as Microsoft have added additional support to the reduction of piracy. Microsoft announced that it would invest significantly in Argentina and build its technological base so Argentina can become one of the top exporters in the southern hemisphere.[256] Companies such as Microsoft and Unisys lose up to $1.8 billion annually to software

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[249] *See id.* at 447-49. Two questions remain after the India decision. First, will the expiration of the transition periods for developing countries cause a flood of suits for non-violatory complaints. Second, how will the WTO handle such complaints? Reichman emphasizes that since "the tribunal took pains to link the bargained for expectations of member countries" the provisions of TRIPS will still be interpreted strictly. *See id.* at 449.

[250] *Software Makers in Argentina Launch Campaign for Compliance With Piracy Law*, PAT. TRADEMARK & COPYRIGHT L. DAILY (BNA), (DEC. 2, 1998), *available in* LEXIS, News Library, BNA file.

[251] *See id.*

[252] *See id.*

[253] *See id.*

[254] *See id.*

[255] *See id.*

[256] *See id.*

pirates and their situation bears many similarities to the U.S. pharmaceutical manufacturers.[257] In exchange for the transfer of technology, Argentina has agreed to devote more resources to copyright protection and enforcement.[258] Overall, the strategy of the software giants seems to be making more progress through cooperation.[259] Indeed, technology infusion into Argentina may be the carrot needed to strengthen IP protection for pharmaceutical manufacturers. Former Secretary of Commerce William Daley recently concluded a trip to Latin America to discuss IP issues concurrently with negotiations to boost electronic commerce in Argentina.[260] President De la Rua of Argentina stated, "Argentina can and wants to be a production center for information technology for software for the Latin American market and even for the United States."[261] There is early evidence that such cooperative efforts are working. During the February negotiations, Argentina agreed not to enact legislation to renew the TRIPS transition period.[262] Argentina's compromise should not be underestimated. During the WTO negotiations in Seattle, WTO members were very close to allowing a three-year blanket extension to developing countries to implement their TRIMS, TRIPS and Custom Valuation obligations because of the transactional costs needed to enforce the treaty provisions.[263]

IV. CONCLUSION

Implementing the TRIPS Agreement in developing countries will reach a critical point after the Year 2000 deadline. Successful enforcement will depend on structural, political and economic variables that will vary from country to country. While the TRIPS Agreement has forced many countries to make changes to their patent laws, the events in Argentina have proved that the TRIPS Agreement is not the final answer or even a starting point to strong IP protection. There are too many forces in Argentina and in the TRIPS Agreement that are not solvable by sanctions or WTO panel decisions. This does not mean that developing countries should be relieved

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[257] *See* Baker & McKenzie, *supra* note 210.

[258] *Id.*

[259] *Id.*

[260] Andrew Hay, *Argentina Says US Trade Can't Be One-Way Street*, Reuters Eng. News Serv., Feb. 16, 2000.

[261] *See id.*

[262] *See id.* In January eight developing countries, including Argentina, filed formal requests with the WTO to extend their deadlines under the TRIPS Agreement. Argentina originally sought to increase its transition period another seven years. *See* Daniel Pruzin, *Quad Group, Developing Countries Split Over Deadline Extensions*, 17 INT'L TRADE REP. (BNA) No. 4, 143-44 (Jan. 27, 2000).

[263] *See id.* at 143.

from their obligations; rather it means that countries like the United States need to look beyond the TRIPS provisions to get hard results.