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LESSONS FROM THE UNITED STATES TRADE POLICIES TO CONVERT A "PIRATE": THE CASE OF PHARMACEUTICAL PATENTS IN ARGENTINA.

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This analysis describes the radical transformations in pharmaceutical intellectual property protection in Argentina during the 1990s. Most importantly, it highlights the consequences of the use by the United States of unilateral trade weapons to pressure Argentina to adopt certain standards in this field. The enforcement or threatened enforcement of Section 301 of the US Trade Act, along with GSP restrictions, have proven to be controversial tools in protecting US interests abroad, as is demonstrated by the Argentine case. Some positive results were achieved for United States' interests but the United States created at the same time negative implications by pressuring for more protection in a shorter time than is mandated under TRIPs: in other words, requiring "TRIPs–Plus" standards. The conclusions of this paper could prove useful when analyzing similar cases over remaining TRIPs "transitional period" years in developing and least developed countries regarding the protection of pharmaceutical intellectual property rights.

I. INTRODUCTION

Countries, much like individuals, often seek to protect their interests when they feel their rights have been threatened or violated. One of these interests is the right to intellectual property. In the past fifteen years, countries all over the world have become increasingly engaged in the protection of their nationals' intellectual property rights from infringement by forces outside of their country. These battles are fought on a global level, where issues of patents and trade often intersect, and decisions made in one country can greatly influence policies in another.

Overseas "piracy"[1] in the pharmaceutical industry has for some time been considered by the United States to be a serious threat to the ability of its companies to compete in foreign markets. Since the strength of intellectual property protection in foreign countries often

1 Christopher Scott Harrison, *Protection of Pharmaceuticals as Foreign Policy: The Canada-U.S. Trade Agreement and Bill C-22 Versus the North American Free Trade Agreement and Bill C-91*, 26 N.C J. INT'L L. & COM. REG. 457, 495 (2001) (noting that "the pharmaceutical industry was able to frame the issue of intellectual property protection by using the term 'piracy' to refer to the unlicensed use of intellectual property").

has a direct influence on the amount and type of technology transferred by the United States to those countries, the weakness of protection in Argentina[2] has made the transfer of technology to that country a controversial issue.

In the pharmaceutical field, the process of discovering a new drug is long and resource intensive[3]; however, once an effective drug is on the market, it is comparatively easy to replicate. Since inventors are forced to share how they made the product in order to receive patent rights, the opportunities for piracy are endless. If the host country provides no patent protection on pharmaceuticals, as was the case with Argentina, drug companies' interests are deeply affected.[4]

Due to its interests in this field, Pharmaceutical Research and Manufacturers of America (PhRMA) was able to convince the United States government of "the need to link trade and [intellectual property rights] in order to increase the returns on [research and development] and to prevent imitation."[5] The issue took on a political dimension, with the U.S. Senate being involved at one point. As a result, the United States was the country that most aggressively acted to raise standards of pharmaceutical intellectual property protection in Argentina and the rest of Latin America.

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2 *See* Margalit Edelman, *The Argentine Trade Tango: Out of Step on Intellectual Property Protection*, AdTI Issue Brief No. 172 (July 1999), *at* http://www.adti.net/html_files/ip/Argentine_Trade_Tango.html (last visited Feb. 20, 2003) (on file with the Yale J.L. & Tech.) ("As Latin America's leading patent pirate, Argentina costs the United States pharmaceutical industry $600 million annually. … [Argentina] is responsible for an astonishing 10% of global pharmaceutical losses.").

3 *See* Press Release, PhRMA, Statement by PhRMA President and CEO Alan F. Holmer on the Importance of Intellectual Property for Patients Worldwide (Nov. 20, 2002), *available at* http://www.phrma.org/mediaroom/press/releases/20.11.2002.628.cfm (last visited Feb. 20, 2003) (on file with the Yale J.L. & Tech.) (noting that expenditures by research-based pharmaceutical and biotechnology companies were more than $30 billion in 2001).

4 *Submission of PhRMA for the "Special 301" Report on Intellectual Property Barriers*, PhRMA (Sept. 15, 2001), *at* http://www.phrma.org/international/special301/argentina.cfm (last visited Feb. 20, 2003) (on file with the Yale J.L. & Tech.) (estimating the total losses in Argentina to be more than $750 million a year, conservatively). PhRMA estimated in 1999 that "[i]f current trade barriers were removed, PhRMA member company affiliates in Argentina would enjoy a potential increase in sales of over US $500 million dollars [sic]." *Priority Foreign Countries*, PhRMA (1999), *at* http://www.cptech.org/ip/health/phrma/301-99/argentina.html (last visited Feb. 20, 2003) (on file with the Yale J.L. & Tech.).

5 CARLOS M. CORREA, INTELLECTUAL PROPERTY RIGHTS, THE WTO AND DEVELOPING COUNTRIES; THE TRIPS AGREEMENT AND POLICY OPTIONS 4 (2000).

Argentina's adoption of the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs Agreement) represented a crucial change in its protection of intellectual property, with profound implications in the field of pharmaceutical products. At the inception of the Uruguay Round of trade negotiations, about 50 countries did not confer protection for pharmaceutical products. The TRIPs Agreement obliged all WTO Member countries to recognize such protection.[6] During the last half of the 1990´s Argentina modified its laws in order to meet its international commitments, to avoid trade sanctions, and in the hopes of bringing in additional foreign investment.

Sections II, III, IV and V of this Article explore the process of legal reforms that took place in the Argentine Republic in the field of pharmaceutical patents. Section VI then describes the trade policy tools utilized by the United States in order to "pressure" Argentina to comply with U.S. standards. These standards were in many cases higher than the TRIPs Agreement standards. Section VII describes, in a time line format, the effects of the trade policy tools utilized during enactment of the protection laws. Section VIII explores the inconsistencies of using unilateral measures after TRIPs to protect IP rights overseas. Section IX provides some thoughts on the dangers that the United States' "overseas IP defense policy" can create when trying to impose standards higher than those established in international agreements by means of unilateral mechanisms. Section X proposes alternative mechanisms that could be employed in similar cases arising in developing countries during transitional periods under TRIPs. Finally, in Section XI the paper reaches a conclusion regarding the final outcome of a process that played itself out over a decade.

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6 Carlos M. Correa, *Recent Developments in the Field of Pharmaceutical Patents: Implementation of the TRIPs Agreement*, Universidad de Buenos Aires, *at* http://www.haiweb.org/campaign/novseminar/correa2.html (last visited Feb. 20, 2003) (on file with the Yale J.L. & Tech.).

II. ARGENTINA UNDER LAW NO. 111: NO PATENTS FOR PHARMACEUTICAL PRODUCTS

Argentine Law No. 111, which was enacted in 1864[7] and set the legal standard for Argentina in this field for over 130 years, did not allow for patents of pharmaceutical products. It did, however, recognize patents for the pharmaceutical *process*. However, it is often difficult to determine the way in which a possible transgressor has manufactured the product, as the final chemical structure of the product will be the same, independent of the process used. For this reason, it was virtually impossible to claim property rights under this system.[8]

For over 100 years there was controversy over Article 4 of Law No. 111 and its lack of protection for pharmaceutical products. The main objection was of a constitutional nature: the Argentine Constitution in Article 17 states "every author or inventor is the exclusive owner of his work, invention or discovery, during the term provided by law." The Argentine Supreme Court, however, rejected the claim of unconstitutionality under Article 4 considering that "constitutional rights are subject to regulation, and that it is not possible to consider invalid a legal provision that, on security, moral or public health grounds, denies the protection granted in general by Article 17 to inventions that, for one reason or other, are considered harmful to the high objectives of the State."[9]

Starting in 1960, several legislative bills sought to permit patents for pharmaceutical products but never became law.[10]

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7 FUNDACIÓN DE INVESTIGACIONES ECONÓMICAS LATINOAMERICANAS (FIEL), PROTECTION OF INTELLECTUAL PROPERTY RIGHTS, THE CASE OF THE PHARMACEUTICAL INDUSTRY IN ARGENTINA 65-66 (1990) ("An analysis of this regulation shows, as in the case of other countries' legislation, a noticeable influence of the French law of 1844. Particularly regarding the subject under consideration, the fact stands out that this law provided that pharmaceutical compounds or medicines of any kind were not patentable. … It should be noted in this respect, that a major reform was effected in France in 1959. Since then the issuance of patents for pharmaceutical products has been authorized. Argentina, however, did not carry out this revision.").

8 *Id.* at 70 ("It should be noted, however, that in practice this protection proves ineffective due to the fact that in Argentine legislation the burden of proving the assumed infringement is borne by the patent owner. This proof cannot be produced on the basis of the substance itself. It must be obtained at the place of production, something virtually impossible if the substance – as it is generally the case in Argentina – has been imported from another country.").

9 "American Cyanamid Co. c. Unifa, S.A.," CSJN 164 Fallos 284 (1970) (translation by author)

10 FIEL, *supra* note 7, at 70 n.20 (noting that some of the bills presented include drafts by Breuer Moreno, 1960; Senator Barbich, 1965;

III. THE TRIPS AGREEMENT

On December 15, 1993, President Clinton submitted to the United States Congress a series of documents concerning the Uruguay Round Agreements.[11] Those negotiations led to the TRIPs text covered by the Dispute Settlement Understanding (DSU),[12] which promised to ensure intellectual property rights among the Member Countries and included the possibility of trade sanctions[13] if a Member violates its obligations.[14]

One major omission of the TRIPs provisions was the lack of "pipeline" or retroactive protection for inventions that were not protected under the old laws.[15] The U.S government and pharmaceutical industry have attempted to obtain retroactive recognition for patented pharmaceuticals. Because the "pirate" pharmaceutical industry in Argentina is worth $4.6 billion and supplies the rest of Latin America with pirated copies of U.S.-patented pharmaceuticals,[16] the lack of pipeline protection remains a troubling issue for U.S. investors in pharmaceutical industries. Brazil, in response to similar concerns, enacted a patent law in June of 1996 that

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Congressman Tecera del Franco, 1965; Congressmen Gonzalez, Ghiano and Riquez, 1984; Senator G. Feris, 1986; and Congressman E. Varela-Cid, 1989).

11 58 Fed. Reg. 67263 (Dec. 15, 1993).

12 Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, pt V, art. 64, par. 1, 33 I.L.M. 81, 106 (1994) [hereinafter TRIPs], ("The provisions of Articles XXII and XXIII of GATT 1994 as elaborated and applied by the Dispute Settlement Understanding shall apply to consultations and the settlement of disputes under this Agreement except as otherwise specifically provided herein.")

13 In this sense, President Clinton's message to Congress for the approval of the Uruguay Round Agreements pointed out that a measure adopted through Special 301 would be legitimized "[A]t the end of the dispute settlement process…" as contemplated in the DSU. 58 Fed. Reg. 67263, 67292 (Dec. 15, 1993).

14 FOLSOM, GORDON & SPANOGLE, JR., INTERNATIONAL BUSINESS TRANSACTIONS 853 (4th ed. 1999).

15 *See* PABLO CHALLU & MIRTA LEVIS, ADECUACION DE LA LEY ARGENTINA DE PATENTES AL GATT 41 (1996) ("Section 8 (of TRIPs Article 70) mandates that during the transition period and from the date of entry into force of the WTO Agreement (January 1, 1995) patent applications for those sectors (pharmaceutical and agricultural chemical products) must be received, under certain conditions from which it is clear that retroactivity or pipeline is absent.") (translation by author).

16 Edgardo Buscaglia & Clarisa Long, *U.S. Foreign Policy and Intellectual Property Rights in Latin America*, Hoover Institution, Stanford University, *at* http://www.hoover.stanford.edu/publications/epp/epp77.html (last visited Feb. 20, 2003) (on file with the Yale J.L. & Tech.).

grants pipeline protection for pharmaceuticals.[17] Mexico did so in 1991.

Under the TRIPs Agreement, not all countries were required to reach the same levels of intellectual property protection at the same time. The most developed countries would be held to the TRIPs standards as early as January 1, 1996. The group of countries known as the "developing countries," among which Argentina was included, had an additional period, which ended on January 1, 2000, to create or modify their internal legislation in order to meet the standard protection for intellectual property rights. Finally, the "least developed country Members" had a 10 year transition period beginning Jan. 1, 1995, the date the TRIPS Agreement came into force, with the possibility of further extensions.[18] This form of "country classification" seemed to arise from the United Nations economic development guidelines.[19]

Before the TRIPs Agreement there was no protection (or obligation to implement protective legislation) for pharmaceutical patent rights under Argentine law. Under Article 65.4 of TRIPs, Argentina had the possibility of "delaying" implementation of pharmaceutical patents until Jan. 1, 2005, not because it was classified as a "developing country", but because there was no protection (or obligation to implement protective legislation) for this field under local law.[20] The inclusion of such "phase-in" periods was a direct result of extensive negotiations between Member countries. Through the negotiations, developing countries were allowed the necessary time involved in adopting the required legislation to implement these drastic changes. The Members wanted to make sure that enough flexibility was given, so that the adaptation process could come about gradually. That would ensure real and uniform protection of intellectual property

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17 *See* Christopher S. Mayer, *The Brazilian Pharmaceutical Industry Goes Walking from Ipanema to Prosperity: Will the New Intellectual Property Law Spur Domestic Investment?*, 12 TEMP. INT'L & COMP. L.J. 377, 387 (1998) ("In fact, the [Brazilian] Industrial Property Law exceeds the minimum requirements of TRIPS by providing for 'pipeline protection,' … The pipeline protection allows foreign pharmaceutical companies to obtain patent protection in Brazil for the remainder of the term of their patents in their home country.").

18 TRIPs, *supra* note 12, pt. VI, art. 66, 33 I.L.M. at 107.

19 "Pirelli S.p.A. c. Instituto Nacional de la Propiedad Industrial," CNFed. Civ. y Com. [1999-A] L.L. 27 (Amadeo, J.).

20 TRIPs, *supra* note 12, pt. VI, art. 65, par. 4, 33 I.L.M at 107 ("To the extent that a developing country Member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that Member, as defined in paragraph 2, it may delay the application of the provisions on product patents of Section 5 of Part II to such areas of technology for an additional period of five years.").

rights in the long run, whereas a drastic change might lead only to partial fulfillment of the protection standards.[21] These transitional periods, in the case of pharmaceuticals, were never accepted by the United States.[22] In fact, the United States Trade Representative (USTR) stated explicitly that "ensuring that developing countries come into full compliance with the [TRIPs] Agreement *before* the end of the transition periods is one of this Administration's highest priorities."[23] This is not a minor point. As shall be examined, many developing countries (including Argentina) came under extreme pressure to accelerate the pace of their reforms in order to fulfill the TRIPs standards before the deadlines established under the agreement.[24]

IV. LAW NO. 24.481: ARGENTINE PATENT LAW

Argentine Law No. 24.481 internalized the TRIPs Agreement and its standards of patent protection. However, Argentina had already adhered to the WTO Uruguay Round Agreements containing TRIPs.[25]

The law underwent some modifications by Argentine Law No. 24.572.[26] This was a direct result of pressure exerted by the United States, which maintained that the original text of Law No. 24.481 did not offer high enough standards of protection. As a result, President

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21 *Hearing to Review U.S. Trade Policy Objectives and Initiatives Before the Subcomm. on Trade of the House Comm. on Ways and Means*, 105th Cong. (1997) (statement of Alan F. Holmer, President of the PhRMA) ("Regrettably, the intellectual property section of the WTO Uruguay Round Agreement, the Trade Related Aspects of Intellectual Property, or TRIPs, falls short of the NAFTA standard. Although the two agreements contain similar substantive provisions, TRIPs, at the insistence of a number of developing countries, allows such countries to delay pharmaceutical patent protection until 2005."), *available at* http://waysandmeans.house.gov/legacy.asp?file=legacy/trade/105cong/3-18-97/3-18holm.htm (last visited Mar. 14, 2003).

22 *See Menem Afirmó que Vetaría Una Nueva Ley de Patentes,* LA NACIÓN LINE, June 17, 1999 ("[U.S. ambassador to Argentina James] Cheek said that the [Argentine patent] law was for a country such as 'Burundi,' and that Argentina should not have established any transition period.")(translation by author).

23 Press Release, Office of the USTR, USTR Announces Results of Special 301 Annual Review (Apr. 30, 1999) (on file with the Yale J.L. & Tech.).

24 CARLOS M. CORREA, DERECHO DE PATENTES 395-396 (1996) ("[T]he position of the United States´ Government, which required not only immediate patents for pharmaceuticals but also retroactivity through the pipeline formula.") (translation by author).

25 Law No. 24.425, Boletín Oficial [B.O.] Jan. 5, 1995.

26 CORREA, *supra* note 24, at 399 ("Law 24.481 . . . established an 8 year time frame for the recognition of pharmaceutical product patents. As a result of the enactment of Law 24.572, it was shortened to 5 years as is stated in article 100 of the law.") (translation by author).

Carlos Menem[27] vetoed 16 articles of Law No. 24.481, in exchange for which the United States did not impose trade sanctions on Argentina in 1995. The final modifications were introduced into the text of Law No. 24.481 by Presidential Decree No. 260/96.[28] In this way, Law No. 24.481 is still recognized as the "Argentine Patent & Models of Utility" law with the Law No. 24.572 modifications as established by Presidential Decree No. 260/96. However, all of these laws, as well as others that were enacted during this time, contributed to much confusion in the field for several months.[29]

Article 100 is the most important section of the law with respect to pharmaceuticals. This article establishes: "The inventions of pharmaceutical products shall not be patentable before FIVE (5) years from the publication of the present law in the *Boletín Oficial*. Until that date none of the articles contained in the present law which mandate the patentability of pharmaceutical product inventions shall be under force, including those other precepts that are inseparably related to the patentability of such product."[30] However, the following article goes on to say that "[a]pplications for pharmaceutical product patents may be submitted in the form and terms established under the present law, and shall begin to be granted five years from the publication of the law in the Boletín Oficial."[31] The duration of such patents, once they became available on October 24, 2000,[32] should be the length stated in Article 35 of Law No. 24.481: twenty years, non-renewable, counted from the date the application is filed.[33]

The TRIPs Agreement does not define exclusive marketing rights (EMRs), although it does mention the conditions under which they shall be granted.[34] The Agreement does not shed any light as to

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27 Carlos S. Menem was President of Argentina from 1989 – 1999.

28 Decree No. 260/96, B.O. Mar. 22, 1996.

29 An example of this can be found in Law No. 24.603, B.O. Jan. 5, 1996, which partially cleared up the situation by establishing the Official Patent Law of the Argentine Republic, Law No. 24.481, B.O. Mar. 22, 1996, with its modifications. On the other hand, Law 24.603 also generated some debate between the Executive and Legislative branches as to the Executive's role in the implementation of the law (this is reflected by Presidential Decree No. 3/96 published on the same day).

30 Law No. 24.481, art. 100, B.O. Sept. 20, 1995.

31 Law No. 24.481, art. 101, B.O. Sept. 20, 1995.

32 This is the date that results from adding 5 years to the date of publication of Law No. 24.572 as stated in Law No. 24.481, art. 101.

33 This coincides with the established term under TRIPs. TRIPs, *supra* note 12, pt. II, sec. V, art. 33, 33 I.L.M. at 96. ("Term of Protection: The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.")

34 TRIPs, *supra* note 12, pt. VII, art. 70, par. 9, 33 I.L.M at 110. ("Where a product is the subject of a patent application in a Member in accordance with paragraph 8(i) above, exclusive marketing rights shall be granted,

the content or scope of these rights,[35] and there seems to be no documentation tracing their origin. However, it would seem logical to infer that the holder of an EMR could not be in the same position as a patent holder. If that were the case, the "transition periods" established by the TRIPs Agreement would have no practical effect.[36] The TRIPs Agreement obligated countries such as Argentina to provide a system whereby patent applications for pharmaceutical products can be "deposited" (often referred to as a "mailbox" system). In the event that the subject of such a "mailbox" application obtains marketing approval before a decision is reached on its patent, an EMR of up to five years will have to be granted – provided that the established conditions set forth in Article 70.9 are met.[37]

These EMRs were greatly opposed by the local lobbies in Argentina because:

1. The "transition period" for granting pharmaceutical patents would not be applicable in these cases.

2. The rights would be even greater than those granted by a patent because they would not be limited for reasons of abusive practices, exploitation, or national security.

3. A person could obtain exclusivity for a product that would not be patentable under the Argentine Patent Law.

4. They would permit the temporary exclusivity of products that were already in the public domain.

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notwithstanding the provisions of Part VI above, for a period of five years after obtaining marketing approval in that Member or until a product patent is granted or rejected in that Member, whichever period is shorter, provided that, subsequent to the entry into force of the WTO Agreement , a patent application has been filed and a patent granted for that product in another Member and marketing approval obtained in such other Member.").

35 CHALLU & LEVIS, *supra* note 15, at 42 ("[T]his concept [of EMR's], which is ambiguous and lacks precise definition even by the WTO.") (translation by author).

36 CARLOS CORREA, ACUERDO TRIPS 234 (1996) ("[T]he exclusive marketing rights grant an *ius exclusivum* but not an *ius prohibendi*. This last one characterizes a patent. This means that the holder of such rights could commercialize his product and eventually require a payment from third parties that are also commercialising it but could not exclude them from such commercialisation.") (translation by author). However, groups such as CILFA (Argentine pharmaceutical trade association) were opposed to these rights because, in their view, these rights are the equivalent of granting a patent since they recognize the same rights a patent would.

37 TRIPs, *supra* note 12, pt. VII, art. 70, par. 9, 33 I.L.M at 110.

5. They would refer to products that were already commercialized in the Argentine market.

The EMRs resulted in major conflicts with the United States, but they also caused serious contentions within Argentina. The Argentine patent law does not deal with "exclusive marketing rights," although the implementation decree of Article 101 does.[38] This was the cause of great debate.[39] The Argentine Executive introduced these rights through the law's implementation decree and substantially modified the law that the Congress had drafted.[40] The article states that the application for exclusive marketing rights during the "transition period" (from Oct. 23, 1995, to Oct. 23, 2000), shall be presented before the National Institute of Industrial Property (INPI).[41]

As can be concluded from the above explanation, the text of the Argentine patent law (along with its corresponding implementation decree) is in harmony with the TRIPs standards regarding these rights. However, it should be noted that while the "transition period" for the Argentine Republic was in effect, only two such "exclusive marketing rights" were actually granted. One was for "Zyprexa" (Olanzapine/Olanzapina) during September 1998, and the other was for "Xenical" (Orlistat).[42] The problem with the few EMR's that were granted was that "the Argentine agency ANMAT, a functional equivalent of the U.S. Food and Drug Administration, refused to enforce the EMR by suspending regulatory approvals for . . . copied products."[43] The agency alleged that it did not count with the necessary specific rules in order to enforce the EMRs.. This provoked the response of the United States, which also expressed that "during the remainder of 1999, INPI failed to act on a number of well-

38 Decree No. 260/96, B.O. Mar, 22, 1996.

39 *See* CORREA, *supra* note 24, at 402 ("[D]ecree 260/96 . . . has exceeded its implementation power because the law does not create any type of exclusive marketing rights. Such a creation . . . cannot result from an administrative rule such as a decree.") (translation by author). *See generally* BIDART CAMPOS, TRATADO ELEMENTAL DE DERECHO CONSTITUCIONAL ARGENTINO 307 (1995) ("The (Argentine) Supreme Court of Justice has said that the implementation decrees are obligatory for the inhabitants as if their dispositions were stated in the law, as long as they are within the limitations of Article 99, Clause 2, of the Constitution; they are considered as an integral part of the law.") (translation by author).

40 Decree No. 260/96, B.O. Mar, 22, 1996.

41 *Id.*

42 Interview with Engineer Luis Nogués, Commissioner of the Argentine National Patent Administration (part of the INPI), in Buenos Aires, Argentina (June 25, 2001).

43 Riker, Danzig, Scherer, Hyland & Perretti LLP, *4/00 Patent Protection in Argentina*, *at* http://www.riker.com/feature/3361.html (last visited Jan. 1, 2002) (on file with the Yale J.L. & Tech.).

documented EMR applications by U.S. firms, and denied one application on seemingly unsustainable grounds."[44]

V. UNDISCLOSED INFORMATION UNDER TRIPS & ARGENTINE LAW

Section 7 of the TRIPs Agreement refers to "Undisclosed Information."[45] Through it, member countries agreed to protect certain test data from disclosure. In other words, the parties thereto agreed to enact legislation guaranteeing *minimum protection to undisclosed information*. In the case of pharmaceuticals, this is of vital importance. The development of a drug is a very lengthy process that requires extensive data to be gathered during the pre-clinical and clinical trials. Such trials are the only way to ensure that a certain drug is safe and has the quality and efficacy necessary to be prescribed to patients. It is not uncommon for several years to pass from the discovery of a drug to the moment that it is actually marketed. The average cost for this process is over $500 million.[46]

The protection of data provides incentives for the development of innovative pharmaceutical products. While data exclusivity and patents are the two most critical and, hence, relevant intellectual property rights for the pharmaceutical industry, they are distinct forms of protection; protection of one right is neither dependent on nor linked to the other. Countries with the leading research-based pharmaceutical industries recognize the strong incentive provided by data exclusivity. They have taken steps to ensure that the proprietary registration data submitted in order to gain marketing approval are protected against unfair commercial use and disclosure.[47] Under the TRIPs Agreement, Argentina was required to protect this type of data.

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44 Office of the USTR., *2000 National Trade Estimate Report on Foreign Trade Barriers*, *available at* http://www.ustr.gov/reports/nte/2000/nte2000.pdf (last visited Jan. 1, 2002) (on file with the Yale J.L. & Tech.).

45 TRIPs, *supra* note 12, pt. II, sec. 7, 33 I.L.M at 98.

46 PhRMA has stated that "the average pre-tax cost of developing a drug introduced in 2001 is over $500 million, including the cost of research failures as well as interest costs over the entire investment period." PhRMA, *Intellectual Property: Overview, at* http://www.phrma.org/publications/publications/profile01/intro.phtml (last visited Jan 1, 2002) (on file with the Yale J.L. & Tech.).

47 In this sense, "[I]n order for patent protection and data protection to be meaningful, PhRMA believes that U.S. trade partners need to establish a linkage between the national patent authority and the central health regulatory authority. In other words, there needs to be communication between the Patent Office and the Health Ministry to ensure that the health regulatory authority does not provide marketing authorization for unauthorized copies of products subject to patent

On December 20, 1996, Argentine Law No. 24.766[48] was enacted. Its short text discusses the process through which pharmaceutical products are approved for commercialization. The information needed for such authorization is related to the composition and the production process of a medication that is about to be commercialized. This authorization stage comes after a patent has been issued and may require that certain information pertaining to the efficacy of the product be made available to the local health authority. The law protects this information from "[a]ny dishonest commercial use" and states that it "shall not be disclosed."[49] However, under Article 5, "similar products" can be approved by the "local sanitary authority" once the original product has been registered in Argentina, the United States, or any other country mentioned in Annex I. In this case an "abbreviated procedure" is implemented. According to Article 5, if someone has a "similar product" to one that has already been registered, that person can rely on and use the same "tests" that had to be performed to obtain commercial authorization for the existing product.[50] In other words, a party that has performed extensive tests and research trusts confidential information to the corresponding health authority in order to authorize its product; that information, however, can also be used by others seeking authorization for similar or identical products. The article ends by stating that "[t]he approval of the registration or of the authorization for commercialization by the local administrative authority under the procedures established in this article for similar products does not imply the use of the confidential information protected under this law."[51]

This led to one of the United States' main complaints regarding inadequacies in the Argentine protection of intellectual property rights in the pharmaceutical field. The big pharmaceutical manufacturers also opposed the "abbreviated procedure" allowed by Article 5.[52] The

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protection. Governments, not patent offices, are bound by the WTO TRIPS Agreement, and it is the responsibility of all relevant government agencies to ensure that TRIPS obligations on patent protection and data exclusivity are met." PhRMA, *at* http://www.phrma.org/policy/aroundworld/special301/append_a.phtml (last visited Jan. 1 2002).

48 "Law on the Confidentiality of Information and Products that are legitimately under the control of a person and that are improperly disclosed in a way inconsistent with Trade Practices."

49 Law No. 24.766, art. 4, B.O. Dec. 30, 1996.

50 Law No. 24.766, art. 5, B.O. Dec. 30, 1996.

51 *Id.*

52 *See Hearing to Review U.S. Trade Policy Objectives and Initiatives Before the Subcomm. on Trade of the House Comm. on Ways and Means*, 105th Cong. (1997) (statement of Alan F. Holmer, President of the PhRMA) ("On December 18, 1996, the Argentine Congress approved legislation on trade secrets that also falls far short of international standards and TRIPs. The law does not provide any protection to the

main objection to the law was the "similarity" concept contained in the text, which allows anyone to use an inverse formula to arrive at an original pharmaceutical product. This was viewed as protecting local Argentine laboratories because it permitted the registration of drugs that were similar to, but not necessarily identical to, others that were already on the market. Drug manufacturers from outside Argentina argue that very precise proof should be required to verify that when someone tries to register a medication similar to another he is using a different production process than that used by the inventor of the drug.

The problem was exemplified during the "transition period," in which Argentina did not issue patents for pharmaceutical products. The following example illustrates the United States' concern in this area. When Pfizer, the first company to introduce *Viagra* (sildefil), obtained marketing authorization from the Administración Nacional de Medicamentos, Alimentos y Tecnología Medica (ANMAT),[53] several local companies quickly followed with requests to authorize "similar products."[54] Since there were no pharmaceutical patents issued at the time, a company could copy *Viagra*[55] and easily obtain authorization to commercialize it by relying on the original company's information and the "similarity" provision in Article 5.[56] Local companies were required, however, to demonstrate to the ANMAT

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proprietary data that pharmaceutical companies submit for registration. Article 5 compels the Ministry of Health to approve similar products (i.e., copies) in a maximum of 120 days based on the submission of minimal information. By not providing a term of protection (as is the case with similar legislation in other countries), a competitor does not have to submit its own data during that term and, thus, can be in the market in less than four months."), *available at* http://waysandmeans.house.gov/legacy.asp?file=legacy/trade/105cong/3-18-97/3-18holm.htm (last visited Mar. 14, 2003).

53 ANMAT is the Argentine equivalent of the Food and Drug Administration.

54 *See generally* Virginia Santana, *Investigar No Sera Redituable Si No Se Protegen Las Patentes*, LA NACIÓN LINE, Oct. 30, 1998 (stating that only one local Argentine pharmaceutical company, Bago, obtained a license from Pfizer to produce the product, which it marketed under the name "*Lumix*.").

55 Juan Aznarez, *El Viagra Reabre La Puja Por La Ley De Patentes,* LA NACIÓN LINE, July 1, 1998 (quoting Clives Miles, Director of Pfizer Argentina, as stating "We spend 450 million dollars to develop the product [Viagra] and here they copy us to make money without investing anything.") (translation by author).

56 Natalia Chientaroli, *El Viagra Avivo La Pelea Entre Los Laboratorios Locales y Extranjeros*, LA NACIÓN LINE, July 19, 1998 ("Currently seven local (Argentine laboratories) have obtained authorization from the National Administration of Medication, Food and Medical Technology (ANMAT) to produce medication made with the base drug, sildenafil. Two additional laboratories await approval.") (translation by author).

their capability of producing a medication similar to the one produced by Pfizer.[57]

The concern expressed over this law by the United States and by pharmaceutical companies during the transition period was well founded. However, once Argentina started to grant patents on new products in October 2000, the available protection improved. Even though the information that was submitted to the health authority could be used by another company to obtain commercial approval for a "similar drug," the other company could not legally produce the product without the corresponding license and royalty payment.[58]

Local pharmaceutical companies in Argentina, as well as other groups, viewed the opposition to the law as "backdoor attempts to convey private monopoly power for drugs that do not qualify for patent protection."[59]

Additionally, there are two other concerns over this law. First of all, the law has been in force since January 1, 1997, but was never implemented by the Executive. This has made its actual application difficult because, due to the law's importance, an Executive decree is necessary for its correct implementation. Secondly, there is no "linkage" obligation established between the ANMAT and the Argentine Administración Nacional de Patentes (National Patent Administration).[60] This could lead to the marketing authorization of a medication produced by a company that has not obtained the corresponding license to manufacture the patented product. In other words, unauthorized copies of products subject to patent protection could obtain commercialization approval.

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57 *Id.*

58 It must be remembered, however, that there is no retroactive or "pipeline" protection under the Argentine Patent Law.

59 *USA Urged to Withdraw Action Against Argentina*, MARKETLETTER, Feb. 17, 1997.

60 Interview with Alba Duchowna, legal advisor, ANMAT, in Buenos Aires, Argentina (July 2, 2001) ("Unfortunately, there is no contact between us and the Administracion Nacional de Patentes (National Patent Administration)").

VI. TRADE "WEAPONS" UTILIZED BY THE UNITED STATES TO PRESSURE ARGENTINA TO ENACT LEGISLATION ACCELERATING PATENTS ON PHARMACEUTICALS

A. SPECIAL 301

The "Special 301" provisions of the Trade Act of 1974, as amended[61], require the USTR to identify foreign countries that deny adequate and effective protection of intellectual property rights or deny fair and equitable market access for U.S. companies that rely on intellectual property protection.[62] This provision has been referred to as a "crowbar" to pry open foreign markets and also as the "H bomb of trade policy."[63] Special 301 was amended in the Uruguay Round Agreements to clarify that a country can be found to deny adequate and effective intellectual property protection even if it is in compliance the TRIPs Agreement. It was also amended to direct the USTR to take into account a country's prior status under Special 301, the history of U.S. efforts to achieve stronger intellectual property protection in the country, and the country's response to such efforts. Once the pool of countries has been determined, the USTR is required to decide which, if any, of these countries should be designated Priority Foreign Countries. Priority Foreign Countries are those countries that:

1. Have the acts, policies, and practices that are the most onerous, egregious, and have the greatest adverse impact (actual or potential) on relevant U.S. products; and,

2. Are not engaged in good faith negotiations or making significant progress in addressing these problems.

While the TRIPs Agreement is a multilateral agreement through which protection of intellectual property rights was agreed upon by many countries, Special 301 allows the threat of "unilateral retaliation" by the United States in order to persuade countries to raise their standards of protection in this field.[64] Once TRIPs was enacted,

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61 *See* Omnibus Trade and Competitiveness Act of 1988, Pub. L. No. 100-418, 102 Stat. 1107 (1988) (codified as amended in scattered sections of 19 U.S.C.).

62 19 U.S.C. § 2242 (2003).

63 Judith H. Bello, *Section 301: The United States' Response to Latin American Trade Barriers Involving Intellectual Property* , 21 INTER-AM. L. REV. 495, 495 (1989).

64 *See* Robert Pechman, *Seeking Multilateral Protection for Intellectual Property: the United States "TRIPs" over Special 301*, 7 MINN. J. GLOBAL TRADE 179, 197 (1998) ("In the first Special 301 report released by the USTR in May 1989, no cited countries were identified as PFCs [priority foreign countries] even though the USTR concluded that none of the countries cited provided adequate protection of

the United States began to use Special 301 to monitor how Members were complying with it and also as a tool "to accelerate implementation of this [TRIPs] Agreement,"[65] even though certain transition periods had been established.

For several years, many countries had complained that, in their view, Section 301 of the Trade Act of 1974 was not WTO-consistent and that unilateral action was contrary to the letter and spirit of TRIPs because it supersedes WTO dispute settlement under the DSU. This issue had a partial, but not very clear, resolution in January 2000. The WTO's Dispute Settlement Body (DSB) adopted the report of a Dispute Settlement Panel upholding the WTO consistency of Section 301 of the Trade Act of 1974. The Panel rejected a complaint by the European Union (EU) that Section 301 was inconsistent with WTO rules.[66] Although the United States took this as a victory,[67] the decision must be analyzed closely.[68] This is because the decision was based in

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intellectual property. Twenty-five of those countries were named to watch lists, and the USTR scrutinized those watch listed countries for progress in improved recognition of intellectual property rights. In April 1990, the USTR again declined to designate any watch-listed country as a PFC, under the rationale that adequate progress had been made. The first PFC′s, China, India and Thailand were designated by the USTR in its third annual report in 1991. This more proactive approach by the USTR coincided with stalled TRIPs negotiations. Thus, negotiation challenges in the Uruguay Round shifted US policy toward placing more emphasis on Special 301.").

65 Press Release, Office of the USTR, USTR Announces Two Decisions: Title VII and Special 301 (Apr. 30, 1996) (on file with the Yale J.L. & Tech.).

66 *See WTO Upholds Section 301 of Trade Act*, Tech Law Journal (Jan. 29, 2000) ("The EU filed its complaint against the United States with the WTO on November 25, 1998. The WTO established a panel to review the complaint on March 2, 1999. This panel issued its report on December 22, 1999. The WTO Dispute Settlement Body adopted this report [in January 2000]. [T]he EC alleges that Title III, chapter 1 (sections 301-310) of the Trade Act, as amended, and in particular sections 306 and 305 of the Act, are inconsistent with Articles 3, 21, 22 and 23 of the DSU; Article XVI: 4 of the WTO Agreement; and Articles I, II, III, VIII and XI of GATT 1994. The EC also alleges that the Trade Act nullifies and impairs benefits accruing, directly or indirectly, to it under GATT 1994, and also impedes the objectives of GATT 1994 and of the WTO."), *at* http://www.techlawjournal.com/trade/20000129.htm (last visited Dec. 4, 2002).

67 *Id.* ("'We are pleased that the WTO has now formally confirmed the panel's conclusion that Section 301 is consistent with U.S. WTO obligations,' stated [USTR] Charlene Barshefsky in a press release on January 27. 'Today's action by the WTO closes the door on the EU's unfounded claims regarding the legitimacy of Section 301. Section 301 has been and will remain essential to our efforts to enforce our international trade rights.'").

68 *Id.* ("The EU released a statement which concluded that 'The Panel concluded that the relevant part of the legislation as such was inconsistent with the WTO. It also came to the final conclusion that it could be considered in conformity with the WTO -- but only because the US undertook before the Panel that in each

full or in part on US undertakings (that "the administration cannot make any unilateral determinations")[69] made in the past or to the Panel.[70] In this sense, Ranabir Ray Choudhury explains the report's last paragraph: "significantly, all these conclusions are based in full or in part on the US Administration's undertakings . . . It thus follows that should they be repudiated or in any other way removed by the US Administration or another branch of the US Government, the findings of conformity (with WTO rules, generally speaking) contained in these conclusions would no longer be warranted."[71]

B. GENERALIZED SYSTEM OF PREFERENCES

The United States Generalized System of Preferences (GSP) constitutes an additional "trade weapon" through which threats of unilateral retaliation were used to pressure Argentina to raise its levels of intellectual property protection on pharmaceuticals. The GSP program is chaired by the Office of the United States Trade Representative (USTR) and was instituted on January 1, 1976 to promote economic development in developing countries through increased trade.[72] The program extends preferential tariff treatment (low or zero duties for designated products), which provides a

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and every case it would use its discretionary powers under Section 301 to act in compliance with WTO rules and procedures.'").

69 *See* Chakravarthi Raghaven, *WTO Panel Upholds U.S. Sanction Law*, THIRD WORLD NETWORK, Dec. 23, 1999, ("The ruling, and the reasoning, handed down in a report published on 22 December, by a 3-member panel in a dispute between the European Community and the United States, appears to be a "political" rather than rules-based "legal" judgment, based not upon the letter of the US law that enables US unilateralism, but on the US administration's undertakings (and interpretation) that the administration cannot make any unilateral determinations") *at* http://www.twnside.org.sg/title/uphold-cn.htm (last visited Mar. 27, 2003).

70 *See* WTO Secretariat, *Excerpt from the WTO's Overview of the State-of-play of WTO Disputes.* (Jan 13, 2000) ("The Panel found that Sections 304(a)(2)(A), 305(a) and 306(b) of the US Trade Act of 1974 were not inconsistent with Article 23.2(a) or (c) of the DSU or with any of the GATT 1994 provisions cited. The panel noted that its findings were based in full or in part on US undertakings articulated in the Statement of Administrative Action approved by the US Congress at the time it implemented the Uruguay Round agreements and confirmed in the statements by the US to the panel. The panel stated therefore that should those undertakings be repudiated or in any other way removed, its findings of conformity would no longer be warranted. The report of the panel was circulated to Members on 22 December 1999."), *available at* http://www.techlawhournal.com/trade/20000113.htm (last visited Dec. 1, 2002).

71 Ranabir Ray Choudhury, *India: Wielding the "Big Stick" in Trade*, WORLD REPORTER, Jan. 10, 2000.

72 In addition to the United States, the European Union, Australia, Belarus, Bulgaria, Canada, Czech Republic, Hungary, Japan, New Zealand, Norway, Poland, Slovak Republic, Switzerland, and the Russian Federation currently have GSP programs.

competitive advantage in the markets of industrial countries. It is, however, a unilateral grant of tariff concessions; developing countries are not required to extend reciprocal tariff reductions.[73]

Title V of the Trade Act of 1974,[74] as amended, authorizes the President of the United States to provide duty-free treatment for any eligible product from any beneficiary developing country (BDC) and establishes criteria for designating eligible countries and products. Among other points, the President must take into account the level of economic development of the country, its commitment to a liberal trade policy, and the extent to which it provides adequate protection of intellectual property rights. This last point was of great importance in justifying the use of the GSP as a bargaining weapon against Argentina. The Trade Act also authorizes the President to withdraw GSP treatment for any article or any country. Beneficiary GSP countries are persuaded to change objectionable policies or practices by the mere threat of losing these benefits.

During the years before Argentina finally started to issue pharmaceutical patents on Oct. 24, 2000, Special 301 and the GSP were the United States' main weapons of persuasion.

C. WTO DISPUTE SETTLEMENT PROCEEDINGS

Disputes regarding compliance with the TRIPs agreement were to be settled under the procedures in the Dispute Settlement Understanding (DSU).[75] The United States could have presented this dispute over intellectual property rights in Argentina before the World Trade Organization much earlier than it actually did. Instead, it chose not to do this for many years, utilizing unilateral devices such as the

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73 WILLIAM H. COOPER, CONGRESSIONAL RESEARCH SERVICE, CRS REPORT FOR CONGRESS 97-389: GENERALIZED SYSTEM OF PREFERENCES (2001) ("The preferential and unilateral nature of GSP is a departure from the principles that have guided post-World War II multilateral tariff reductions under the General Agreement on Tariffs and Trade (GATT). The GATT provides that trade must be conducted on a nondiscriminatory, or most-favored-nation (MFN), basis. Generally, members of the World Trade Organization (the organization that replaced the GATT Secretariat in 1995 and currently administers world trading rules) must extend any tariff concessions to all trading partners. Tariff reductions under the GATT have also been based on reciprocity: tariff concessions from each member country are reciprocated by concessions from others. Since 1971, however, a GATT waiver has allowed the industrial countries to extend preferential tariff treatment for developing countries."), *available at* http://www.cnie.org/nle/crsreports/economics/econ-60.cfm (last visited Jan. 1, 2002).

74 19 U.S.C. § 2101 *et seq* (1994).

75 TRIPs, *supra* note 12, pt. V, art. 64, 33 I.L.M at 106.

Special 301 and GSP as it did in cases involving other countries.[76] The USTR did finally initiate a "request for consultation" under the WTO Dispute Settlement Understanding in May 1999 to address concerns in this area. A year later, Ambassador Barshefsky, the USTR, "supplemented" the original consultation request to address additional concerns that had arisen as a result of Argentina's failure to implement obligations that came due on January 1, 2000.[77]

VII. SPECIAL 301, GSP, AND WTO DISPUTE SETTLEMENT PROCEEDINGS: USE AND EFFECTS

This section will examine the interaction between the United States´ trade policy tools and the results of their pressure on Argentina's pharmaceutical patent regime. In order to achieve this, a "time line" format shall be utilized. As was stated earlier, the Special 301 and GSP were the two foreign policy "tools" utilized by the United States to coerce Argentina into adopting U.S. standards of intellectual property protection. On some occasions, they were directly applied (or withdrawn in the case of the GSP); however, at other times, they were equally as effective as threats. Beginning in May 1999, consultations were also initiated under the DSU.

The beginning point of the analysis is the late 1980´s. In 1988 the Pharmaceutical Manufacturers Association (PMA) filed a petition under Section 301 as a consequence of Argentina's refusal to accept patents on pharmaceutical products.[78] A year later, in September of

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76 *See* Pechman, s*upra* note 64 at 197 (commenting on the case of Argentina's neighbor, Brazil). The USTR initiated a Special 301 action against Brazil in 1987 due to lack of pharmaceutical patent protection. *Id*. Brazil did not negotiate and as a result the United States imposed 100% tariffs on $39 million worth of Brazilian exports. *Id*. Brazil consequently complained that this was illegal under GATT. *Id*. Once Brazil agreed to work on legislation that included pharmaceutical patents, the US withdrew the sanctions and Brazil dropped its GATT complaint. *Id.* However Brazil's promises were not kept and the United States designated it as a PFC in April 1993. *Id*.

77 Letter from Rita D. Hayes, Ambassador Permanent Mission of the United States to the World Trade Organization, to H.E. Mr. Juan Carlos Sánchez Arnau, Ambassador Permanent Mission of Argentina (Geneva) (May 30, 2000) (on file with the Yale J.L. Tech.) (*"*This request for consultations supplements and does not replace the United States' earlier request for consultations made in WTO Document WT/DS171/1, notified May 6, 1999."), *available at* http://www.cptech.org/ip/health/c/argentina/consultationmay302000.html (last visited Jan. 1, 2002).

78 CONSUMER PROJECT ON TECHNOLOGY, BILATERAL TRADE DISPUTES INVOLVING THE UNITED STATES, OVER INTELLECTUAL PROPERTY AND HEALTH CARE ("On August 10, 1988 the Pharmaceutical Manufacturers Association (PMA) filed a petition [citing] Argentina's denial of product patent protection for pharmaceutical products and discriminatory product registration procedures… On

1989, one of the first "threats" of utilizing trade policy devices was issued to pressure Argentina into protecting intellectual property. During this month, the USTR declared that it would apply sanctions totaling $80 million to steel pipes imported from Argentina as a consequence of the economic losses suffered by US companies because of the lack of patent protection.[79] However, the measure was never executed in exchange for a promise made by Domingo F. Cavallo, who was the Argentine Minister of Foreign Relations at the time, to enact a new patent law.[80] Cavallo's commitment was that in a two-year period a bill allowing, among other things, the patentability of pharmaceutical products would be sent to Congress. As a result, the United States Government temporarily suspended inquiry proceedings, initiated under Section 301. The promise was kept, but not until three and a half years later. The Executive presented the bill for the Patent Law to the Senate on May 6, 1993.[81] This bill was truly revolutionary in Argentina where pharmaceutical patents were concerned, and it signified a shift in policies behind the proposed legislation.[82] Its stated objective was to "make the Argentine patent law comply with the standards and levels agreed upon internationally."[83] This demonstrates that Argentina was committed (at least through the

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September 25 1988, USTR initiated an investigation regarding PMA's allegations. Following consultations, the petition was withdrawn on September 23, 1989 because of Argentina's willingness to modify its pharmaceutical registration procedures and to address constructively the issue of patent protection for pharmaceutical products."), *available at* http://www.cptech.org/ip/health/country/allcountries.html (last visited Feb. 20, 2003).

79 Sebastián Curet, La Relacion EEUU-Argentina-Brasil Analizada en la cuestión de patentes farmaceuticas 23 (1999) (unpublished manuscript, on file with the Yale J.L. & Tech.).

80 *See* Buscaglia & Long, *supra* note 16 ("Argentina was subject to a Section 301 investigation of pharmaceutical patent protection in 1988, which was withdrawn in 1989 on the basis of expected legislative reform.").

81 Diario de Asuntos Entrados, Año IX – Nro. 9 (Viernes 07/05/1993) Senado de la Nación, Secretaría Parlamentaria, Dirección de Publicaciones, 115. (on file with the Yale J.L. & Tech.).

82 In the 1993 bill, the Executive initially makes important considerations regarding how Argentina had been internationally marginalized for not having tackled this reform in legislation earlier on. It goes on to state that the standards of intellectual property protection for the next century must be set and suggests the following questions to keep in mind in order to make a just analysis of the convenience of granting pharmaceutical product patents in Argentina:

1. How many medicines have been invented in our country?
2. Under the old law (No. 111) how many patent holders for technology are Argentine?
3. How much does Argentina spend on health related research and development?
4. How much royalty payments are made for the use of technology applied in the medical field?

See Diario de Asuntos Entrados, *supra* note 81 at 116.

83 *See* Diario de Asuntos Entrados, *supra* note 81 at 116.

Executive) to embracing the international standards of intellectual property protection almost two years before the TRIPs Agreement was finalized. The bill granted immediate patent protection for pharmaceutical products,[84] and it did not contain a "local production clause." In other words, it did not mandate that any patented product be produced locally (as long as the final price of the medication was not the result of illegal, anticompetitive acts). It did contemplate situations in which compulsory licenses could be granted.

Argentine Law No. 24.481,[85] which the Congress passed almost two years later (before the modifications introduced by Law No. 24.572), contained some important sections that were greatly opposed by the United States.[86] Sixteen of these sections were vetoed by the Executive through Presidential Decree 548/95 two weeks after the bill was passed.[87] Presidential Decree 548/95 constituted one of the first signs of how the United States´ threat of trade sanctions were beginning to have an effect on pharmaceutical patent protection in Argentina. Through this decree, the Argentine Executive rejected some articles of the law that were in direct opposition to the policies and standards maintained by the United States.[88] One such article was Article 42, which mandated that the patent holder was obligated to manufacture the product locally and was prohibited from importing it.[89] This article (which contradicted Article 27.1 of TRIPs) constituted a key point defended by local laboratories. The Presidential Decree's importance in this analysis cannot be underestimated; it goes as far as stating that pharmaceutical patent rights should be granted immediately. It thus opposes the transition periods adopted through Articles 104 and 105 of the original text of Law 24.481 by stating that "these…would only delay investments in research and development, and in consequence industry growth as well as general economic activity… at the same time they [the delays] would continue to segregate [the Argentine Republic] from the vast majority of the

84 *Id.*

85 Sanctioned by the Argentine Congress on March 30, 1995.

86 The US government placed Argentina on the 1995 Watch List for reasons including inadequate protection of test data submitted for marketing approval. CONSUMER PROJECT ON TECHNOLOGY, *supra* note 78.

87 Decree No. 548/95, B. O. Apr. 21, 1995.

88 The Menem Administration vetoed the portions of the law that did not comply with the TRIPs agreement and replaced them with an interim decree by the end of April 1995. CONSUMER PROJECT ON TECHNOLOGY, *supra* note 78. These actions would have provided strong patent protection in Argentina by Jan. 1, 1996, and TRIPs-consistent compulsory licensing measures. *Id.* However, in late May 1995, the Argentine Senate voted to override portions of Menem's veto, re-instituting an eight year transition period for pharmaceutical patent protection and onerous compulsory licensing provisions. *Id.*

89 Law No. 24.481, art. 42 (original text). *See also* Decree No. 548/95, B.O. Apr. 21, 1995.

countries of the international community that recognize and respect intellectual property rights for pharmaceutical products."[90]

As a result of the veto, the United States did not impose commercial sanctions on Argentina (although it did suspend peanut imports).[91] Argentine Law No. 24.481 went back to Congress and was passed on May 23, 1995 with only a few minor modifications. The law still contained many articles that did not conform to the United States' desires. This meant that the Executive had much work ahead in trying to modify the articles. The main conflicting articles regarding pharmaceutical products were Articles 104 and 105, which stated that patent protection would be available as of January 1, 2003.[92] Although this was within the time frame allowed by the TRIPs Agreement, it did not satisfy the United States. This led to a very peculiar decision by the Executive: it delayed publishing the law in the *Boletín Oficial*.[93] It did this in the hopes that the United States Government would not impose any sanctions on the country.[94] Meanwhile, the Menem administration tried to convince members of the Congress to introduce an amendment to the law. It succeeded during the month of July 1995, when the Senate voted in favor of the changes in the law, but the Cámara de Diputados (lower House) would not be as easily swayed.[95]

At this point, the United States utilized the GSP to exert pressure on the Argentine Congress in the treatment of the modifications to the law. On August 16, 1995 the U.S. Government turned down Argentina's request to incorporate 25 new products into the GSP.[96] In September 1995 Law No. 24.572 was passed and introduced the new date for patent protection on pharmaceuticals: October 24, 2000.[97] However, the complex legislative process that had

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90 *Id.*

91 Curet, *supra* note 79.

92 Law No. 24.481, art. 104, 105, B.O. Sept. 20, 1995.

93 *Enardece a opositores el 'minicongreso' de Menem*, AMBITO FINANCIERO, June 15, 1995.

94 Article 2 of the Argentine Civil Code states that "The laws are not obligatory until after their publication and from the day they determine. If no time is designated, they shall be obligatory after 8 days following their official publication." CÓD. CIV. art. 2. This was the reason for the very unusual procedure adopted by the Executive: by delaying publication, the law was not obligatory although it had been passed by Congress.

95 Curet, *supra* note 79, at 24.

96 *Id.*

97 Law No. 24.572, B.O. Oct. 23, 1995. Law No. 24.481 was finally published in the Boletín Oficial on September 20, 1995, almost 4 months after it was passed. Law No. 24.481, B.O. Sept. 20, 1995.

taken place, added to the different laws and decrees on the subject, had created an extremely imprecise regulation of pharmaceutical patents.[98]

In 1996 the United States announced that it would continue to exert pressure on countries such as Argentina "to accelerate implementation of this [TRIPs] Agreement."[99]

In early 1997 the dispute over pharmaceutical patents became very tense. The United States based its complaints on the insufficient level of protection provided by the Argentine Patent Law and the Confidentiality of Information Law which, as explained, were not well received by the Clinton Administration.[100] This situation ultimately led to President Clinton's announcement of sanctions in the form of a 50% reduction in benefits granted to Argentina under the GSP.[101] The measure was executed on April 15, 1997.[102] This constituted a victory for PhRMA, who had been trying to persuade the U.S. Government to adopt stronger methods to increase the level of intellectual property protection in Argentina.[103] However, Argentina's minister of Foreign Relations Guido DiTella, stated that the patent law conformed to

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98 *See* "Dupont de Nemours, E.I. Company c. Estado Nacional – Ministerio de Economía," CNFed. Civ. y Com. [1996-A] L.L. 321 ("[a] normative panorama that is messy, imprecise and not coherent."); "Sandoz Ltd. C. Instituto Nacional de la Propiedad Industrial," CNFed. Civ. y Com. [1998-D] L.L. 556 (Delgado, J.) ("[t]he legislative and implementation disorder that dominated the scene in this field."); Jorge Otamendi, *Un Golpe Al TRIPs*, [1999-C] L.L. 120 ("In the chaotic and shameful sanction of the patent law 24.481…").

99 Press Release, Office of the USTR, *supra* note 65.

100 *See* Jorge Elias, *Patentes: Impulsan en el Congreso la Ley del Talion*, LA NACIÓN LINE, Jan. 9, 1997 (USTR Charlene Barshefsky expressed that she was very worried that Argentina had not taken adequate measures to improve the protection of patents, particularly of pharmaceutical products).

101 Press Release, Office of the USTR, USTR-Designate Announces GSP Sanctions Against Argentina for Continuing IPR Problems (Jan. 15, 1997) (on file with the Yale J.L & Tech.) ("United States Trade Representative designate Charlene Barshevsky announced today the Clinton Administration's decision to withdraw 50% of trade benefits granted to Argentina under the U.S. Generalized System of Preferences (GSP). Duty free importation of products from Argentina will be withdrawn with respect to approximately $260 million of trade. This decision was the result of the "out of cycle" review under the U.S. Government's "Special 301" Program, designed to advance the protection of U.S. intellectual property rights around the world.*"). But see*, Luis Cortina, *Las Sanciones Comerciales Golpean Duro a las PYME,* LA NACIÓN, Jan. 16, 1997 (stating that the amount was closer to $515 million).

102 Martin Boerr, *Trabas de EE.UU. Para Productos Argentinos,* LA NACIÓN LINE, Apr. 16, 1997 (President Clinton announced to the United States Congress that he had determined that, under its laws, Argentina failed to provide adequate and effective measures to foreigners to defend, exercise, and affirm their exclusive rights to intellectual property.).

103 *See generally* Jorge Elías, *Las Sanciones Comerciales Golpean Duro a las PYME*, LA NACIÓN LINE (Jan. 16, 1997) (pointing out that the amount of the penalty imposed on Argentine exports was estimated to total $50 million).

TRIPs standards and that the "Argentine Government would not modify legislation it was completely satisfied with."[104]

The 50% reduction in benefits under the GSP towards Argentina has a "double reading." It could be argued that it demonstrated the close relationship of the Menem administration to the United States (so close that only a 50% reduction would be applied instead of the 100% available). After all, it was under the Menem administration that every effort was made to send to the Argentine Congress the levels of pharmaceutical patent protection within the TRIPs Agreement plus time frames pushed by the United States. Since the implementation decree of the Confidentiality of Information Law was pending, the Argentine Executive could still "improve" legislation to better comply with standards proposed by the US.[105] On the other hand, it also meant that an additional 50% of the GSP benefits remained available for more pressure in the future.

Argentina, like the United States, chose not to present the case to the WTO, although some legislators did toy with the idea for a brief time. The reasons for this were most likely twofold. In the first place it would have been difficult to make a case before the WTO that the withdrawal from Argentina of 50% of the benefits under the GSP constituted a "commercial sanction" since it could be viewed as a unilateral concession made by the United States.[106] Secondly, a case before the WTO over the GSP would have had additional complexity since no similar case had ever been presented to the panel. All this having been said, the Argentine Government lost a chance to present the issue before the WTO under the DSU. For all practical considerations, the withdrawal of benefits under GSP is the equivalent of a commercial sanction and was even categorized in this way by the United States Government through the USTR.[107]

Enacting this reduction, the United States ended $260 million in trade preferences for 113 Argentine imports.[108] The range of products included items from chemicals to certain metals to a variety of manufactured products and agricultural items.[109] Added to this there

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104 Boerr, *supra* note 102.

105 It should be noted however, that under Argentine Law the implementation decree cannot modify "the spirit of the law." CONST. ARG. art. 99, cl. 2.

106 *See Citing Patent Piracy, US Ends Trade Benefits*, LAGNIAPPE LETTER, Apr. 18, 1997.

107 Press Release, Office of the USTR, *supra* note 101.

108 *Citing Patent Piracy, US Ends Trade Benefits*, *supra* note 106.

109 *See* Mercedes Tira-Andre, *US Priority Watch Listing for RP Recommended*, BUSINESSWORLD, Apr. 30, 1997, at 1.

was also a perceived delay by the Clinton Administration in accepting Argentine exports of beef and peanuts.[110]

During 1998, the United States Senate became involved when the Chairman of its Foreign Relations Committee, Jesse Helms, asked USTR Charlene Barshefsky to impede imports from Argentina on products such as grapefruits, lemons and oranges as a result of the lack of protection for pharmaceutical products.[111] This came just a few days before the United States Department of Agriculture's final authorization for such imports, which had been under an extensive review for the previous five years in order to verify that they met the requirements necessary for introduction into the U.S. market. Senator Helms based his request on the fact that the United States Government had been pressuring the Argentine Government for over a decade to convince it to enact and reinforce its patent laws without achieving this objective. Secondly, the members of CILFA (the powerful Argentine pharmaceutical trade union) were still acting in the same way they had for years, copying patented products. Finally, the GSP reductions failed (in the Senator's opinion) to influence Argentina's conduct.[112]

Senator Helms´ request was successful to some extent. After this episode, Argentine citric imports were in effect suspended for 120 days by rescheduling the public hearings[113] on the USDA's "proposed rules"[114] to allow the importation of grapefruit, lemons, and oranges from Argentina. In this way, the issue of sanctions related to pharmaceutical patents in Argentina was placed on the agenda once again.

In May of 1999 the United States Government opted for an approach that Argentina, particularly through its Legislative branch, had been requesting. This was to take the Argentine case to the WTO in the form of a "request for consultations" as is mandated under the TRIPs Agreement, which at this point had been in force for over four years. [115] Some of the reasons behind the United States' action can be summarized as follows:

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110 *See Argentina won't Alter Patent Law Despite U.S. Trade Measure,* Dow Jones News Service, Apr. 15, 1997.

111 Jorge Elías, *Los EE.UU. Piden Trabas Para Citricos Argentinos,* LA NACIÓN LINE, Oct. 10, 1998. Senator Helms, in his note to the USTR expressed that he was amazed that the administration was offering a new market area to an Argentine industry. In his view, this action could suggest that the administration was not serious in resolving the intellectual property issue. *Id.*

112 *Id.*

113 Press Release, USDA, USDA Reschedules Public Meeting on Importation of Argentine Citrus (Dec. 3, 1998) (on file with the Yale J.L & Tech.).

114 63 Fed. Reg. 43124-43125 (Aug. 12, 1998).

115 Dispute Settlement Update, Office of the USTR (last modified Jan. 30, 2003) ("On May 6, 1999, the United States filed a consultation request

1. The absence in Argentina of either patent protection for pharmaceutical products or an effective system for providing exclusive marketing rights in such products.

2. Argentina's failure to protect confidential test data submitted to government regulatory authorities for pharmaceuticals.

3. Argentina not having met the obligations established under the TRIPs Agreement to make internal legislation comply with such agreement.

4. Argentina's control organisms, such as the INPI, not functioning properly.

5. Argentina's failure to provide provisional measures, such as preliminary injunctions, to prevent infringements of patent rights.

The news was not well received in Argentina. A bill was immediately presented by legislators in which the "transition period" for the issuance of pharmaceutical patents was pushed back to 2005 (the maximum allowed under the TRIPs Agreement).[116] The bill also contained a "local production" clause[117] (as is mandated in Brazil) as well as certain additional requirements before exclusive marketing rights for pharmaceuticals would be granted. There were, however,

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challenging Argentina's failure to provide a system of exclusive marketing rights for pharmaceutical products, and to ensure that changes in its laws and regulations during its transition period do not result in a lesser degree of consistency with the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights ('TRIPS Agreement'). Consultations were held on June 15, 1999, and again on July 27, 1999. On May 30, 2000, the United States expanded its claims in this dispute to include new concerns that have arisen as a result of Argentina's failure to fully implement its remaining TRIPS obligations that came due on January 1, 2000. These concerns include Argentina's failure to protect confidential test data submitted to government regulatory authorities for pharmaceuticals and agricultural chemicals; its denial of certain exclusive rights for patents; its failure to provide such provisional measures as preliminary injunctions to prevent infringements of patent rights; and its exclusion of certain subject matter from patentability. Consultations continued until April 16, 2002, when the two sides agreed to settle eight of the ten issues in the dispute. Argentina and the United States notified a settlement of these issues to the DSB on May 31, 2002. Consultations continue on the unresolved issues."), *at* http://www.ustr.gov/enforcement/update.html (last visited Mar. 15, 2003) (on file with the Yale J.L. & Tech.).

116 *See Menem Afirmo que Vetaría una nueva Ley de Patentes,* LA NACIÓN LINE, June 17,1999. The Bill was presented by Diputados Emilio Martínez Garbino (PJ), Juan Pablo Baylac – Rafael Flores (Alianza) and Humberto Roggero (PJ). *Id.* However, President Menem stated that he would veto such a law. *Id.*

117 *See Amenaza de EE.UU. Por La Ley de Patentes,* LA NACIÓN LINE, Feb. 18, 2000. The clause was incorporated by Diputado Rafael Flores. *Id.*

some positive reactions among local politicians who thought that the controversy over pharmaceutical patents should have been presented to the WTO long before. The Argentine International Economic Relations Secretary, Jorge Campbell, thought that the decision had a positive side to it because it recognized the dispute settlement mechanisms of the WTO.[118] These considerations come as no surprise, mainly because the WTO DSB is viewed by smaller countries as a forum in which they can compete on the same level with the most powerful ones.

An important victory for the United States came in February 2000 when the De la Rúa Administration[119] changed the principal officers of the INPI. The three removed directors had been named during Menem´s last days as President in 1999 and were always suspected of favoring local pharmaceutical companies because of their ties to Diputado Humberto Roggero. Coincidently, the measure was announced during a visit to Buenos Aires by Deputy USTR Richard Fisher. Mr. Fisher had pressured for the removal of the INPI Directors during his trip[120] and warned of further sanctions if the Argentine Patent Law was modified to lessen US backed levels of protection for pharmaceuticals.[121]

A few months later, in April 2000, yet another victory for the Clinton Administration came as the Argentine Executive and legislators agreed to "freeze" all talks of changing the articles of the Patent Law that referred to pharmaceuticals.[122] The road was cleared for granting pharmaceutical patents by October 24, 2000.

The following table summarizes the interactions between Argentina and the United States over a 14 year period in the Pharmaceutical Patents Case:

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118 *See* Jorge Rosales, *Embate de EE.UU. por las Patentes,* LA NACIÓN LINE, Apr. 29, 1999. In this sense, Diputado Humberto Roggero stated that "I am very pleased that they [the USA] understand that the WTO and arbitral tribunals exist so that in this way the threats, pressures and sanctions will stop given that we are convinced that our laws on intellectual property do not violate international laws." *Id.* (translation by author).

119 Fernando De la Rúa, President of Argentina 1999 – 2001.

120 *See Cambios en el INPI,* LA NACIÓN LINE, Feb. 18, 2000. (quoting Richard Fisher, Deputy USTR, as stating that the INPI has been a problem and that he hoped that the new government exerts real leadership) (translation by author).

121 *See Amenaza de EE.UU. Por La Ley de Patentes, supra* note 117.

122 *See* Laura Serra, *Patentes: Congelan la Discusion Legislativa,* LA NACIÓN LINE, Apr. 9, 2000.

Event in Argentina	Event in the United States
Patent Law No. 111 did not recognize pharmaceutical product patents.	On August 10, 1988, the Pharmaceutical Manufacturers Association (PMA) filed a petition citing Argentina's denial of product patent protection for pharmaceutical products and discriminatory product registration procedures. On September 25, 1988, the USTR initiated an investigation into PMA's allegations.
Domingo F. Cavallo, the Argentine Minister of Foreign Relations, promised to enact a new patent law (Publicly announced at the Argentine Advertisers Chamber, October 1989).	Following consultations, the petition was withdrawn on September 23, 1989 because of Argentina's willingness to modify its pharmaceutical registration procedures and to address constructively the issue of patent protection for pharmaceutical products.
The bill for the new Patent Law was presented to the Senate by the Argentine Executive on May 7, 1993.	The bill was received well by the United States, mainly because it granted immediate patent protection to pharmaceuticals; it did not mandate that any patented product be produced locally, but did contemplate situations in which compulsory licenses could be granted.
In April 1995, the Argentine Congress passed a patent law (original text of Law No. 24.481) that included an eight year transition period for pharmaceutical patent protection.	The US government placed Argentina on the 1995 Watch List for reasons including inadequate protection of test data submitted for marketing approval.
Sixteen sections were vetoed by the Executive through Presidential Decree 548/95, two weeks after the law was passed.	As a result of the veto, the United States did not impose commercial sanctions on Argentina.

The law went back to Congress and was approved on May 23, 1995 with only a few minor modifications. The law still had a number of articles that did not conform to the requirements of the United States, and the Executive would have much work ahead in trying to modify them. The main articles in conflict were Articles 104 and 105, which stated that patent protection would be available as of January 1, 2003.	On August 16, 1995 the U.S. Government turned down Argentina´s request to incorporate 25 new products into the GSP system.
In September 1995, Law No. 24.572 was passed, introducing changes to the date for patent protection for pharmaceuticals: October 24, 2000.	The United States announced, in 1996, that it would continue to pressure countries such as Argentina to raise the levels of intellectual property protection.[123]
In early 1997, the situation over pharmaceutical patents became very tense. The United States based its complaints on the insufficient level of protection of the Argentine Patent Law and the Confidentiality of Information Law passed in December 1996.	President Clinton announced the reduction of 50% of the benefits granted to Argentina under the GSP on January 15, 1997. The measure was executed on April 15, 1997.
Argentina did not modify any of the questioned laws.	Argentine citric imports were suspended for 120 days, in October of 1998, and the issue of sanctions related to pharmaceutical patents in Argentina was again placed on the agenda. In May of 1999, the United States brought the Argentine case to the WTO.

123 See, Inti Linkletter Knapp, *The Software Piracy Battle in Latin America: Should the United States Pursue its Aggressive Bilateral Trade Policy Despite the Multilateral TRIPs Enforcement Framework?*, 21 U. PA. J. INT'L ECON. L. 173, 205 (2000) ("The United States indicated that it will continue to engage in an aggressive section 301 policy because it can pressure developing nations to enact even greater intellectual property protection than required by TRIPs.").

February 2000: the De la Rúa Administration changes the principal authorities of the INPI. April 2000: the Argentine Executive and legislators agreed to "freeze" all talks of changing the articles (to lessen protection standards) of the Patent Law that referred to pharmaceuticals. However, Argentina did not modify any of the questioned laws to comply with US complaints.	The USTR released its "Special 301" Report 2000 (1999 period). In this evaluation, Argentina was classified as a "priority watch list" country and a second WTO dispute settlement case (expanding its claims against Argentina) was announced.
Argentina started issuing pharmaceutical patents on October 24, 2000.	The USTR released its "Special 301" Report 2001 (2000 period). In this evaluation, the USTR recognized that Argentina began to issue pharmaceutical patents for the first time and reported progress toward resolution of the case against Argentina. It also stated Argentina had fulfilled some, but not all, of its long-standing commitments to the United States on intellectual property.

VIII. THE CORE OF THE CONTROVERSY

The inconsistency of United States policy is a central problem when trying to get developing countries to make massive legislative changes to their pharmaceutical patent protection standards. On the one hand, the Clinton Administration heavily promoted the standards contained in the TRIPs Agreement. But once Argentina enacted TRIPs standards internally, the United States began to pressure for earlier implementation of the standards[124] and higher standards, such as pipeline protection, using unilateral trade sanctions. As the USTR stated, "U.S. law determines that a foreign country may be deemed to deny *adequate and effective* protection of IPR's [intellectual property rights] notwithstanding compliance of the said country with the specific obligations stipulated by the TRIPs Agreement."[125] The point here is obvious: if the United States wants countries to comply with standards mutually agreed upon, it should not at the same time bypass the agreed upon mechanisms such as the DSU by unilaterally pressuring for higher standards through mechanisms such as Special

124 *See* Press Release, Office of the USTR, *supra* note 65. *See also* Press Release, Office of the USTR, *supra* note 23.

125 CORREA, *supra* note 5, at 110.

301 or GSP withdrawal.[126] President Clinton's address to Congress revealed the inconsistency which led to the described controversy: "If members of the DSU do not comply with their obligations at the end of the dispute settlement process, trade action under section 301 of the Trade Act of 1974 will be legitimized…"[127] In other words, sanctions imposed by the U.S. before the DSU process was initiated and completed were not legitimate. The crux of the issue is that, after TRIPs, retaliation can only be authorized by a ruling of a panel under the Dispute Settlement Understanding.[128] Section 301 actions, however, did not cease despite the enactment of TRIPs.[129] The USTR, moreover, admitted that GSP withdrawal constituted a "sanction" against Argentina.[130]

The United States waited too long in bringing its complaints about Argentine patent protection to the WTO under the DSU. When it finally did so, in May 1999, it had arguably already violated the letter of the TRIPs Agreement[131] by reducing benefits under the GSP in 1997[132] and suspending Argentine citric imports in 1998. The following section assesses the negative consequences such coercive mechanisms, after TRIPs, can have on a developing country.

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126 *See* Knapp, *supra* note 123 at 176 ("The United States should no longer combat software copyright piracy using unilateral trade threats to force bilateral agreements; instead, the United States should use WTO enforcement mechanisms created by TRIPs.").

127 Memorandum for the United States Trade Representative, 58 Fed Reg. 67263, 67292 (Dec. 15 1993).

128 *See* Pechman, *supra* note 64, at 201.

129 *See also* Knapp, *supra* note 123, at 179 ("In its legislation adopting TRIPs, the U.S. House of Representatives stated that 'nothing in this Act shall be construed . . . to limit any authority conferred under a law of the United States, including Section 301 of the Trade Act of 1974, unless specifically provided for in this Act.'").

130 *See* Press Release, Office of the USTR, *supra* note 101. *See also,* Wendy S. Vicente, *A Questionable Victory For Coerced Argentine Pharmaceutical Patent Legislation*, 19 U. PA. J. INT'L ECON. L. 1101, 1108 (1998) ("The United States responded with trade sanctions on $260 million of Argentina's exports… ").

131 *See* Pechman, *supra* note 64 at 202 ("The DSU requires Members to invoke the dispute settlement mechanism without making unilateral determinations regarding violations of any of the WTO Agreements.").

132 *See* Press Release, Office of the USTR, USTR Announces List of Argentine Products to Lose GSP Benefits as a Result of "Out-Of-Cycle Review" (Apr. 15, 1997) (on file with the Yale J.L. & Tech.). Some of the Argentine products that lost duty-free treatment included: sea bass, milk protein concentrates, garlic, gold compounds, butanone, certain drugs, paints and varnishes based on synthetic polymers, essential oils of grapefruit, certain perfume mistures, shampoos, personal deodorants and antiperspirants, prepared glues, photographic plates, certain radial tires, fur clothing accessories, writing paper, tempered safety glass, some engine parts, parts of frames and mountings for spectacles, and wooden furniture. *Id.*

IX. ASSESSING THE NEGATIVE CONSEQUENCES OF COERCIVE MECHANISMS AFTER TRIPS

The use of unilateral sanctions by the U.S. has numerous negative consequences, detailed below.[133]

A. NEGATIVE IMPRESSION OF THE U.S.

Under the TRIPs Agreement, retaliation is permitted after utilizing the DSU procedures only in the same trade sector.[134] The unilateral measures taken by the United States, however, not only may have violated the letter of TRIPs by not following the DSU, but also exceeded the "scope" of permitted retaliation. This is evidenced in GSP withdrawal as well as in the commercial sanction of Argentine grapefruits, lemons, and oranges, which are not even remotely related to the pharmaceutical industry. This increased the negative perception that Argentines had of United States policy.[135] A disdain of U.S. "economic imperialism" was reflected in the statements of the president of the local pharmaceutical association.[136]

B. RISK OF PROVOKING RETALIATION

The level of pressure that the United States exerted over the Argentine government in the case of pharmaceutical patents came very close to backfiring. An example of this can be drawn from the events that took place after President Clinton's decision to reduce 50% of the benefits granted to Argentina under the GSP on January 15, 1997. First of all, the United States' unilateral action ignited a great deal of debate in Argentina. The GSP is a unilateral "preference" by the United States, and some might argue that, in this sense, it can legally be taken away in the same manner it was given. It is clear, however, that in the Argentine case the restriction of a percentage of GSP preferences was actually used as a *commercial sanction* against the country since it was directly linked by the Clinton Administration to

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133 *See also* ERNEST H. PREEG, FEELING GOOD OR DOING GOOD WITH SANCTIONS: UNILATERAL ECONOMIC SANCTIONS AND THE U.S. NATIONAL INTEREST (1999) ("The use of unilateral economic sanctions for foreign policy objectives has a number of inherent, or at least highly likely, downsides that need to be taken into account when considering the use of such sanctions. These downsides do not mean that the imposition of sanctions cannot achieve a given purpose, but rather that they need to be factored into the overall basis for decision…").

134 Pechman, *supra* note 64, at 203.

135 *See also* Knapp, *supra* note 123, at 209 (2000) ("Latin American countries have been enraged by perceived U.S. capitalist bullies…").

136 *See Argentina Slams US Decisions on Sanctions*, MARKETLETTER, Jan, 27, 1997.

the standards of protection in local intellectual property laws.[137] Many arguments and anti-American sentiments, particularly in the Cámara de Diputados, could have been avoided if the controversy had been presented before the WTO at this time. Since it was not, the general perception was that the Argentine laws conformed to TRIPs standards. This, in turn, led to unexpected consequences. For example, Diputado Humberto Roggero (P.J.-Córdoba), President of the Industry Commission and one of the legislators most critical of the United States' decision, stated that it constituted "an interference in internal affairs of Argentina." Roggero also suggested raising internal taxes on cola beverages as an act of retaliation towards the United States´ decision.[138] He even presented a bill that would have excluded from public bids any company whose capital had its origin in any country or countries that had adopted unilateral commercial sanctions against Argentina.[139]

Other bills presented during this time included:

1. A bill introducing a modification of the patent law, pushing back the availability for pharmaceutical patents to 2005.[140]

2. A bill mandating that the Executive apply commercial sanctions to those countries "which violating WTO laws apply sanctions that affect our commerce."[141]

3. A bill containing a "local production" clause, putting the issue once again in the eye of the storm.[142]

These examples demonstrate that members of foreign legislatures do not differentiate between negative consequences resulting from Special 301 pressure and those resulting from GSP withdrawal.

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137 *See* Press Release, Office of the USTR, *supra* note 101. *See also* Judith H. Bello & Alan F. Holmer, *"Special 301": Its Requirements, Implementation, and Significance*, 13 FORDHAM INT'L L.J. 259, 262 (1989) ("If the acts, practices, or policies continue, the USTR is authorized, but is not required, to retaliate by increasing duties or imposing other restrictions on imports.").

138 *See* Luis Cortina, *Las Sanciones Comerciales Golpean Duro a las PYME,* LA NACIÓN LINE, Jan. 16, 1997. The proposal was to raise taxes on cola beverages from 4% to 24%. *Id*.

139 *See Patentes: Rechazan una Sanción,* LA NACIÓN LINE, Apr. 15, 1997.

140 *See Patentes: Los Legisladores Contraatacan,* LA NACIÓN LINE, Apr. 24, 1997.

141 *Id.*

142 *Id.*

C. WEAKENING EXCLUSIVE MARKETING RIGHTS

With all the U.S. sanctions and threats of sanctions, EMR's were not granted except in the two cases described. This shows that it would have been better for the United States to take the issue before the WTO under the DSU sooner than it did. By the time "consultations" under the DSU began, only 16 months were left until Argentina would begin issuing patents on pharmaceuticals, thus reducing the EMR's importance. Once the corresponding patent is granted (or if the patent application is rejected), such rights are terminated.

D. EFFECT ON U.S. IMPORTERS OF ARGENTINE PRODUCTS

The potential for negative effects on U.S. importers arising from measures such as Argentine product withdraw from the GSP should also be considered. In other words, "[w]hen the United States imposes trade sanctions against a Special 301 target country, those industries in the United States that rely on importing targeted products and consumers who wish to purchase targeted products are adversely affected."[143] These negative effects are even more evident when the amount and diversity of the merchandise are taken into account. For example, when the U.S. announced trade sanctions against Brazil for its lax intellectual property protection, many U.S. companies expressed opposition.[144] In any event, this is another component that should be considered when analyzing the "local" consequences of certain mechanisms employed to improve intellectual property standards overseas.

E. EFFECT ON THE FUNCTIONING OF DEMOCRATIC INSTITUTIONS IN DEVELOPING COUNTRIES

U.S. actions to pressure Argentina to increase protection of pharmaceutical patents at times interfered with the functioning of the Argentine government. The delay of the Argentine Executive in publishing Law No. 24.481 is one example of U.S. interference with Argentine democratic institutions. The declarations of the Deputy USTR in Buenos Aires regarding the removal of the INPI Directors also border on interference into an internal matter of another country and jeopardize the proper functioning and designation of authorities of

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143 Harrison, *supra* note 1, at 483.

144 *Id.* at 484 ("[c]orporate officials from General Electric, Xerox, Dow Chemical, Rohm & Haas Co., Ford Motors, Black & Decker and others [who] testified that proposed tariffs would increase costs from U.S. companies and consumers and would affect U.S. interests more than Brazilian interests.").

a governmental agency. These public statements do not seem to accelerate the granting of patents. On the contrary, they tend to spark reactions from sectors that view this as going too far and intruding in the functioning of a local agency.

This issue should be considered with great caution by future administrations if they pursue enhanced IP protection in developing countries that do not have a long tradition of uninterrupted democratic governments. The main point to make here is that the United States will have to decide what it considers more valuable: the interests of associations such as PhRMA, or the promotion of well functioning democratic institutions in developing countries. In a country with a strong Executive (compared to the other branches), maneuvers that obstruct laws not "in the interests" of the United States can only damage democratic principles.[145] Sidestepping a weak legislature can only exacerbate the problems that such a country's young democracy already has. Of course, it would be illogical to fault the United States for political and institutional problems in another country. Nevertheless, political realities should not be ignored when pressure is exerted on a foreign Executive in order to improve US interests.

F. THE "LEGAL MAZE" OF PATENT PROTECTION IN ARGENTINA DURING THE MID-1990'S.

The United States' pressure for earlier and higher standards than those required under TRIPs led to a series of laws, decrees, and implementations that went back and forth between the Argentine Executive and its Legislature. The end result was a puzzle that only specialized attorneys could understand. Practitioners were not even sure of the dates on which patents would be allowed under existing law.[146] Needless to say, this did not contribute to stronger IP rights in the pharmaceutical field.

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145 *See* Wendy S. Vicente, *A Questionable Victory For Coerced Argentine Pharmaceutical Patent Legislation*, 19 U. PA. J. INT'L. ECON. L 1101, 1116 (1998) ("The United States treads on thin democratic ice when it encourages Menem to disrespect the Argentine Congress and force stronger intellectual property laws upon Argentina.").

146 *See* Ernesto O´Farrell, *Tres Fallos Polémicos*, [1999-A] L.L. 26 ("As a conclusion, it should be noted that it will still take a long time to sort out the mess derived from the confusing legislative process.").

G. EFFECTS ON FUTURE EFFORTS OF HARMONIZATION IN OTHER FIELDS

The conclusions that developing countries could draw from the actions taken by the United States after the implementation of TRIPs may reach other fields as well. For example, in the future the U.S. might push for adequate levels of "privacy" protection on the Internet through a multilateral agreement. The disregard for established procedures and mechanisms described above can only undermine such future efforts to harmonize other areas of law. How will the United States argue that it intends to be bound by international agreements after the example it set in the case of Argentine pharmaceutical patents?

H. SHOULD THE U.S. LET PHRMA INFLUENCE ITS FOREIGN IP PROTECTION POLICIES?

The Argentine case demonstrated just how much of an influence PhRMA had on the United States' policies in this field. It may seem surprising that "a U.S. Trade Representative official admitted that it decided to enforce the patent law-related sanctions based entirely on data and information supplied by PhRMA."[147] The U.S. should not base its decisions on applying trade sanctions based solely on information supplied by an interested party. Furthermore, in the case of Argentina, a U.S. governmental agency (the Patent and Trademark Office), denied members of ALIFAR (the Latin American Pharmaceutical Association) the chance to participate in a conference dealing with intellectual property.[148] Actions such as these have been directly linked to the pressures exerted on the U.S. Government by this powerful association.[149]

X. PROPOSED ALTERNATIVE MECHANISMS

This section proposes a few alternative mechanisms to the DSU to help further IP protection in developing countries. Such mechanisms were either not applied soon enough or were never pursued at all in the case under analysis.

147 Vicente, *supra* note 145, at 1108.
148 *See id.* at 1127.
149 *Id.*

A. TRIPS ARTICLE 67

Article 67 of the Agreement imposes some "cooperation duties" on its developed country Members towards developing and least-developed country Members. These duties can include assistance in the preparation of laws and regulations on the protection and enforcement of intellectual property rights, training of personnel and support in the establishment of offices and agencies relevant to such matters.[150] This provision encourages and facilitates the implementation of the standards under TRIPs.

During the time that the described reforms were taking place, Argentina needed assistance in many areas related to IP protection. Failures in the computer systems, thousands of applications for patents without approval (24,801 as of June 1999), and irregularities in its treasury and in the designation of its employees (some of which lacked the necessary experience) were the main flaws pointed out in relation to the management of the INPI by diplomatic sources.[151]

This TRIPs instrument, amazingly, was not utilized by the United States during the five years in which the dispute over pharmaceutical patents was at its peak (1995-2000).[152] Article 67 could have provided an additional mechanism to achieve supplemental goals in this field by allowing the United States to collaborate with local agencies such as the INPI. This agency is crucially important but unfortunately lacks the necessary budget to meet its obligations. This TRIPs device is an additional "peaceful weapon" that could have been utilized in this case; training or support of personnel could have helped sway public opinion that in turn could have pressured members of the Argentine Congress to reach a solution to the conflict.

B. PROMOTE LOCAL RESEARCH AND DEVELOPMENT THROUGH FOREIGN AID TO TARGETED COUNTRIES

Another alternative mechanism is for the United States to "[p]rovide foreign aid earmarked for Latin American research and development. Although such an investment would result in potential competition for U.S. companies, it would also increase Latin American self-interest in enforcing effective intellectual property

150 TRIPs, *supra* note 12, pt. VI, art. 67, 33 I.L.M at 108.
151 *See El INPI, Otra Pesada Herencia,* LA NACIÓN LINE, Nov. 19, 1999.
152 Interview with Engineer Luis Nogués, *supra* note 42.

protection."[153] Drug companies could also participate in encouraging foreign research.[154]

C. JUDICIAL REFORM

This issue can be summarized as follows: what is the sense of promoting strong patent legislation overseas if it can never be effectively enforced due to the inefficiencies of a judicial system?[155] The case of Argentina clearly demonstrates this point. Reports such as those of the World Bank on the Argentine judiciary reflect just how critical the problems in the judiciary are.[156] It has been stated that "a right without a remedy is but an expensive illusion."[157] In other words, what would be the practical effect of obtaining a patent if effective enforcement is not available? Another important issue that should be addressed is the need to create specialized intellectual property courts in Argentina, analogous to the Federal Circuit in the United States, which could help upgrade intellectual property protection. Some Latin American countries such as Peru, Chile and Panama already have these specialized judicial structures in place.[158]

The United States Government could contribute funds for judicial sector reform. PhRMA could also fund some of the specific reforms that might be needed in the intellectual property field such as the creation of specialized patent courts. Such reforms could work to their benefit, although the involvement of PhRMA in the judiciary raises the concern of industry interference with the courts' impartiality. Having a well trained and funded judiciary might prove very helpful to PhRMA members in obtaining objective results in patent infringement cases.

Finally, judicial reform not only improves intellectual property protection but also encourages and sustains other elements of economic development.[159]

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153 *See* Knapp, *supra* note 123, at 210.

154 *See* Vicente, *supra* note 145, at 1137.

155 *See* Knapp, *supra* note 123, at 200 ("The judiciary in these countries often needs training in new matters of high-tech intellectual property. In addition, some Latin American judicial systems lack the same adequate remedies or enforcement procedures that the U.S. judicial system employs.").

156 *See generally* LEGAL VICE PRESIDENCY, THE WORLD BANK, ARGENTINA LEGAL AND JUDICIAL SECTOR ASSESSMENT (2001) (assessing the state of the judicial branch in Argentina).

157 *See* Robert M. Sherwood, *Intellectual Property for Latin America: How Soon Will it Work,* 4 SPG NAFTA: L. & BUS. REV. AM. 77, 88 (1998).

158 *Id.* at 89.

159 *Id.* at 90.

D. EDUCATING SOCIETY ON THE IMPORTANCE OF PHARMACEUTICAL PATENT RIGHTS

Finally, it should be noted that swift section 301 results might not guarantee that intellectual property is protected.[160] Societies tend to respect property rights that they recognize. Such is the case with "real property." However, intellectual property rights present an additional challenge because in many cases they deal with high-tech issues that might not seem as "tangible." Associations such as PhRMA might benefit from following the example of some U.S. software companies that "have worked to increase awareness in both the public and private sectors about the benefits of intellectual property protection to a domestic economy."[161] Educational programs to promote "IP awareness" could be put in place if the proper funding were made available. Education, rather than coercion has been suggested[162] but not applied in the pharmaceutical field. This would be especially helpful in cases of countries such as Argentina, where intellectual property protection is not highly regarded among the general population.[163]

160 *See* Knapp, *supra* note 123, at 205 ("When the United States opts for swift section 301 results over slower WTO dispute settlement procedures and lower TRIPs protection requirements, the United States is not laying the foundation for true cultural acceptance of intellectual property rights. Rather, U.S. trade aggression increases the Latin American perception that the true beneficiaries of intellectual property rights are U.S. capitalists.").

161 *Id.* at 208.

162 *See id.* at 210.

163 *See* Robert M. Sherwood, *Intellectual Property Systems and Investment Stimulation: The Rating of Systems in 18 Developing Countries,* 37 IDEA 261, 290 (1997) ("While a tradition of esteem for literary accomplishment has given copyright protection some public backing [in Argentina], an assertive campaign against patent protection for pharmaceuticals has produced a predominantly negative impression of intellectual property in much of the population.").

XI. CONCLUSION

This analysis describes the radical transformations in pharmaceutical intellectual property protection in Argentina during the 1990s. Most importantly, it highlights the effect of the use by the United States of unilateral trade weapons to pressure Argentina to adopt certain standards in this field.

The enforcement or threatened enforcement of Section 301 of the US Trade Act, along with GSP restrictions, have proven to be controversial tools in protecting US interests abroad as is demonstrated by the Argentine case. Some positive results were achieved for United States' interests but the United States created at the same time negative implications by pressuring for more protection in a shorter time than is mandated under TRIPs: in other words, requiring "TRIPs–Plus" standards. [164] "[R]etaliatory trade policies and other efforts to coerce the premature adoption of intellectual property protection can damage developing economies and run counter to U.S. goals. This is especially true where the intellectual property in question is pharmaceutical patents."[165]

The following tables summarize the results of the United States' utilization of its trade policy mechanisms to influence in Argentine pharmaceutical intellectual property protection:

What the U.S. was able to achieve through its trade policy

1. A patent law covering pharmaceutical products was sent to the Argentine Congress and passed in 1995.

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164 Knapp, *supra* note 123, at 205 ("The United States is required under TRIPs to submit intellectual property complaints to the Dispute Settlement Body of the WTO and abide by the WTO ruling. However, the United States indicated that it will continue to engage in an aggressive section 301 policy because it can pressure developing countries to enact even greater intellectual property protection than required by TRIPs."). *See also* Chakravarthi Raghaven, *United States Pushes for Greater IPR Privileges in FTAA*, THIRD WORLD NETWORK, Apr. 3, 2001, ("The U.S. intent [referring to the Free Trade for Americas Agreement (FTAA)] also represents a case of TRIPs-plus because it calls for exclusive rights in handling data presented for registering pharmaceutical … products, which would generate a monopoly situation even without the existence of a patent."), *at* http://www.twnside.org.sg/title/pushes.htm (last visited March 14, 2003) (on file with the Yale J.L & Tech.).

165 Stefan Kirchanski, *Protection of U.S. Patent Rights in Developing Countries: U.S. Efforts to Enforce Pharmaceutical Patents in Thailand*, 16 LOY. L.A. INT'L & COMP. L.J. 569, 607 (1994).

2. The "transition period" for granting pharmaceutical patents was brought down to 5 years from the original 10 years under TRIPs and the 8 years that were contemplated in the original Argentine patent law.

3. The patent law's implementation decree included the "exclusive marketing rights" that were not contemplated in the text of the law.

4. The "local production clause" was not included in the patent law and no modification containing it was approved by the Argentine Congress. Brazil's law has such a clause.

5. The INPI's directors were replaced in 2000.

6. Although one aspect of compulsory licenses is still a conflicting issue, up to the present date none have been granted for pharmaceutical products.

What the U.S. was *not* able to achieve through its trade policy

1. Make Argentina grant "pipeline" or retroactive protection for pharmaceuticals (as Brazil's law does). Note, however, that "pipeline" protection is not required under TRIPs. [166]

2. Full recognition of EMR's.

3. "Linkage" between ANMAT and the INPI (although this was a concern expressed for by PhRMA more than by the US Government).

4. The Argentine Law No. 24.766 on confidentiality of information, has still not been implemented.

166 *See* Holmer, *supra* note 21. President Memen may have promised the U.S. that Argentina would establish pipeline protection. *Id*. "The new legislation falls far short of the commitment made by President Menem in 1989 to enact a patent law in Argentina that would afford product protection for pharmaceuticals immediately, provide protection to products in the pipeline, and severely limit the compulsory licensing of patents." *Id*.

Request for consultations under the DSU presented by the U.S.[167]

1. Article 42 of the Argentine patent law: "Other Uses without the authorization of the Patent Holder" also known as Compulsory Licenses. However, since the INPI directors were removed this does not constitute the same threat as it did in the past for US interests.

2. Exclusive Marketing Rights issue.

3. Law on confidentiality issue / protection of undisclosed test or other data.[168]

4. Failure to provide prompt and effective provisional measures, such as preliminary injunctions, for purposes of preventing infringements of patent rights from occurring.

5. Improper limitation of judiciary authority to shift the burden of proof in civil proceedings involving the infringements of process patent rights.

In order to make a fair judgment of the effectiveness of the U.S. trade policy tools utilized in the Argentine case, several points must be kept in mind. First, it should be remembered where Argentina stood on pharmaceutical patent protection ten years ago: no patents were available for pharmaceutical products. Second, the TRIPs Agreement came to life in the mid 1990´s setting certain minimum standards. The United States was able to expedite the application of these standards by pressuring Argentina to begin working on a new patent law several years before TRIPs was concluded. After this, the trade policy tools described helped to set a 5 year transition period instead of a 10 year

167 Certain Measures on the Protection of Patents and Test Data, Request for Consultations by the United States, WTO Doc 00-2220 (June 6 2000); Argentina - Patent Protection for Pharmaceuticals and Test Data Protection for Agricultural Chemicals - Request for Consultations by the United States, WTO Doc 99-1954 (May 10, 1999).

168 *See generally,* Robert S. Tancer & Shoshana B. Tancer, *MERCOSUR and the Pharmaceutical Industry-Waiting for a Common Patent Regime,* LATIN AM. L. & BUS. REP., Apr. 30, 1997, (explaining the U.S. drug industry believed that this piece of legislation "[w]as a thinly disguised attempt to invalidate the pharmaceutical patent protection which had just recently been approved. This new law developed the argument that patent protected products available in international markets were no longer 'novel' and therefore were ineligible for patent protection in Argentina. This opened the door for imitations which could be protected under Argentine law using the very information which was part of the original patent grant.").

period.[169] Even though this was not as good as the result achieved in Brazil,[170] five years is a respectable time especially considering the amount of money that was involved in the Argentine "pirate" pharmaceutical industry.[171] Additionally, the directors of the INPI, who were suspected of being a threat to intellectual property rights, were replaced as a direct result of pressure exerted by the United States government. Thus the power of these tools should not be underestimated; they were, at the very least, taken into consideration when the decision to remove the INPI directors was taken during the early months of the De la Rúa Administration.

The United States, however, did not obtain 100% of its initial objectives and had to deal with additional and unforeseen complications. First of all, the United States did not win pipeline protection of pharmaceuticals. The Argentine Congress maintained a position that is hard to refute: the TRIPs Agreement does not require it and in consequence pipeline protection constitutes a nonnegotiable item. Second, the delay by the United States to initiate DSU consultations and failure to present the case to the WTO made the Argentine people believe that the local law did comply in full with what was mandated under TRIPs. This, in turn led to anti-American sentiment that was taken advantage of by members of Congress to introduce bills that could have further damaged United States' interests (such as extending the transition periods to take advantage of the full length established under TRIPs or taxing American products such as cola beverages). Third, the facts demonstrate that in some cases, pressures by the United States tend to complicate rather than to facilitate the process of legislative change.[172]

Additionally, it should be noted that all the events described took place during the radical Argentine economic transformations of the 1990's.[173] This was a decade in which diplomatic and commercial

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169 *See also* Buscaglia & Long, *supra* note 16 ("TRIPs and the expected trade gains have tipped the balance in favor of introducing a stronger intellectual property framework that is more compatible with U.S. laws; Yet . . . U.S. foreign policy pressure is necessary to keep the momentum of legal reform going.").

170 *See* Pechman *supra* note 64, at 200 ("The Brazil pharmaceuticals case is an early indication of the efficacy of such a plan [using Special 301 to persuade developing countries to comply with TRIPs standards as quickly as possible]. Due to continued threats of retaliation under Special 301, Brazil ultimately agreed to immediate implementation of TRIPs standards without regard to the transition period it was allowed as a developing country.").

171 *See also* Buscaglia & Long, *supra* note 16 (observing that the pirate pharmaceutical industry in Argentina was estimated to be worth $4.6 billion).

172 CORREA, *supra* note 5, at 210.

173 For a description of another area of radical transformations in Argentina during the 1990's, see Hernan L. Bentolila, *Privatization & Deregulation of the Argentine Telephone Service 1990-2000;* 6 NAFTA: L. & BUS. REV. AM. 557 (2000).

relations between both countries were at the closest level they had ever been. Argentina was "[o]ne of its [United States] closest allies in South America . . ."[174] Throughout this process the United States was able to count on the full political support of the Argentine Executive, which utilized all of its constitutional powers as well as its influence over the Argentine Congress. When analyzing the Argentine case as a guide for future strategies for extending pharmaceutical IP protection in other countries, the above political consideration should be kept in mind. The United States might also employ TRIPs Article 67 in future cases and collaborate with local agencies such as the INPI.

Few countries in the world underwent such radical transformations in pharmaceutical intellectual property protection as Argentina did during the 1990´s. The Argentine foreign policy shifted towards embracing United States´ standards of competition and an open market economy. At the same time issues such as pharmaceutical intellectual property protection were successfully placed by the United States at the center of the negotiation table. Unilateral pressure is still an important part of United States trade policy even after the DSU under WTO.[175] The United States continues to apply unilateral trade pressure by keeping Argentina on the USTR's "priority watch list," which may lead to additional trade sanctions. It has been said that even after TRIPs and its DSU, "merely carrying a big stick is, in many cases, as effective a means to having one's way as actually using the stick."[176] In the case of Argentina, both threat and actual use of the stick were employed by the United States. However, although in this case a respectable outcome for the United States' interests was achieved, the risks and potential costs of employing a "big stick" policy should at the very least provoke additional consideration in similar cases over remaining "transitional period" years in developing and least developed countries regarding the protection of pharmaceutical intellectual property rights.[177]

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174 *US May Hike Tariffs on Argentine Imports*; L.A. TIMES, Jan. 16, 1997, at D3.

175 *See* Graciela Guadalupe, *Patentes: EE.UU. Sancionó a la Argentina,* LA NACIÓN LINE, Jan. 15, 1997.

176 Choudhury, *supra* note 71.

177 It should be noted that "the WTO Council responsible for intellectual property, on June 27,2002, approved a decision extending until 2016 the transition period during which least-developed countries (LDCs) do not have to provide patent protection for pharmaceuticals." Press Release, World Trade Organization, Council approves LDC decision with additional waiver (June 28, 2002), *available at* http://www.wto.org/english/news_e/pres02_e/pr301_e.htm (last visited Mar. 14, 2003) (on file with the Yale J.L. & Tech.). A waiver also exempts least developed countries from having to give exclusive marketing rights. *Id.*