A QUESTIONABLE VICTORY FOR COERCED ARGENTINE PHARMACEUTICAL PATENT LEGISLATION

WENDY S. VICENTE*

1. INTRODUCTION

Argentina recently passed legislation strengthening its patent laws, capitulating to intense pressure from the U.S. drug industry that has lasted for over a decade. The pharmaceutical dispute between the United States and Argentina is not over, however. The United States imposed sanctions against Argentina on $260 million of its U.S. exports in early 1997 to protest alleged inadequacies in the new patent law.

President Clinton’s October 1997 visit to Argentina failed to resolve the ongoing conflict. Clinton argued that his 1994 proposal for the Free Trade Area of the Americas (“FTAA”) should be adopted by 2005. Argentina made it clear that the FTAA will be negotiated without side-stepping the sub-regional trading bloc, Common Market of the South (“MERCOSUR”), which loosely joined the markets of Argentina, Brazil, Uruguay,


1 See The Path to Patent Law as Taken by Argentina, MARKETLETTER, Jan. 29, 1996, available in 1996 WL 8314654.

2 See Menem Rejects U.S. Request to Reform Law on Medicine Patents, XINHUA NEWS AGENCY, Mar. 26, 1997, available in 1997 WL 3752343 (statement of Jorge Campbell, Argentina’s Secretary of International Economic Relations) (“The legislation on medicine patents will be ‘a permanent issue’ for discussion on the agenda of both countries.”).


5 See id.
and Paraguay in 1995 with surprising success. The United States seeks to increase trade with Latin America to make up for lost time during which the European Union became MERCOSUR's main trading partner. The United States is still the leading foreign investor in Argentina, having already invested $8 billion and promising about $5 billion over the next five years. The growing market for pharmaceuticals and health care products makes the drug industry an attractive investment, especially if patent laws prevent copiers from competing with brand-name, patented drugs. The U.S. pharmaceutical industry typically aims trade complaints at countries with developing industries, like Argentina, that compete successfully against U.S. manufacturers in their domestic markets. Argentina's health care market, valued at $3.7 billion, grew 80.2% from 1991 to 1995. The potential health care markets in developing countries in Latin America and Asia may dwarf the existing pharmaceutical markets in the developed world.

President Menem of Argentina proved to be Clinton's strongest ally during his tour of Latin America. Argentina,

---

8 See Argentina-U.S.: Clinton Reaffirms Alliance with Argentina, INTER PRESS SERVICE, Oct. 16, 1997, available in 1997 WL 13257172 (emphasizing that Argentina prefers to negotiate for FTAA within MERCOSUR and that the FTAA will not serve as replacement for the subregional bloc).
11 See Latin America: Brazil is Booming, Argentina and the Rest Lag Behind, MED AD NEWS, May 1, 1997, at 4. But see Robert M. Sherwood, *The TRIPS Agreement: Implications for Developing Countries*, 37 IDEA 491, 501 (1997) (noting that the total pharmaceutical industry accounts for less than 1.5% of the nation's economy and predicting a barely discernible macro-economic impact if the prices of drugs increase).
democratic since 1983, performed an about-face in the late 1980s and began to support the U.S. position on many international issues. For intellectual property, however, Argentina has continued to carve out an independent position. Since 1985, the U.S. Trade Representative, through the efforts of a strong drug industry lobby lead by the Pharmaceutical Research and Manufacturers Association ("PhRMA"), has tried to overcome Argentine resistance to a strong intellectual property regime and present Argentina to the rest of Latin America as an example of the economic cost of not respecting strong patent rights.

Intellectual property issues have grown in prominence over the last ten years, particularly for trade policy. Governments exercise an exceptional degree of scrutiny and control over patents for pharmaceuticals because of their social relevance to national health. In both the United States and Argentina, powerful drug lobbies contribute to a highly politicized battle over Argentina's self-determination to develop a patent regime that adequately meets its need for progress and stability. Political, social, and judicial resistance to a strong intellectual property regime remain strong despite the new legislation. The U.S. drug

14 See Alejandro M. Garro, Nine Years of Transition to Democracy in Argentina: Partial Failure or Qualified Success?, 31 COLUM. J. TRANSNAT'L L. 1, 7 (1993) (chronicling the Argentine transition to democracy).
15 Valente, supra note 7; See also CARLOS ESCUDÉ, FOREIGN POLICY THEORY IN MENEM'S ARGENTINA 1-2 (1997) (describing the hostility that used to characterize the relationship between Argentina and the United States).
16 See Fidler, supra note 6, at 1.
17 See generally The Path to Patent Law as Taken by Argentina, supra note 1.
19 See NATIONAL RESEARCH COUNCIL, GLOBAL DIMENSIONS OF INTELLECTUAL PROPERTY RIGHTS IN SCIENCE AND TECHNOLOGY 65 (Mitchel B. Wallerstein et al. eds., 1993) [hereinafter GLOBAL DIMENSIONS OF INTELLECTUAL PROPERTY RIGHTS] (explaining that the globalization of markets and the increase of high-technology products in international trade have brought attention to intellectual property rights).
21 In Argentina, "an assertive campaign against patent protection for
industry should engage in non-lobbying activities that will inspire respect for strong patent protection from within the country while exploring other alternatives to protect its business interests in Argentina.

This Comment explores Argentina's resistance to strong intellectual property protection. Section 2 reviews the history and current state of Argentina's patent regime, including a discussion of judicial and enforcement problems, compliance with international agreements, and the conflict that U.S. pressure has generated between Argentina's executive and legislative branches. Section 3 discusses, in general terms, the factors that determine what patent regime a nation will adopt and proposes an equation to broadly illustrate how a valuation of these factors determines a particular regime. Section 4 presents both the case for and against a strong intellectual property regime in Argentina, concluding with the stronger case of recognizing Argentina's sovereignty to determine its own patent policies. Even if a stronger regime is theoretically better for Argentina in the long term, the current coercive activity of the U.S. drug industry to enact Argentine legislation results in democratic instability and its effectiveness is severely limited by Argentine resistance. Section 5 proposes non-patent alternatives to protect pharmaceutical patent rights and foster more respect for such rights.

2. ARGENTINA'S LEGAL PATENT SYSTEM

2.1. Legislation

2.1.1. History

Argentina's 1864 patent law excluded pharmaceutical

pharmaceuticals has produced a predominantly negative impression of intellectual property in much of the population.” Robert M. Sherwood, Intellectual Property Systems and Investment Stimulation: The Rating of Systems in Eighteen Developing Countries, 37 IDEA 261, 290 (1997); see also Argentina Won't Alter Patent Law Despite U.S. Trade Measure, Dow Jones News Service, Apr. 15, 1997, at 23:55:00 (noting the Argentine Foreign Minister's refusal to change the controversial patent law); cf. Conferences, 52 PAT. TRADEMARK & COPYRIGHT J. (BNA) 392, 393 (1996) (discussing a “fundamental cultural difference”—Latin Americans do not believe that a creation of the mind should be linked to money).
compositions from patent protection. Drug prices remained low for over a century because Argentina recognized process, not product, patent protection. The U.S. drug industry found that the difficulty in proving process infringement made these patents ineffective. In 1985, the U.S. Trade Representative encouraged Argentina to amend alleged inadequacies of the 1864 patent law by placing Argentina on either the Special 301 "watch list" or the "priority watch list" from 1989 through 1993. Menem warded off trade retaliation under this special watch status by promising to bring patentability of pharmaceutical products in line with modern legislation.

Initial bills in the Argentine Congress offered hope for greater protection, but progress on a patent bill was tabled in 1993 until the Uruguay Round of the General Agreement on Tariffs and Trade negotiations concluded. Argentina ratified the World Trade Organization (formerly "GATT") and Trade-Related Intellectual Property Rights ("TRIPS") in January 1995. TRIPS

---


23 If only a process is protected, an imitator may legally devise a similar but distinct way to make and market the same product. See Mahesh Uniyal, GATT: Drug Firms Fear U.S.-Based TNC's Will Swamp Global Markets, INTER PRESS SERVICE, Sept. 9, 1993, available in 1993 WL 2535843.

24 See President Pharm. Research and Mfr. of Am. before the Senate Comm. on Gov't Affairs, July 27, 1994, at 312 (statement of Gerald J. Mossinghoff, president of PhRMA) [hereinafter Mossinghoff Testimony].


Under “Super 301” from the Omnibus Trade and Competitiveness Act of 1988, the U.S. Trade Representative may investigate and retaliate against countries who engage in "unfair competition." "Priority Foreign Countries" have the most "onerous or egregious" practices that deny intellectual protection or equitable market access. Retaliation usually takes the form of suspending trade benefits, imposing duties or other import restrictions and entering binding agreements designed to stop the offending practices. See Theresa Beeby Lewis, Patent Protection for the Pharmaceutical Industry: A Survey of the Patent Laws of Various Countries, 30 INT'L LAW. 835, 852-53 (1996).

26 See id.

27 See The Path to Patent Law as Taken by Argentina, supra note 1; see generally Agreement on Trade-Related Aspects of Intellectual Property Rights,
lived up to its expected ability to achieve a high threshold of intellectual property protection because it was the first international intellectual property negotiation within a specific trade context, namely the GATT. TRIPS effectively links preferential trade treatment with patent protection. The threat of costly trade sanctions deters nations from deviating from TRIPS standards. Developing nations, although submitting to a framework of very high protection, negotiated general wording into Article 30, which allows exceptions to conferred patent rights.

2.1.2. Current Legislation

Argentina's Congress undertook the task of passing a bill in 1995 that would conform to its broad interpretation of exceptions under Article 30 of TRIPS and respond to the demands of its strong pharmaceutical industry. In April of 1995, under intense pressure from the United States, Menem vetoed provisions of this drug-patent legislation that allegedly conflicted with a U.S.-Argentina trade accord. Menem then issued a "Regulatory Decree" which would protect pharmaceutical patents as of January 1, 1996, and give immediate retroactive pipeline

See generally The Path to Patent Law as Taken by Argentina, supra note 1 (noting PhRMA's disgust with the "watered down" bill).

32 See Calvin Sims, Argentine President Vetoes Patent Measure, N.Y. TIMES, Apr. 19, 1995, at D5. The provisions that supposedly conflicted with the trade accord included both a requirement that the patent holder produce the product in Argentina and an eight-year grace period without royalties for using others' inventions. See id. But see Correa, supra note 29, at 331, 334 (describing an allowable grace period of ten years for new patentable areas such as pharmaceuticals in Argentina that were not previously protected and an interpretation of TRIPS that would allow granting compulsory licenses for lack of importation if such a license was granted on equal footing with a license for lack of domestic production).
When the Senate returned to patent legislation in May 1995, it immediately overturned ten of the sixteen key provisions of Menem’s Presidential Decree. The Argentine House concurred with the Senate’s vote and passed Law 24,481. Menem then submitted a “corrective law” in June 1995 which reduced the transition period for implementing pharmaceutical protection from ten to five years. Congress responded with a law in March 1996 implementing Menem’s five-year transition period and establishing a framework for compulsory licensing. Menem signed a decree on March 22, 1996, enacting this legislation. On December 18, 1996, Congress passed a surprising new non-patent provision which permits an innovator’s competitors to use the innovator’s test data when the competitors seek marketing approval. The U.S. drug industry charged that this additional “data confidentiality” legislation “was a thinly disguised attempt to invalidate the pharmaceutical patent protection which had just recently been approved.”

---

33 See The Path to Patent Law as Taken by Argentina, supra note 1.

Pipeline protection requires nations with newly-enacted patent laws to recognize products already patented in other nations for the remainder of their patent terms, even though they are not “new,” the usual condition for patentability. See Michael L. Doane, TRIPS and International Intellectual Property Protection in an Age of Advancing Technology, 9 AM. U. J. INT’L L. & POL’Y 465, 478-79 (1994) (discussing the particular effect of pipeline protection on the pharmaceutical industry).

34 See The Path to Patent Law as Taken by Argentina, supra note 1.

35 See id.


A compulsory license requires a patent-holder to grant non-exclusive licenses to competitors or other interested persons in exchange for a reasonable licensing fee. See Weissman, supra note 9, at 1073. Under the 1996 legislation, licenses must be granted when the patent is not exploited in Argentina. The production, distribution, and commercialization of products must satisfy the demands of the national market. See Laurinda L. Hicks & James R. Holbein, Convergence of National Intellectual Property Norms in International Trading Agreements, 12 AM. U. J. INT’L L. & POL’Y 769, 813 (1997).

37 See Lewis, supra note 25, at 858.


39 Tancer & Tancer, supra note 25.
2.1.3. Sanctions

The United States responded with trade sanctions on $260 million of Argentina's exports, revoking half of its favorable tariff treatment under the Generalized System of Preferences pursuant to Section 301 of the 1988 Trade Act. 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. Currently, the U.S. Trade Representative is considering revoking the rest of Argentina's preferential tariff treatment. Argentina has responded by threatening to push back the transition period for TRIPS compliance by five more years to 2005.

2.1.4. Comparative Analysis of the Strength of Argentina's Patent Regime

Robert Sherwood, an international business advisor for intellectual property issues, reviewed intellectual property regimes using a point scale to assess a regime's effectiveness in stimulating private investment. Argentina, as of April 1996, received thirty-nine of one hundred possible points. Sherwood found its patent regime particularly weak, subtracting thirteen of seventeen possible points; he believes that the 1996 patent law clashes with the TRIPS Agreement and creates complexities that...
will likely require litigation before it is workable.\textsuperscript{46}

Despite Sherwood's criticism, he acknowledges that the 1996 bill improves protection in many respects. Patent protection extends to a broader range of subject matter, including utility models.\textsuperscript{47} Also, protection is for a full twenty-year term.\textsuperscript{48} Although compulsory licenses for dependent patents are given almost readily, this provision may actually encourage innovation.\textsuperscript{49} Provisions allowing compulsory licensing with many novel features, however, diminish the overall value of a patent. For example, if the price of a patented product is higher than an unpatented equivalent, use of the patented invention can be granted to others without the approval of the patent holder.\textsuperscript{50}

\subsection{2.2. Compliance with International Agreements}

\subsubsection{2.2.1. TRIPS Compliance}

Negotiating international agreements is less coercive than applying unilateral economic sanctions to achieve extra-territorial legislative goals.\textsuperscript{51} WTO membership is a carrot that eases the growing pains of stronger patent regimes in developing countries.\textsuperscript{52} Argentina was in fact "one of the first developing countries to promote international agreements as a traditional tool of economic policy.\textsuperscript{53}"

\begin{footnotesize}
\begin{itemize}
\item \textsuperscript{46} See id. at 289 (discussing the possibility of a new matrix for litigation).
\item \textsuperscript{47} See id.
\item \textsuperscript{48} See id.
\item \textsuperscript{49} See id. Dependent patents are granted to improvements of existing patented inventions. Producing the invention of the dependent patent will generally infringe the original patent unless the original patent grants a license. Thus, the compulsory license encourages the development of improvements by third-party inventors who would otherwise be unable to practice their invention. Compulsory licenses for dependent patents make sense especially when the original patent contributes very little value as compared to the improvement. They encourage inventive rivalry, productive licensing agreement, and, above all, practice of the dependent invention. See Gianna Julian-Arnold, \textit{International Compulsory Licensing: The Rationales and the Reality}, 33 IDEA, 349, 364-67 (1993).
\item \textsuperscript{50} See Sherwood, \textit{supra} note 21, at 289.
\item \textsuperscript{51} Bilateral agreements are more likely to cause resentment, especially when one country tries to dictate another country's statutory regime. Multilateral agreements, however, are subject to deadlock and other collective action problems. See Lewis, \textit{supra} note 25, at 853-54.
\item \textsuperscript{52} WTO member nations enjoy a relatively liberal and organized trade regime, a means of dispute resolution, and the possibility of most favored
\end{itemize}
\end{footnotesize}
nations to codify . . . TRIPS.”

Pablo Challu, the executive director of CILFA, the Argentine Association of Pharmaceutical Laboratories, asserts that Argentina has gone above and beyond what TRIPS requires. CILFA maintains that Argentina has already reduced the permitted ten-year transition period to five years in a show of good will. It further argues that TRIPS permits parallel imports, and authorizes compulsory licenses if “the proposed user has made efforts to obtain authorization of the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time.”

Argentina permits a generic manufacturer to rely on safety tests conducted by another drug company to obtain public health approval. “Under U.S. law, . . . only the company that conducted the safety tests is permitted to use the test data” for a nation trading status, among other benefits. See generally Agreement Establishing the Multilateral Trade Organization, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 31; 33 I.L.M. 13 (1994).


See Argentina Takes Issue with PhRMA over Sanctions Threat, PHARMACEUTICAL BUS. NEWS, Mar. 13, 1996, at 14 [hereinafter PhRMA].

Parallel imports, commonly known as “gray market goods,” are lawfully made products not intended to be distributed in the exporting country. Under the doctrine of exhaustion of rights, once the right holder produces the protected good and it enters into the stream of commerce, the right holder has exhausted the right and is no longer able to prevent further distribution of the good. See Hicks & Holbein, supra note 36, at 810-11.

Hicks & Holbein imply that TRIPS forbids member nations to allow exhaustion of rights. Cf. id. at 811 (“[F]or the purpose of dispute settlement under the agreement, member nations are not to invoke provisions to address the issue of exhaustion of rights.”). For a different view, see Correa, supra note 29, at 330 (“Article 6 of the Agreement, which implicitly allows parties to provide for the exhaustion of intellectual property rights, subject to the national and most-favoured-nation treatment.”).

PhRMA, supra note 54, at 14. CILFA did not address concerns about data confidentiality protection in this pre-December 1996 statement. See id.

See An Unhealthy Trade Policy, supra note 3, at 6.
The recent sanctions are aimed at this lack of protection for safety data, which is required by TRIPS under a strict interpretation of unfair commercial use. Much of the developing world does not read TRIPS as strictly as does the U.S. drug industry, and questions the assumption of TRIPS data confidentiality protections. TRIPS Article 39, paragraph 3 states that data shall be protected against unfair commercial use. Argentine Articles 4 and 11 of Law 24,766 protect test data only in cases of dishonest commercial practices, which are narrowly defined. No protection is granted to data which becomes public following publication of any protected data in scientific and academic circles.

Challu believes the United States, not Argentina, violates international treaties. According to Challu, the unilateral trade sanctions aimed at meeting U.S. Trade Representative demands, not TRIPS demands, clearly reek of “economic imperialism.” He believes that this conflict would be resolved in an official discussion at the WTO if there were any merit to the U.S. accusations.

2.2.2. Regional Trade Agreements

TRIPS is already seen as a victory for the intellectual property interests of developed countries. The United States, however, pushes to achieve even higher levels of protection for especially troubling countries like Argentina. The United States successfully negotiated higher-than-TRIPS levels of patent protection with Canada and Mexico under NAFTA.

MERCOSUR, unlike NAFTA, does not offer region-wide

---

58 Id.
59 See id.
60 See id.
61 See Sherwood, supra note 21, at 289.
62 See id.
63 See id.
65 Id.
66 See id.
67 See An Unhealthy Trade Policy, supra note 3, at 6 (noting that TRIPS requires Argentina to adopt “U.S.-style patent laws”).
68 See Weissman, supra note 9, at 1077.
standards of intellectual property protection. MERCOSUR nations continue to wrestle with intellectual property standards but have yet to resolve differences. For example, Argentina does not provide for pipeline protection under its new patent law. This issue sparked a hot trade debate with Brazil, which provided for pipeline protection only after succumbing to the threat of U.S. sanctions. All MERCOSUR countries are TRIPS signatories and offer at least this level of protection, assuming TRIPS compliance. Developed nations are pushing NAFTA as a model for MERCOSUR to implement stronger patent protection. Regional agreements can achieve stronger protection at a faster pace than multilateral treaties, but MERCOSUR nations have thus far rejected alleged advantages of integrating their patent protection standards. MERCOSUR, unlike NAFTA, has no developed member nation which insists on a high level of intellectual property protection for all member nations. The United States plans to use the FTAA to foster greater-than-TRIPS levels of intellectual property protection with MERCOSUR and other Latin American nations.

2.3. Administrative and Enforcement Problems

The specifics of implementing patent protection began awkwardly in Argentina, but will improve if the political climate warms to stronger protection. Application processing delays in the 1992-renovated patent and trademark office routinely frustrate prospective patentees. A new computer system and newly-trained patent examiners yield Argentina seven of ten administrative “points” under Robert Sherwood’s rating

69 See Tancer & Tancer, supra note 25.
70 See Hicks & Holbein, supra note 36, at 812.
71 See id.
72 See id.
74 See Conferences, supra note 21, at 393; Philip Peters, Opinion, Why Latin America Matters to California, SAN DIEGO UNION-TRIBUNE, Sept. 26, 1997 at B5, B9 (“The incentives will change dramatically when Washington returns to trade talks, and Argentina will have to meet high standards of intellectual property protection in order to join the FTAA.”).
75 See Sherwood, supra note 21, at 288.
Once a patent is granted, there is no guarantee that the Argentine government will grant relief against infringers even under the new patent laws. Some estimates put the "piracy" rate of drugs at about twenty-five percent, but until the complexities of the new laws are ironed out, the definition of "piracy" itself is open to administrative interpretation. Argentina's drug copy industry operates legally until product protection begins in 2000.

Enforcement itself brings no guarantee that piracy will end. Despite raids, the Chinese piracy rate remained above 95% in 1996. Without prison sentences, fines, and the destruction of imitation products, piracy is interrupted, not deterred. Comprehensive patent protection absolutely depends on efficient administration and judicial cooperation.

2.4. Judicial Antagonism Toward Patent Protection

Legislation requires a competent and willing judiciary if it is to be meaningfully enforced. Judges wield exceptional authority in patent cases because they apply a relatively simple statutory law to a set of extraordinarily complex factual circumstances. Robert Sherwood gives Argentina only four of twenty-five possible points for judicial enforcement of intellectual property.

---

76 See id.

77 See Health Care in the Developing World, supra note 12. "Piracy" itself is a term adopted by PhRMA to frame intellectual property rights as absolute rights in a moral drama. See Weissman, supra note 9, at 1086-89.

78 See Invention Patents and Utility Models Act, Law No. 24, 481, VIII, reporter 100, in Argentine Patent Act, supra note 22, at Argentina-9.19 ("Until such date none of the articles contained in this Act laying down the patentability of inventions of pharmaceuticals shall be in effect.").


80 See Piracy-Related Trade, supra note 79, at 1 (statement of Mark Traphagen, vice president and counsel of Software Publishers Association).


82 See Sherwood, supra note 21, at 288.
He finds that judges are not held in high regard despite strong educational backgrounds. One Gallup Poll found, for example, that only thirteen percent of the Argentine public has confidence in the administration of justice.

Although corruption is widely suspected, the issue is getting increasing media attention and corruption cases decreased dramatically following privatization of many state enterprises after 1989. While the court routinely hears trademark cases, patent litigation is almost unknown. Judges are unfamiliar with patent law and grant only nominal statutory penalties for patent infringement, if any at all.

An Argentine criminal appellate court recently shocked the intellectual property community when it overturned a 1995 infringement decision in favor of Autodesk, a U.S. business software company. The court decided that computer programs are not protected by Argentine copyright law, despite a 1994 presidential decree that data bases and computer programs were protected by copyright. The Supreme Court recently affirmed, ruling that it is not illegal to copy computer programs.

Argentine courts have long disfavored recognizing strong patent rights. The Supreme Court of Argentina ruled that, in the unusual case where only one chemical process may produce a specific pharmaceutical product, the patent for such a process was tantamount to a prohibited product patent and thus unenforceable. Because the plaintiff carries the burden to prove that the defendant used the patented process, the copiers nearly

---

83 See id.
85 See Sherwood, supra note 21, at 288.
86 See Argentina: Investment Climate Statement for 1997, supra note 41.
87 See Sherwood, supra note 21, at 288.
88 See id.
89 See Abraham, supra note 79, at 460, 460 n.ii; Piracy Related Trade, supra note 79, at 1.
90 See Abraham, supra note 79, at 460 n.ii.
always win. Argentine courts, however, do not generally assert positions contrary to those of a strong executive branch. The Supreme Court commonly sides with the executive in any case in which the administration has a high stake in the outcome. Given Menem’s inclination to accede to U.S. demands for higher intellectual property protection, the courts may look more favorably upon judicial enforcement of the 1996 law. This deference to political pressure, however, affects the credibility of the entire judiciary.

2.5. Executive and Legislative Conflict over Patent Legislation

President Menem exemplifies the strong executive who rules a young democracy that succeeds a dictatorship. Argentina’s dark period of military rule ended in 1983, when Raul Alfonsin was elected. Carlos Menem stepped into power in 1989, facing grave hyperinflation. Although Menem has largely turned the economy around, Professor Alejandro Garro notes that Menem has sidestepped Congress and ruled the country by presidential decree to force his economic program upon Argentina.

Argentina has an under-developed sense of the separation of powers which inhere in the ideal of democratic decentralization.

93 See id. TRIPS Art. 38, however, purports to reverse the burden of proof in civil litigation involving process patents. See Correa, supra note 29, at 333. Correa describes the difficulty of coming to a compromise between developed and developing nations for this issue. See id. He believes that “[t]he established reversal should only operate if and when the process invention is clearly and completely described, since this is a condition for any potential infringer to know to what extent his acts are legitimate or not.” Id.

94 See Garro, supra note 14, at 76.

95 See id. at 74, 76 (noting that President Menem increased the membership of the Supreme Court from five to nine justices for purely political reasons).

96 See id. at 76-77.

97 See Garro, supra note 14, at 2.

98 See id. at 7 (“From 1976 to 1983, Argentina lived one of the darkest periods of its history, when a military regime became an agent of terror by conducting a ‘dirty war’ resulting in the disappearance, torture, and murder of thousands of people.”).

99 See id. at 8.

100 See id.
Menem freely issues "presidential decrees" when he disagrees with legislation from Congress, as he did with the 1995 patent legislation. These decrees empower him to "correct" the legislation to an unascertainable degree.

The United States treads on thin democratic ice when it encourages Menem to disrespect the Argentine Congress and force stronger intellectual property protection upon Argentina. The U.S. government, Menem's administration, and foreign drug companies are in a "tug-of-war" with the Argentine Congress and domestic drug companies. Menem's chief of staff blames Congress for bringing on U.S. sanctions: "It was parliament, not government, that passed this law." Government does not, in his eyes, include Congress. The Argentine Congress does exert some power to legislate, but this power is not respected by either Menem's administration or the U.S. government, especially for patent legislation.

Garro believes it is very important to encourage a self-restrained president in Argentina to avoid the abuses of a system without checks and balances on power. The United States should respect Argentina's sovereignty to decide its patent laws so as to not force Menem to continue to encroach upon the independent powers of Congress and the judiciary.

3. Fitting National Sovereignty into the Intellectual Property Equation

3.1. How Much Intellectual Property Protection is Enough?

The public benefits from a system of patents which encourages and rewards innovation. A patent regime must balance this benefit with the detriment to the public of

101 See id. at 85-87. ("Argentine federalism . . . was built upon a somewhat artificial redistribution of powers of a previously unitary State among its newly created provinces.").

102 See, e.g., Garro, supra note 14, at 8, 83 (discussing the transformation of the President's regulatory power into legislative power by Argentine decrees).

103 See Lewis, supra note 25, at 857.

104 See Paula L. Green, Range of Argentine Exports Threatened; Affected Goods Should Be Known by March, J. COM., Jan. 17, 1997, at 3A.

105 See Garro, supra note 14, at 102.
monopolistic pricing. The optimal length of patent life is a function of market demand and technological factors. Thus, national interests, not merely principles, define optimal patent protection. Nation states pragmatically change their patent laws to accommodate interests which vary from country to country. Governments grant statutory patent rights designed to maximize inventive activity for the public, not natural patent rights aimed at personally rewarding inventors. The balance of the equation measuring the benefits of promoting inventive activity versus the detriment of a monopoly should be allowed to shift to recognize unique valuation of many variables.

The question of how much protection is enough, of course, depends on who asks the question. Sherwood's point system requires a score of at least 50 to 60 out of 100 to adequately promote lower levels of technological activity. A score of about 60 to 70 will probably stimulate higher levels of technological activity. Argentina's score of 39 appears dismal under this system. Sherwood gives TRIPS a '55' rating and NAFTA a '68'.

Developed countries can liberally grant long and various monopoly patent powers because consumers expect innovation

---


108 See id. at 56.

109 See id.

110 See, e.g., “Royalties Not Monopolies” says ALIFAR, MARKETLETTER, June 14, 1993, *available in* 1993 WL 2827949 (arguing for a system of automatic royalty collection rather than patent monopolies to prevent excessively rewarding innovators at the expense of other national priorities).

111 See id.

112 See Sherwood, supra note 21, at 353.

113 See id. at 353.

114 See id. at 362, 366.
and are more likely to be able to pay for it. For example, A broadly represents public benefits, traditionally the promotion of inventive activity, the development and commercial use of the inventive activity, and disclosure to the public. Where M is the price of granting a monopoly:

\[ A > M \]

The price of a monopoly may be substantial, however, even for industrialized nations that produce a lot of innovation. President Clinton’s campaign to reform national health care in the early 1990s was driven in part by excessive prices of the monopolistic system. Jose Carlos Magalhaes of ALANAC, the Brazilian national pharmaceutical association, says that the United States “is now addressing the realities of monopolistic patents which result in high drug prices and high health care costs, and they want to impose the same system on Third World countries.” By charging monopolistic prices to less developed nations, U.S. companies can hope to recoup some of the losses they experience in their own price-dependent, patent-monopolized market. In effect, poorer countries subsidize the burden of protecting the intellectual property of wealthier countries. Carlos Correa, an international intellectual property

\[115\] Americans “demand and receive the most advanced healthcare in the world.” Mossinghoff notes that most products are cheaper in developing or newly industrialized countries than in the United States. See Mossinghoff Testimony, supra note 24.


\[117\] Strictly speaking, a patent does not confer a monopoly. It confers only the right to exclude the public from practicing the patented invention during the patent term.

\[118\] “Royalties Not Monopolies” Says ALIFAR, supra note 110.

\[119\] See id.

\[120\] The TRIPS agreement is expected to bring in $5 billion more to American pharmaceutical companies alone. See Intellectual Property... Is Theft, ECONOMIST, Jan. 22, 1994, at 72.

\[121\] Carlos Correa accuses the U.S. drug industry of exporting “a system that has failed in its own country to ensure access to medicines at reasonable prices for all Americans.” Patents: Private Rights and Public Interests, MARKETLETTER, Nov. 2, 1992, available in 1992 WL 2794546.
expert from the University of Buenos Aires, urges the United States to refrain from exporting its patent system to countries where the average income is only a fraction of the average U.S. income.122

The variables M and A reflect shifting valuation preferences. The equation for maximal intellectual property protection in developing nations thus may have a very different balance than what is seen above for developed nations. A, the public benefits, lose importance when a nation produces little innovation itself. M, the price of the monopoly, becomes very politically and economically costly when it threatens a strong local copy-industry. Drugs may not even sell at monopoly prices if most people cannot afford them. A nation may choose to forego a pharmaceutical patent policy altogether and adopt a policy of disseminating a core group of the most essential drugs at low prices.123

Different variables enter the equation for developing countries who wish to adjust their intellectual property laws to maximize direct foreign investment, here represented as B. Developing nations may also be concerned about variable C, pleasing a coercive nation. New legal institutions themselves cost a considerable amount to create and maintain, here represented as variable D.124 Thus, when a strong patent regime is disfavored:

\[ A + B + C < M + D \]

The variables on the left side of the equation represent the benefits to a developing nation of a strong intellectual property regime. The variables on the right side reflect the cost of such a regime. Patent legislation reflects the inclusion and valuation of various factors in this equation. In Argentina, where President Menem highly values variable C, pleasing the United States, the balance tips toward granting more patent protection when Menem can influence legislation.125 Congress, however, is more

---

122 See id.
123 See Weissman, supra note 9, at 1121.
125 See, e.g., Nathaniel C. Nash, Gore Sees Privatization of Global Data
directly under the political influence of local interests who have the most to lose under strong patent protection.  

Pablo Challu of the Argentine drug industry proposes a system of what he calls "automatic" licenses, which provide multinational pharmaceutical companies with the same amount of money that they could obtain from monopolistic patents. This respects the right to provide an incentive to innovate, while at the same time respects the rights of Latin American countries to develop their national industries, the rights of their citizens to consume affordable medication, and additionally allows the region's governments to establish health care systems.

The influence and valuation of variable C, foreign coercion, skews the intellectual property equation toward granting more patent protection than a developing nation would choose to do by itself. Section 3.2. discusses the positive value of creating a system of uniform, international, intellectual property protection. The United States and other developed nations may have legitimate reasons to coerce Argentina into passing laws that it would not otherwise pass. Section 3.3. explores the independence that Argentina has demonstrated in the face of strong coercion.

3.2. The Case for Strong Intellectual Property Protection in Argentina

3.2.1. Foreign Investment

U.S. coercion to upgrade foreign intellectual property protection paternalistically promises to improve foreign investment prospects. Argentina may in fact be losing foreign
investment because of its low level of patent protection. Its pharmaceutical market dropped 2% in 1995 when Brazil adopted a stronger intellectual property law and dominated the Latin American pharmaceutical market.\textsuperscript{130} A questionnaire by economist Edwin Mansfield studied the responses of ninety-four U.S. firms in six manufacturing industries. It indicated that intellectual property rights could be an important factor in those firms' investment decisions, especially in high-technology sectors.\textsuperscript{131}

### 3.2.2. Pharmaceutical Availability

Developed nations also suggest that patented medicines will become more widely available when patent protection increases for pharmaceuticals.\textsuperscript{132} However, developing countries often argue that they deserve to treat health knowledge as part of the public domain for the benefit of all.\textsuperscript{133} The U.S. drug industry rejects giving away technological rights as a development tool. Rather, it finds that the social value of pharmaceuticals presents an especially strong case in favor of patent protection.\textsuperscript{134} Because drugs are so expensive to produce, they will not be produced at all if no means exist to recoup development costs through a tariff and non-tariff barriers and tax concessions. In April 1991 Argentina launched a successful attempt to curb hyperinflation, restore fiscal balance, and stabilize prices. See Economic Developments Outside the OECD, OECD ECON. OUTLOOK, Dec. 1991, at 60.

\textsuperscript{130} See Latin America: Brazil is Booming, Argentina and the Rest Lag Behind, supra note 11.


\textsuperscript{132} See Drug Makers Seek Action on Argentina, CHEMICAL MARKET REP., Apr. 28, 1997, at 14. CAEME, the representative body of Argentina's multinational pharmaceutical industry, reports that new patented medical products account for only 1% of those sold in the country and says that stronger patent protection would increase the number of medicines available in Argentina. See Argentine Senate Group Against Patents Bill, MARKETLETTER, Jan. 10, 1994.

\textsuperscript{133} See generally Julian-Arnold, supra note 49, at 356.

\textsuperscript{134} Twelve years and $359 million dollars are required, on average, to discover and develop a new drug. See Mossinghoff Testimony, supra note 24. The pharmaceutical industry is unique in its need for incentives to undertake costly research and development activities. See Wendy W. Yang, Note, Patent Policy and Medical Procedure Patents: The Case for Statutory Exclusion From Patentability, 1 B.U. J. SCI. & TECH. L. 5, 54 n.156 (1995).
limited monopoly patent grant.\footnote{See id.}

3.2.3. Encourage Domestic Activity

In addition to increasing the availability of existing patented medicines, patent laws often encourage domestic research activity. Argentina’s relatively sophisticated domestic industry is well-poised to take advantage of stronger patent protection. For instance, Gador, a wholly Argentine-owned drug company, developed a test for Chagas’ disease, a disorder prevalent in Latin America.\footnote{See MacDonald, supra note 10, at 21.} The timing of this development coincided with legislative activity moving toward greater patent protection.\footnote{See id.} Significantly, Gador lacked funding to further the research to develop a vaccine for Chagas’.\footnote{See id.} Had a system with a potential monopoly reward been in place, arguably development of a vaccine would now be well under way.\footnote{See id.} The private sector will be increasingly responsible for contributing to the technological base as Argentina becomes increasingly privatized.\footnote{Local companies frequently lack funding to perform research in Argentina, even when the skills and motivation are present. See id.} This will strengthen the call for patent protection to protect private developments from unfair competition.

3.2.4. Eliminate Compulsory Licenses

Compulsory licenses may not reward innovation enough to make continued aggressive drug research worthwhile for developed countries, whose industries increasingly rely on the profitability of foreign drug markets.\footnote{See id. at 78 (forecasting privatization, especially in the agricultural sector).} Furthermore, compulsory licenses encourage copy-industries which play a game of perpetual catch-up and do not contribute to an original research base.\footnote{See Julian-Arnold, supra note 49, at 357; Mossinghoff, supra note 92, at 308.} Even Robert Weissman, who defends compulsory licenses, concedes that the promise of patent

\footnote{See Julian-Arnold, supra note 49, at 360.}
monopolies probably encourages some research that would not otherwise take place under a liberal compulsory license regime.\textsuperscript{143}

\section*{3.2.5. Data Confidentiality}

Data confidentiality promotes the submission of important testing data for new pharmaceuticals that is critical for public health safety.\textsuperscript{144} Where there is great incentive to defraud the public health approval agency with misleading test data, the agency should encourage full and open disclosure with the promise of protection.\textsuperscript{145} Both NAFTA and the United States Food and Drug Administration ("FDA") require a "five year hold provision" on test data.\textsuperscript{146} Although test data is outside the scope of patent protection, the expense of generating proprietary data could justify this short period of monopoly rights for its use.\textsuperscript{147}

\section*{3.2.6. Protectionism}

Economic protectionism arguably explains Argentine resistance to strong patent protection. The Argentine copy-industry does not deserve to reap the same profits as the companies who invest enormous amounts of research to develop drugs.\textsuperscript{148} Some copied drugs are even more expensive than patented equivalents.\textsuperscript{149} The Argentine drug industry in

\begin{itemize}
\item \textsuperscript{143} See Weissman, supra note 9, at 1122.
\item \textsuperscript{144} See, e.g., E. Patrick McGuire, The Underreporting of Product-Related Injuries, 5 PRODCT LIABILITY LAW AND STRATEGY 4 (1997) (finding endemic underreporting of important drug testing information to the FDA).
\item \textsuperscript{145} See id.
\item \textsuperscript{146} See Eileen McMahon, NAFTA and the Biotechnology Industry, 33 CAL. W. L. REV. 31, 46 (1996).
\item \textsuperscript{148} Drug pirates are not "Robin Hoods" – they make handsome profits. Local firms are likely to go out of business as stronger patent rules come into force. See Intellectual Property . . . Is Theft, supra note 120, at 72.
\item \textsuperscript{149} See Tancer & Tancer, supra note 25. Multinational drug companies say that Argentine imitators charge as much as 30\% more for the final product than multinational manufacturers, representing an enormous profit because they did not incur the research and development costs of the drugs. See Nash, supra note 18, at D3; see also Health Care in the Developing World, supra note 12 (citing multinational drug companies findings' that pirated products are priced

\end{itemize}
particular has proven itself more aggressive in exploiting weak patent laws than local firms in other industries.\footnote{See Edwin Mansfield, \textit{Unauthorized Use of Intellectual Property: Effects on Investment, Technology Transfer, and Innovation}, in \textit{GLOBAL DIMENSIONS OF INTELLECTUAL PROPERTY RIGHTS}, supra note 19, at 126.} Its exporting activities demonstrate that its activity is not just for the public benefit of making these products available to Argentines.\footnote{Argentine drug makers sell their products throughout South America. \textit{See} Helene Cooper, \textit{Argentina Faces Sanctions by U.S. Over Drug Patents}, WALL ST. J., Jan. 16, 1997, at A11.} As the world moves toward economic globalization, it is important to recognize the rights of national sovereignty only to the extent that national laws do not threaten free trade with selfish protectionism.\footnote{The United States, for example, values the sovereignty of its states and their ability to find diverse solutions to similar problems. The Commerce Clause, however, enables the Court to strike down protectionist state provisions which unfairly burden interstate commerce. \textit{Cf.} U.S. CONST. art. I, § 8, cl. 3. Intellectual property received generous federal treatment early on in part because it was particularly vulnerable to protectionist concerns. \textit{Cf.} U.S. CONST. art. I, § 8, cl. 8.}

3.2.7. \textit{Drug Prices Not Unreasonable}

Patent protection rarely results in unmanageably high drug prices. Ninety percent of essential drugs are not covered by U.S. patents.\footnote{\textit{See} Julian-Arnold, \textit{supra} note 49, at 361.} One study found that "drug prices in different countries tend to be set at the highest level the traffic will bear."\footnote{Gereffi, \textit{supra} note 20, at 194.} Drug prices are likely to decrease in the developing world as managed health care pressures doctors to prescribe competitive generic drugs.\footnote{IMS International predicts that the next five years will see the growth of managed health care in Latin America, particularly in Argentina and Brazil. Private health insurance schemes are most advanced in Argentina with the deregulation of Obras Sociales (mutuales) which allows more competitive choice between private health schemes. These organizations are also able to lobby for lower drug prices. \textit{See} Price Hikes Drive Latin America's Pharma Market, MARKETLETTER, June 16, 1997, available in 1997 WL 10362483.} The developed world has already observed this trend of lower drug prices.\footnote{Gerald Mossinghoff of PhRMA finds that 1990s healthcare reform has caused a dramatic slowing in drug-price increases, citing the increased use of generics. The Congressional Budget Office reports that "[d]rugs losing their}
able to pressure government and the drug industry to lower drug prices. As expensive as drugs may seem, they are in fact the most cost-effective form of health care because they keep patients out of hospitals and on the job.

Even if drug prices were too high for most, this issue should arguably be addressed by social welfare or national health policy, not by an attack on patent rights. Intellectual property rights merely guarantee that inventive pharmaceutical activity will be encouraged and any results will be disseminated to the public. Few would argue, for example, that AZT should never have been produced because it is currently too expensive for most HIV-positive patients. The drug would not exist at all but for the patent policy. The issue of access to drugs presents different policy questions which may be answered by other free market exceptions.

3.2.8. Quality Assurance

Patent rights for drugs provide the side benefit of more quality control assurance. Copied products may be of suspect quality. Drug companies will be more likely to protect their knowledge under a shroud of secrecy when they cannot receive adequate data protection to operate openly. If generic patents between 1992 and 2000 include 54 of the most popular drugs. The IMS predicts that structural changes in the health care sector will give managed care providers greater purchasing power and provide more competition and thus lower drug prices. It also predicts that the use of generics will increase from 20% to 50%. See Latin America: Brazil is Booming, Argentina and the Rest Lag Behind, supra note 11.

The IMS predicts that structural changes in the health care sector will give managed care providers greater purchasing power and provide more competition and thus lower drug prices. It also predicts that the use of generics will increase from 20% to 50%. See Latin America: Brazil is Booming, Argentina and the Rest Lag Behind, supra note 11.

157 The IMS predicts that structural changes in the health care sector will give managed care providers greater purchasing power and provide more competition and thus lower drug prices. It also predicts that the use of generics will increase from 20% to 50%. See Latin America: Brazil is Booming, Argentina and the Rest Lag Behind, supra note 11.

158 See Mossinghoff Testimony, supra note 24.

159 See generally Robert N. Swidler, Medical Innovations and Ethics: A State Government Perspective, 57 ALB. L. REV. 655, 656 (1994) (noting state’s regulatory role as a subsequent step to state’s role in promotion of public health through innovation).

160 See, e.g., Yang, supra note 134, at 34.

161 Rafael Alonso, representing the multinational companies, says that “quality control among Argentine companies is lax, which poses a potential health risk to the public.” Nash, supra note 18, at D3. Some drugs that are patented and tested by American companies are on the shelves of Argentine pharmacies even before the American manufacturer has approval to sell the drug in the United States. See id.; see also Julian-Arnold, supra note 49, at 362 (discussing the welfare and safety concerns of consumers).

162 See, e.g., Lewis, supra note 25, at 854-55 (discussing ways to limit
producers operate without important production and testing information, the potential for lower quality and even dangerous products are exacerbated. 163

3.2.9. Decreased Transaction Costs

The United States of course has more selfish reasons for wanting greater protection abroad. 164 Aside from benefiting domestic mercantile interests, harmonization of intellectual property laws decreases transaction costs. 165 Achieving patent protection in many foreign countries is administratively costly enough without the required research into how best to achieve protection in countries with unique, narrowly-tailored intellectual property laws. 166 The transaction costs associated with granting compulsory licenses may be especially high because Argentina’s compulsory licensing provisions require extensive fact-finding to determine if a license may be fairly granted under Argentina’s new controversial patent law. Further research would be needed to determine whether a compulsory licensing provision complies with TRIPS.
3.3. The Case for Allowing Argentina to Develop Its Own Patent Regime

3.3.1. Sovereignty

Argentina is entitled to design patent laws suited to its domestic interests. The expression of this national sovereignty is critical to provide a unique voice in what should be an international debate on intellectual property rights. The U.S. drug industry has aggressively silenced voices that suggested levels of patent protection below U.S. standards. For example, members of ALIFAR, the Latin American Pharmaceutical Association, were not even invited to participate on panels in the recent Intellectual Property Conference of the Americas. The trend toward increased harmonization of intellectual property rights is not the natural result of economic globalization. Rather, it is a one-sided, concerted effort of the drug industry to ignore multilateral interests and approaches for its narrow mercantile interests. Ironically, the patent right itself is an exception to the free-market principles that the industry otherwise presses on developing countries to market its


168 Pablo Challu, executive director of Argentina’s drugmakers association, CILFA, claims that this debate is not about intellectual property rights, but about “PhRMA’s interest in obtaining unlimited profits without the inconvenience of legitimate competition. They will use any tool and any government to obtain more protection for their already overly protected industry.” Argentina’s CILFA Slams U.S. Trade Sanctions, supra note 53.

169 See Weissman, supra note 9, at 1075.


171 See Argentina’s CILFA Slams U.S. Trade Sanctions, supra note 53. (discussing the enormous benefits enjoyed by the U.S. pharmaceutical industry under the current TRIPS regime).

172 See id.
products. In a further irony, the United States frustrates the democratic will of the very young democracy of Argentina and creates political instability by forcing repeated confrontations between a strong executive and Congress. Argentina contributes valuable and valid alternatives to the strict regime urged by the United States. Its provision for compulsory licenses for dependent patents, for example, is a creative way to "foster technical progress and should not be overlooked."

3.3.2. Data Confidentiality Protection

TRIPS, already a product of asymmetric negotiations favorable to the United States, does not satisfy U.S. drug industry demands for patent protection. The drug industry continues to press for stronger international agreements and interprets those agreements to exclude valid exceptions that are useful for developing countries. Test data confidentiality requirements create an exclusive right outside of usual patentable matter for the inventors. The Center for the Study of Responsive Law ("CSRL") praises Argentina's position on data confidentiality as "the one that best promotes public health

---

173 See Weissman, supra note 9, at 1069 (noting that patents are a restriction in the trade of goods).

174 See USA Urged to Withdraw Action Against Argentina, MARKET LETTER, Feb. 17, 1997, available in 1997 WL 7972509 (noting that Ralph Nader's letter to President Clinton "[a]lso notes the 'irony' that while the USA is criticized at home for failing to impose trade sanctions on countries that limit dissent, the USTR is 'seeking to impose trade sanctions in an effort to limit dissent in newly democratically-inclined Argentina'").

175 See Julian-Arnold, supra note 49, at 364 (commenting that dependent parties in general may serve to foster technical progress and should not be overlooked).

176 Carlos Correa described TRIPS as "a great victory by industrialized countries and their lobbying groups." Capdevila, supra note 106.


178 See generally Weissman, supra note 9, at 1070.

179 See McMahon, supra note 146, at 46.
interests." The CSRL criticizes U.S. sanctions as "backdoor attempts to convey private monopoly power for drugs that do not qualify for patent protection." For example, Taxol, a cancer drug, was discovered by the National Cancer Institute ("NCI") with government funding. The NCI gave exclusive rights to its test data to Bristol-Myers Squibb. Any company wishing to produce the drug must wait five years or present redundant scientific evidence that Taxol is safe and effective, even though the drug does not qualify for patent protection. Bristol-Myers Squibb expected Taxol sales to exceed $1 billion in 1997 because of its ability to shut competition out under the U.S protection. Argentina's decision not to extend protection to data confidentiality is rational in such a situation, where there is little positive social value in requiring duplicative drug testing. Rewarding non-innovators with a monopoly right does not stimulate innovation.

The Taxol case illustrates a not uncommon phenomenon of the private sector appropriating a monopoly from government-funded research. Although the private sector makes large investments in research and development, evidence suggests that private ventures tend to be lower-risk attempts at less significant therapeutic improvements.

3.3.3. Exaggerated "Piracy" Claims

Besides demanding unfairly high levels of protection, the U.S. drug industry exaggerates why these levels of protection are needed. Complaints by the U.S. pharmaceutical companies that they are losing millions of dollars to piracy are overstated,
according to one expert, because "[o]ne cannot lose what one never had."\textsuperscript{187} Many projected losses due to "piracy" come from studies funded by the drug industry itself.\textsuperscript{188} The risk of imitation inheres in business ventures with Argentina, which allows compulsory licenses.\textsuperscript{189} To reap the benefit of trade with Argentina, one must pay the price of less intellectual property protection or make the best of your foreign investment with non-patent alternatives.

3.3.4. Foreign Investment

The drug industry also overstates the importance of intellectual property rights in its foreign investment decisions. Intellectual property protection is only one factor in an investment decision. Patent protection is rarely determinative, especially for a country like Argentina that offers other trade advantages\textsuperscript{190} and something approaching TRIPS level of patent protection, beginning in 2000.\textsuperscript{191} U.S. sanctions are merely intended to sweeten the deal for the drug industry, which is already making enough money in the Argentine market to make its investment worthwhile.\textsuperscript{192}

The "modernization" theory, developed after World War II, asserts that less developed societies should emulate the models of developed nations for the growth and development of all nations.\textsuperscript{193} Developing nations have since challenged this theory,

\begin{itemize}
\item \textsuperscript{188} See Weissman, \textit{supra} note 9, at 1085 (describing pharmaceutical industry estimates that it had lost billions of dollars in sales annually).
\item \textsuperscript{189} Argentine drug companies assert that multinationals knew they were entering a market with weak protection. For over a century, only process patents were protected. Anibal Caprile, president of CILFA, says, "[w]e use a different process than the original and arrive at the same final product, and that is permitted by our laws." Caprile rejects the labels of "pirates" and "copiers." Nash, \textit{U.S. Presses Argentina on Patents, supra} note 18, at D3.
\item \textsuperscript{190} Argentina has successfully encouraged direct foreign investment in other ways, giving tax concessions and policy adjustments, and deregulating the Argentine economy and restructuring foreign external debt. \textit{See Economic Developments outside the OECD, supra} note 129, at 60.
\item \textsuperscript{191} See Argentine Patent Act, \textit{supra} note 22.
\item \textsuperscript{192} See MacDonald, \textit{supra} note 10, at 21.
\item \textsuperscript{193} See Gereffi, \textit{supra} note 20, at 3-6.
\end{itemize}
finding instead that they are relegated to dependent relationships within a very hierarchical world order.\textsuperscript{194} A patent system simply does not provide what is missing in developing countries, namely, a science and technology infrastructure.\textsuperscript{195} Stronger patent protection does not necessarily attract more foreign investment, according to one United Nations study.\textsuperscript{196} Italy, for example, lost money when it enacted strong patent laws because large multinationals cornered the market and prevented competition.\textsuperscript{197} In 1993, for example, Mexico, South Korea, Singapore, Taiwan, and Thailand all had strong foreign investment and economies and weak patent laws.\textsuperscript{198} Brazil abolished patents for pharmaceutical products in 1949 and for manufacturing processes in 1969.\textsuperscript{199} Foreign investment there increased six-fold between 1971 and 1979 despite strong opposition to these weak laws.\textsuperscript{200}


\textsuperscript{195} See Weissman, supra note 9, at 1124.

\textsuperscript{196} See Pratap Chatterjee, Trade: Study Questions Benefits of Strong Patent Laws, Inter Press Service, Sept. 11, 1993. Chatterjee cites those who say that comparing patent protection and investment patterns is like comparing apples and oranges. Patents are much more directly linked to both product prices and foreign corporate profits. See id.

Similarly, an empirical study of post-1975 investment with regression analysis found no significant relationship between patents and foreign direct investment for less-developed countries. The study cited Brazil and Argentina as examples where the absence of adequate protection for patents in pharmaceuticals did not deter investment. See Belay Seyoum, The Impact of Intellectual Property Rights on Foreign Direct Investment, 31 COLUM. J. WORLD BUS. 50, 57 (1996).

"Investment decisions will continue to have more to do with national laws on ownership, market size and the state of the domestic industry than with intellectual-property protection." Intellectual Property... Is Theft, supra note 120, at 72. But see Parke & Ginarte, supra note 129, and accompanying text, discussing a questionnaire study linking intellectual property as one factor for prospective U.S. drug company investments abroad; see also Finance: Foreign Investment May Be Related To Patent Protection, Inter Press Service, Mar. 15, 1994.

\textsuperscript{197} See Chatterjee, supra note 196.

\textsuperscript{198} See id.

\textsuperscript{199} See id.

\textsuperscript{200} See id.
The study concluded that third world countries may profit from protecting local products with their patent laws rather than foreign products.\textsuperscript{201} ALIFAR blames unemployment and de-industrialization on U.S. pressure on Latin American countries to modernize their patent legislation.\textsuperscript{202}

Even if patent rights invite a greater presence of multinational companies in Argentina, this presence does not guarantee an improvement in the state of Argentine public health care. In Canada, for example, five years after the Canadian government introduced patent laws favorable to the United States, the average cost of pharmaceutical drugs rose by fifty three percent.\textsuperscript{203} The chairman of the Canadian Drug Manufacturers Association says that Canada's decision in 1992 to scrap its seventy-year-old compulsory licensing of patents will cost Canada an extra $7 billion in health care by the year 2010.\textsuperscript{204}

3.3.5. Strengthen Local Industry

The multinational drug industry is also infamous for providing a "very inappropriate assortment of products" to third world countries and ignoring diseases that are a national priority.\textsuperscript{205} The U.S. industry generally develops and markets nonessential drugs aimed at treating the ailments of the affluent.\textsuperscript{206} A strong local industry is much more able to identify and serve national health needs. Argentina has used its intellectual property rights laws to develop a strong pharmaceutical sector which contributes powerfully to its own national economy and the global marketplace.\textsuperscript{207} The industry exerts considerable political

\\textsuperscript{201} See id.
\textsuperscript{203} See Chatterjee, supra note 196.
\textsuperscript{204} See Uniyal, supra note 23. But see Owen Lippert, The Americas: Pirates Plunder Patents; Will the Rule of Law Prevail?, WALL ST. J., Apr. 17, 1998, at A15 (noting the success of Canada's increased patent protection, including an actual decline in drug prices and an increase in research and development spending).
\textsuperscript{205} Gereffi, supra note 20, at 200.
\textsuperscript{206} See Tancer & Tancer, supra note 25.
\textsuperscript{207} See Mark Ritchie ET AL., Intellectual Property Rights and Biodiversity: The Industrialization of Natural Resources and Traditional Knowledge, 11 ST. JOHN'S J. LEGAL COMMENT. 431, 434 (1996).
power, owing much of its success to compulsory licensing provisions. In Argentina, unlike Brazil, the top pharmaceutical companies are Argentine.

3.3.6. Patent Policy Intertwined with Health Care Policy

Developing countries may properly be more concerned with developing a policy of health care access than with assuring monopolies to successful inventors, especially when those inventors are predominantly foreign. Argentina and other developing nations convinced the World Health Organization to draft a resolution that would urge its 101 member nations to loosen patent protections on drugs by ensuring that public health rather than commercial interests have primacy in pharmaceutical health policies. Patent policy is thus not as distinct from health care policy as developed nations assert. Choices to encourage development by granting monopoly powers directly affect current drug prices and limit treatment options for the poor. Argentina's system of compulsory licensing provides competition to U.S. drug manufacturers and, in general, lowers prices. One

208 The Argentine pharmaceutical industry exerts a broad influence on Congress. See Nash, U.S. Presses Argentina on Patents, supra note 18, at D3. It has effectively lobbied against strong pressure from President Menem. See Nash, Gore Sees Privatization of Global Data Links, supra note 125, at D2.

209 See Ritchie, Dawkins & Vallianatos, supra note 207, at 434.

210 See MacDonald, supra note 10, at 21. This difference probably accounts for Argentina's relatively successful resistance to international patent harmonization pressure. See id.

211 The Argentine national drug companies reject charges from multinational manufacturers that they charge more for their copied versions, saying their prices are eight to nine percent lower. See Nash, U.S. Presses Argentina on Patents, supra note 18, at D3.


213 See generally Swidler, supra note 159, at 655. Although Swidler notes the distinction between the state's role in promoting new technology and making choices to regulate it, he finds that the state functions overlap and are occasionally at odds with each other, especially for expensive innovations. See id. If an innovator is able to patent a new technology and invoke Medicaid law to force states to purchase its product, it enjoys a huge compulsory market. See id. at 672-73.

214 See, e.g., Yang, supra note 134, at 34 (discussing how AZT's price-tag puts it out of reach of most HIV-positive patients).

215 Mossinghoff concedes that "patent pirates" in Argentina contribute to
study finds that nearly all pharmaceuticals marketed by Argentine drug firms are sold at prices fifteen to eighty percent lower than global corporation prices. For example, Glaxo's anti-ulcer drug, Zantac, sells for $91 in the United States, but Glaxo charges only $18 in Argentina. National companies that make a similar product charge about $13.

Moral arguments for public health availability lie beneath the surface of the patent protection debate. Even the United States has several exceptions for patentability in the public interest. The social value of new innovation is diminished when it is only available to a select few because of monopoly pricing. The drug AZT, for example, is so expensive that the majority of patients depressed drug prices. See M ossinghoff Testimony, supra note 24.

See Ritchie et al., supra note 207, at 442. Glaxo's Ranitidine was sold in Argentina for $21.95, while in the United States it cost $84.23. See Patents: Private Rights and Public Interests, supra note 121.

The medical profession has historically distrusted "patent medicines" as being contrary to the philanthropic nature of a physician's profession. Early court decisions reveal judicial hostility to medical patents. See Yang, supra note 134, at 3.

South American patent laws demonstrate how the new trade regimen can corrode self-determination and crowd out equity, even where important policy goals such as access to health care are concerned. Multinationals will reap the benefits of expanded patent drug trafficking, as wealth shifts from South American consumers to North American pharmaceutical giants and as monopoly drug prices rise beyond the reach of the poor.


infected with the HIV virus cannot afford the treatment.\textsuperscript{221} AZT, tested and identified as effective against HIV in U.S. government laboratories, is the quintessential example of unjustified monopoly pricing.\textsuperscript{222} Burroughs Wellcome, which acquired exclusive rights for the drug, contributed only to its very early development.\textsuperscript{223}

3.3.7. Autonomy Threatened by Cross Sector Sanctions

Public health and democratic autonomy concerns justify the recognition that valid legal alternatives exist to the strict regime the United States would like to impose on Argentina.\textsuperscript{224} Such regimes, however, fall into disfavor under strong U.S. coercive cross-sector sanctions. Other non-drug industries in Argentina that are affected by the sanctions are thus invited to join the U.S. drug industry in overcoming resistance to strong patent protection.\textsuperscript{225} Even if stronger patent legislation is achieved, it is less likely to reflect true political will when conceived by these cross-sector sanctions.

\textsuperscript{221} See Yang, \textit{supra} note 134, at 34.

\textsuperscript{222} See id.; Weissman, \textit{supra} note 9, at 1092 n.135.

\textsuperscript{223} See generally Burroughs Wellcome Co. v. Barr Lab. Inc., 40 F.3d 1223, 1231-32 (Fed. Cir. 1994) (holding that Burroughs Wellcome's AZT patents were valid despite the difficult question of whether Burroughs Wellcome inventors actually conceived the invention themselves).

\textsuperscript{224} See, e.g., Weissman, \textit{supra} note 9, at 1071-75 (emphasizing that there is more than one single approach to patent policy).

\textsuperscript{225} See id., at 1095-96. The USTR withdrew trade benefits from such Argentine exports as metals and metal products, chemicals, raw cane sugar, anchovies, and garlic. \textit{See Argentina to Lose Benefits Due to Lack of IPR Protection}, Int'l Trade Daily (BNA), Apr. 17, 1997, at D1.

The cross-sector sanctions ironically hurt American companies which rely on Argentine exports more than they affect the Argentine drug industry. See Rossella Brevetti, \textit{PhRMA Says Stronger Action on Argentina IP May Be Required}, Int'l Trade Daily (BNA), Feb. 26, 1997. One leather tannery owner complained that he had spent time and effort developing a relationship with a reliable Argentine leather supplier and the increased import costs would jeopardize jobs and market share. \textit{See id.}

Published by Penn Law: Legal Scholarship Repository, 2014
4. ALTERNATIVES TO PATENT PROTECTION

4.1. Speculative Benefits of a Strong Patent Regime

Patent law legislation in Argentina has far from ended the debate on the question of Argentina's national sovereignty to decide the strength of its patent laws. Unfortunately, there is little empirical evidence to resolve whether U.S. profit-seeking paternalism may contribute to meaningful processes of discovery and invention in Argentina that will outweigh the cost to Argentina of having a strong intellectual property regime.\(^{226}\) Comparative studies of developing nations with and without strong intellectual property regimes are influenced by too many other more determinative trade factors to be conclusive about intellectual property contribution for a particular result.

4.2. Ineffective Forced Legislation

Respect for patent rights begins independently of legislation. Robert Sherwood, an advocate of strong intellectual property rights, concedes that there are "distinct limits to what can result from forcing legislation," saying that "there are at least a hundred ways in which the patent office can defeat you."\(^{227}\) The U.S. drug industry's main strategy depends on persuading U.S. policy makers to coerce third world countries.\(^{228}\) The drug industry should invest more heavily in non-patent alternatives to supplement the questionable victories of its foreign legislative battles, particularly in strategies that foster respect for a strong intellectual property regime.

---

\(^{226}\) See GLOBAL DIMENSIONS OF INTELLECTUAL PROPERTY, supra note 19, at 67.


\(^{228}\) See Weissman, supra note 9, at 1075.
4.3. **Encourage Foreign Research**

Such strategies include encouraging research and development activities. Once a base is established, research activities generally inspire respect for intellectual property rights. Anecdotal evidence suggests that research students who study in a developed country with strong patent protection often return home frustrated because they cannot market their discoveries in their own country without being immediately copied. Drug companies should encourage foreign research with their dollars, not just the protection of domestic research.

4.4. **Industry Partnerships**

Forming partnerships of respect with domestic industries also fosters patent protection. Drug companies should take note of Microsoft’s aggressive marketing strategies abroad. In China, Microsoft builds friendships with various ministries and major manufacturers who become more committed to working with Microsoft in the future and supporting Microsoft operating systems. Recent patent protection legislation threatens the Argentine drug copy industry, putting U.S. drug companies in a favorable negotiating position for forming similar business partnerships.

4.5. **Judicial Reform**

An ineffective judicial system severely threatens opportunities for legislation to take effect. In many countries, judicial ineptness is a delicate topic, although some Argentine officials are quite open about it. United Nations agencies provide some funding.

---

229 See Park & Ginarte, supra note 124, at 60.
231 See generally Lewis, supra note 25, at 855-856 (encouraging investment in foreign countries to increase respect for intellectual property protection).
233 See *Price Hikes Drive Latin America’s Pharma Market*, supra note 155.
234 See Robert M. Sherwood, supra note 11, at 537.
for judicial reform. Japan and the United States have both contributed money for judicial reform efforts.\textsuperscript{235} As Sherwood says, however, "[j]udicial reform is essentially a matter of political will."\textsuperscript{236} Given the extent that PhRMA frustrates the political will of Argentina, specific PhRMA-friendly judicial reforms are unlikely. Contributions for general reform and training could have some effect on improving judicial administration of patent legislation. However, PhRMA and other lobbying organizations should not contribute in a way that threatens the impartiality of Argentine courts of law.

4.6. Contracts and Segmentation

Patents may also be protected through contract agreements with future distributors, although information asymmetry obscures the costs and potential value of discoveries. Such agreements are expensive to tailor to unique situations, but afford an alternative where patent protection does not exist.\textsuperscript{237} Drug companies in developing countries also engage in research segmentation.\textsuperscript{238} The important development steps of drugs-in-progress are compartmentalized so that no single employee can later divulge the complete discovery to a competitor.\textsuperscript{239} This tactic, however, discourages dissemination of information and collaborative research efforts.\textsuperscript{240}

4.7. Product Loyalty

Large companies, which make up the bulk of the U.S. drug

\textsuperscript{235} See Sherwood, supra note 11, at 543.
\textsuperscript{236} Id. at 544.
\textsuperscript{237} See David, supra note 107, at 33-34.
\textsuperscript{238} See id. at 35.
\textsuperscript{239} See id.
\textsuperscript{240} See id.
industry, rely less on patent protection than small companies.241 Brand-name recognition through trademarks is critical for product promotion, often insulating drug companies from meaningful competition.242 Companies can also encourage product loyalty with direct marketing to doctors. Older-style direct-to-doctor market methods still permit multinational companies to do well in the developing world even as these methods are phased out in the developed world.243

5. CONCLUSION

The situation in Argentina exemplifies the ongoing global conflict concerning the proper scope of drug patent protection. Argentina has signed international agreements and made some additional steps to appease the demands of the U.S. drug industry by passing legislation to protect patented drugs from copiers. These steps mark a significant departure from its historical resistance to outside pressure and refusal to protect pharmaceuticals at all. Unlike Brazil, however, it continues to assert its national sovereignty to charter its own course of protection for some issues, thus inviting U.S. Trade Representative sanctions. The recent flurry of activity highlights the traditional story of patent protection: stronger protection means some gain and some loss. Argentina’s youthful industrial base may well benefit from stronger patent protection, even if coerced from abroad. Stronger patent rights could unlock Argentina’s own research capabilities, paving the way for arms-length trading relationships within MERCOSUR and in the proposed FTAA. It is more likely, however, that the push for harmonization of patent protection will bring further instability to the young democracy, unleashing anti-U.S. sentiment that is still quite fresh in Argentina’s memory.

241 See Mansfield, supra note 150, at 66.
242 See GEREFFI, supra note 20, at 206. The brand-name system is critical to promotional activity, just as the patent system is the cornerstone of research activity. There exist, on average, 30 names for each prescription product.
243 Direct-to-doctor marketing in Latin America has been prone to abuse by the drug industry, however. See Health Care in the Developing World, supra note 12. One 1970s study found that drug companies gave more comprehensive warnings about potential adverse drug reactions to U.S. doctors than to Latin American doctors. See GEREFFI, supra note 20, at 209.
Fortunately, differences in opinion about intellectual property rights are not known to inspire deadly conflicts within or between nations, although the issue has brought considerable tension to international relations in recent years. Patent conflicts typically occur between nations that are already significant trading partners. Intellectual property rights may enable the more developed country to sweeten the trading relationship in its favor. The potential gains of this sweetening have spurred alarming attempts by the U.S. drug industry to coerce foreign legislation. It should instead focus its investment-maximization tactics into less coercive and more meaningful methods.