

SOUTH AFRICA'S MEDICINES AND RELATED SUBSTANCES CONTROL AMENDMENT ACT OF 1997

By Duane Nash

The Agreement on Trade-Related Aspects of Intellectual Property Rights¹ ("TRIPS") was designed to strengthen and harmonize the protection of intellectual property rights worldwide.² However, its genesis was complicated by harsh and often volatile disagreements between developed and developing nations.³ The former, who hold the majority of the world's intellectual property rights, desired strong enforcement of these rights.⁴ The latter, on the other hand, preferred less stringent enforcement to allow their economic development to proceed unencumbered by the developed world's monopoly on intellectual property.⁵

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1. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, World Trade Organization, [hereinafter TRIPS], reprinted in INTERNATIONAL INTELLECTUAL PROPERTY LAW 591-618 (Anthony D'Amato & Doris Estelle Long eds., Kluwer Law International 1997).

2. The preface of the TRIPS Agreement states that the purpose of the Agreement is "to reduce distortions and impediments to international trade . . . taking into account the need to promote effective and adequate protection of intellectual property rights. . . ." *Id.* at 591.

3. The developing nations were reluctant to cede jurisdiction of intellectual property protection to the General Agreement on Trade and Tariffs ("GATT") because of their perception that GATT catered to developed nations. As a result, developing nations preferred the World Intellectual Property Organization ("WIPO"). The developed nations, on the other hand, viewed the WIPO as hostile to their needs, and insisted that GATT was the proper forum. See Doris E. Long, *Copyright and the Uruguay Round Agreements: A New Era of Protection or an Illusory Promise?* 22 AIPLA Q.J. 531 (1995), reprinted in INTERNATIONAL INTELLECTUAL PROPERTY LAW, *supra* note 1, at 242-43.

4. "Developed countries uniformly view intellectual property as embodying pure property rights, entitled to comprehensive international protection in order to assure a full economic return to creators and owners. Reducing the potential for uncompensated, infringing uses by enacting and enforcing international protection norms is perceived as beneficial for both developed and developing countries." Doris E. Long, *The Role of Intellectual Property in Developing Nations*, reprinted in INTERNATIONAL INTELLECTUAL PROPERTY LAW, *supra* note 1, at 65. See also Carlos Alberto Primo Braga, *The Economics of Intellectual Property Rights and The GATT: Views from the South*, 22 VAND. J. TRANSNAT'L L. 243 (1989), reprinted in INTERNATIONAL INTELLECTUAL PROPERTY LAW, *supra* note 1, at 48-49.

5. "Because [developing countries] are not major producers of intellectual property, developing countries have little incentive to vigorously protect it. Weak protection is justified on the grounds that the developing world needs maximum access to Western

The intellectual property protection of pharmaceuticals illustrates the developing/developed world dichotomy. The majority of drug research and development occurs in the developed world⁶ and these nations typically favor strong intellectual property protection of pharmaceuticals.⁷ Developing nations, meanwhile, were often reluctant to extend patent protection to drugs.⁸ TRIPS attempted to bridge these differences by requiring the extension of patent protection to drugs in all signatory nations along with a compulsory license provision and staggered compliance deadlines.⁹

Despite the presence of TRIPS, conflicts over pharmaceutical protection continue to arise among signatory nations.¹⁰ In 1997, South Africa enacted the Medicines and Related Substances Control Amendment Act in order to make drugs cheaper and more available to combat South Africa's growing AIDS epidemic.¹¹ In response, the United States, through the United States Trade Representative ("USTR"), threatened economic sanctions against South Africa after alleging the Act's invalidity under TRIPS.¹² South Africa, in return, affirmed the Act's validity under inter-

intellectual goods for its development and that stringent standards of protection are debilitating." Tara Kalagher Giunta & Lily H. Shang, *Ownership of Information in a Global Economy*, GEO. WASH. J. INT'L L. & ECON. 327 (1994), reprinted in INTERNATIONAL INTELLECTUAL PROPERTY LAW, *supra* note 1, at 62; see also Braga, *supra* note 4, at 48-49.

6. See Rachel F. Ochs, *Pharmaceuticals: The Battle for Control in the 21st Century*, 10 J. L. & HEALTH 297, 298 (1995).

7. See Long, *supra* note 4, at 67.

8. For example, Brazil and Thailand did not extend patent protection to pharmaceuticals until they were pressured by the United States to do so. See MICHAEL BLAKENEY, TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: A CONCISE GUIDE TO THE TRIPS AGREEMENT 4 (Sweet & Maxwell 1996); Ted L. McDorman, *U.S.—Thailand Trade Disputes: Applying Section 301 to Cigarettes and Intellectual Property*, 14 MICH. J. INT'L L. 90 (1992), reprinted in INTERNATIONAL INTELLECTUAL PROPERTY LAW, *supra* note 1, 68-70.

9. See TRIPS, *supra* note 1.

10. In 1997, even after the enactment of TRIPS, the World Trade Organization (WTO) investigated complaints by the United States that India provided inadequate patent protection for pharmaceuticals. The WTO Appellate Panel concluded that India's failure to provide patent protection to pharmaceuticals was in violation of TRIPS. See *India—Patent Protection: Report of the Appellate Body*, reprinted in FREDERICK ABBOTT ET AL., THE INTERNATIONAL INTELLECTUAL PROPERTY SYSTEM: COMMENTARY AND MATERIALS, 556 (1999).

11. Medicines and Related Substances Control Amendment Act, No. 90 (1997) (S. Afr.).

12. The USTR report dated April 30, 1999 included the following:

We call on the Government of South Africa to bring its [intellectual property rights] regime into full compliance with TRIPS before the

national law and alleged that the United States was pressuring South Africa simply to protect American pharmaceutical interests.¹³

An examination of the Act itself reveals that its parallel importation provision is valid under TRIPS. The Act's compulsory licensing provision, however, is vague and overly broad: in its current form this provision lacks important limitations enforced by TRIPS. As a result, its application poses a significant threat to the United States' pharmaceutical industry. Moreover, given the vagueness of the term "adequate remuneration," the compulsory licensing provision of TRIPS itself may imperil the pharmaceutical industry if widely employed.

I. BACKGROUND

A. TRIPS

As part of the 1994 Uruguay Round for Negotiations under the General Agreement on Trade and Tariffs ("GATT"), the World Trade Organization ("WTO") adopted TRIPS. This agreement attempts to standardize intellectual property protections at a rudimentary level and compels all signatories to adopt certain minimum standards. These standards include uniformity of patent terms,¹⁴ patentability for inventions in all areas of technology without discrimination,¹⁵ and basic regulations concerning compulsory licensing of intellectual property rights.¹⁶

In return for compliance with TRIPS, Articles 3 and 4 provide signatory nations with two trading benefits.¹⁷ The first is national treatment,

January 1, 2000 deadline . . . and clarify that the powers granted in the Medicines Act are consistent with its international obligations and will not be used to weaken or abrogate patent protection.

United States Trade Representative, *1999 Report of the United States Trade Representative* (visited Sept. 15, 1999) (<http://www.ustr.gov/releases/1999/04/99-41.html>).

13. See *Envoy Says U.S. Not a "Puppet" of Drug Companies*, AIDS Weekly Plus, Aug. 16, 1999, at 1; Josey Ballenger, *U.S. Protectionist Stance Lashed*, BUSINESS DAY (S. Afr.), July 17, 1998, at 3.

14. Article 33 of TRIPS provides that patent terms shall extend for twenty years from the date of filing for all member nations. See TRIPS, *supra* note 1, at 603.

15. See *id.* at 601. This is of particular importance to the pharmaceutical industry, as many countries without significant innovative industry previously excluded pharmaceuticals from subject matter eligibility for patent protection, or granted the protection subject to compulsory licensing schemes. For example, until recently, Canada had a compulsory licensing scheme for pharmaceuticals. See Alexander J. Stack, *TRIPS, Patent Exhaustion and Parallel Imports*, 1 J. OF WORLD INTELL. PROP., 657, 660 (1998).

16. See TRIPS, *supra* note 1, at 602-03 (providing for compulsory licensing in certain conditions). See discussion *infra* Part I.A.1.

17. See TRIPS, *supra* note 1, at 592-93.

which provides that once one member's (foreign) goods have entered another member's market, the goods must be afforded the same intellectual property protection as goods which were domestically produced.¹⁸ The second benefit is most favored nation treatment, which provides that a nation cannot discriminate between WTO trading partners: a lower custom or duty rate given to one WTO nation must be applied to all other WTO nations.¹⁹ Failure to comply with TRIPS or any other WTO agreement can jeopardize a nation's general market access entitlements under the WTO, and leave the nation subject to trade sanctions.²⁰

In addition, as a concession to poorer nations, the deadline for enforcement of TRIPS varies according to a nation's economic development. Article 65.1 of TRIPS grants signatories a grace period of one year from the date of entry into WTO to apply the provisions of TRIPS.²¹ Moreover, Article 65.2 provides "developing countries"²² with four additional years²³ in which to comply, and Article 66 provides least developed countries²⁴ with a ten year grace period with possible extensions granted by the World Trade Council "upon duly motivated request."²⁵ Because TRIPS came into full force on January 1, 1995, developed countries like the United States had until January 1, 1996 to apply TRIPS provisions, while developing

18. Article 3 provides that: "[e]ach member shall accord to the nationals of other Members treatment no less favorable than that it accords to its own nationals with regard to the protection of intellectual property. . . ." TRIPS, *supra* note 1, art. 3, at 592-93. For a discussion of national treatment, see ABBOTT, *supra* note 10, at 317.

19. Article 4 provides that: "[w]ith regard to the protection of intellectual property, any advantage, favor, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members." TRIPS, *supra* note 1, at 593. For a discussion of most favored nation status, see ABBOTT, *supra* note 10, at 316-17.

20. For violations of TRIPS, the WTO Dispute Regulation Body may authorize the imposition of unilateral trade sanctions against a violating nation. As a result, the violating nation may lose its most favored nation status and national treatment benefits. See ABBOTT, *supra* note 10, at 354.

21. See TRIPS, *supra* note 1, at 615.

22. The WTO has no definitions for "developed" or "developing" countries. The latter are designated on the basis of self-selection followed by WTO review. See World Trade Organization, *About the WTO—Summary* (visited Sept. 15, 1999) (<<http://www.wto.org/wto/about/devgroups.htm>>).

23. See TRIPS, *supra* note 1, at 615.

24. See *id.* The WTO recognizes as least-developed countries those countries which have been designated as such by the United Nations. For a list of the 29 least developed countries which are currently members of the WTO, see World Trade Organization, *supra* note 22.

25. See TRIPS, *supra* note 1, at 615-16.

countries like South Africa had until January 1, 2000, to come into full compliance.

An examination of TRIPS itself reveals that the agreement permits compulsory licensing so long as certain conditions are met, and fails to prohibit parallel importation in any circumstance.

1. *Compulsory licensing*

A compulsory license is "an involuntary contract between a willing buyer and an unwilling seller imposed and enforced by the state."²⁶ Article 31 of TRIPS, addressing "Other Use Without the Authorisation of the Right Holder," contains specific examples of the grounds on which member nations may force patent holders to grant compulsory licenses.²⁷ These grounds include refusal by the patent holder to deal on reasonable commercial terms, urgency and extreme emergency, anti-competitive practices by the patent holder, non-commercial use of the patented good, and the presence of dependent patents.²⁸ Commentators contend, however, that Article 31 is merely descriptive and not exhaustive,²⁹ such that other unlisted grounds could justify compulsory licensing under TRIPS. This interpretation is supported by other sections of TRIPS itself, which reinforce the agreement's much stated balance between intellectual property protection and the welfare of member nations.³⁰

Unlike the vaguely delimited grounds under which a nation can engage in compulsory licensing, the conditions regulating the execution of these

26. Gianna Julian-Arnold, *International Compulsory Licensing: The Rationales and the Reality*, 33 IDEA 349 (1993), reprinted in INTERNATIONAL INTELLECTUAL PROPERTY LAW, *supra* note 1, at 357 n.6.

27. See TRIPS, *supra* note 1, at 602-03.

28. See *id.*

29. See Carlos M. Correa, *Patent Rights*, in INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE 189, 208 (Carlos M. Correa & Abdulqawi A. Yusuf eds., Kluwer Law International 1998).

30. TRIPS stated main goal is "to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade." TRIPS, *supra* note 1, at 591. Similarly, Article 7 states that: "The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology . . . in a manner conducive to social and economic welfare, and to a balance of rights and obligations." *Id.* at 593. Finally, Article 8 provides that: "Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement." *Id.* at 594. See also Correa, *supra* note 29, at 208-13.

compulsory licenses are more clearly defined.³¹ According to Article 31, a member nation may only force a patent holder to grant a compulsory license if: "prior to such use, the proposed user has made efforts to obtain authorisation from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time."³² Moreover, the license must be of limited scope and duration, non-exclusive, non-assignable, "predominantly for the supply of the domestic market," and accompanied by "adequate remuneration in the circumstances of each case."³³ Finally, the license must only be granted after a case by case determination, and the patent holder must be allowed the possibility of judicial review.

2. *Parallel importation*

Parallel imports are goods that are purchased in a foreign market by an independent third party and later resold in the domestic market where their much lower prices compete with those of authorized distributors.³⁴ TRIPS avoids mandating worldwide norms on the legality of parallel importation. Article 6 provides that "nothing in this agreement shall be used to address the issue of the exhaustion of intellectual property rights."³⁵

Rules on exhaustion and parallel importation will likely be a major negotiating issue in the next GATT Round.³⁶ The International Law Association International Trade Commission has agreed to focus on this question as a central research topic and to attempt the formulation of a proposal.³⁷ In the meantime, until GATT or another international body³⁸ for-

31. See Correa, *supra* note 29, at 208.

32. Article 31 is unique, because unlike other articles, Article 31(b) provides that this particular requirement "may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use." TRIPS, *supra* note 1, at 602.

33. TRIPS, *supra* note 1, at 602-03.

34. See Stack, *supra* note 15, at 666-67.

35. TRIPS, *supra* note 1, at 593. Exhaustion refers to the doctrine which determines when a patentee or authorized licensee loses the right to control the sale of the patented item. Exhaustion enables parallel importation in that once the patent right is exhausted, the patentee or authorized licensee is unable to prevent parallel importation. See John E. Somorjai, *The Evolution of a Common Market: Limits Imposed on the Protection of National Intellectual Property Rights in the European Economic Community*, 9 INT'L TAX & BUS. L. 431 (1992), reprinted in INTERNATIONAL INTELLECTUAL PROPERTY LAW, *supra* note 1, at 324-27.

36. See F.M. Abbott, *Commentary: The International Intellectual Property Order Enters the 21st Century*, 29 VAND J. TRANSNAT'L L. 471, 478 (1996).

37. See *id.*

38. At the present time, the WTO, under which GATT exists, "is the only international agency overseeing the rules of international trade." World Trade Org., *World*

mulates an agreement on the exhaustion of intellectual property rights, the issue of parallel importation will remain an entirely domestic legal concern.³⁹

B. South Africa's Medicines and Related Substances Control Amendment Act of 1997

In December of 1997, Nelson Mandela, the Prime Minister of South Africa, signed the Medicines and Related Substances Control Amendment Act.⁴⁰ The Act addresses South Africa's AIDS pandemic⁴¹ by providing a mechanism through which antiretroviral agents could be made cheaper and more available to South Africa's poor and HIV infected.⁴²

Trade Organization FAQ (visited Feb. 12, 2000) (<http://www.wto.org/wto/faqs/faq.htm#q1>).

39. In the absence of an international agreement, the majority of nations favor parallel importation free of restraint. See Ako Shimada Williams, *International Exhaustion of Patent Rights Doctrine: Is Japan's Move a Step Forward Or Back From the Current Harmonization Effort?*, 7 D.C. L.J. INT'L L. & PRAC. 327 (1998). For example, in *Jap Auto Products v. BBS Kraftfahrzeug Technik*, Case No. Heisei 7, 1988, HANREI JIHŌ (Sup. Ct., July 1, 1997), the Japanese Supreme Court adopted the principle of international exhaustion. Under this doctrine a patentee's rights are exhausted world-wide after the first sale, allowing that or subsequent purchasers to freely import a good anywhere without the patentee's consent. Moreover, the Court stated unequivocally that when a patentee wishes to exert patent rights in Japan, it is purely a matter of interpretation of Japanese patent law.

40. Medicines and Related Substances Control Amendment Act, No. 90 (1997) (S. Afr.).

41. Half of the world's 45 million HIV infections are located in sub-Saharan Africa. See CNN.com, *Minister Predicts Six Million South Africans with HIV*, Aug. 25, 1999 (<http://cnn.com/world/africa/9908/25/bc-AIDS-SAFRICA.reut>). South Africa appears to be the epicenter of this epidemic with approximately 1600 new infections with HIV per day. See *id.* Currently 22% of pregnant women in South Africa are seropositive. See *Hanging on to the Profits from AIDS*, THE GUARDIAN (London), August 5, 1999, at 18. In six years the number of cases in South Africa is expected to double, and, as a result, in ten years the South African life expectancy will decrease from 59 to 40. See CNN.com, *supra*. While transmission of HIV is generally preventable through safe sex measures and universal precaution procedures in the health care setting, South Africa's dilemma is compounded by the fact that in addition to very high rates of unprotected sex, South Africa also has the highest incidence of rape worldwide. See *Hanging on to the Profits from AIDS, supra*. To make matters worse, the average monthly income in South Africa is \$250, compared to the \$800 per month cost of HIV therapy. See Harry Schwartz, *Unlikely Support*, PHARMACEUTICAL EXECUTIVE, Aug. 1, 1999, at 26.

42. AIDS is a treatable, but incurable and frequently fatal condition caused by infection with HIV. HIV treatment with antiretrovirals is effective in preventing or at least delaying the morbidity and mortality resulting from AIDS. However, treatment has thus far been unable to eradicate HIV from an infected host.

In particular, the Act contains language granting the South African Minister of Health the power to engage in the compulsory licensing and parallel importation of pharmaceuticals. Section 10 provides the Minister of Health with the power to permit the compulsory licensing of pharmaceuticals, so long as the product was initially marketed by the owner or with the owner's consent, but without any other expressed limitation.⁴³ In addition, section 10 allows the Minister to permit parallel importation of drugs.⁴⁴ While this paper focuses on the Act's ability to increase the availability of antiretroviral agents for the treatment of AIDS, it should be noted that the language of the Act is general, allowing the Health Minister to use the Act to increase the availability of any pharmaceuticals used to treat any condition, so long as basic criteria are met.⁴⁵

The Act quickly provoked severe criticism from western governments⁴⁶ and pharmaceutical interests,⁴⁷ who represent the majority of

43. Section 10 of the Act provides that the following be inserted into Section 15C of South Africa's Act 101 of 1965:

The Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular may (a) determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine, or with his or her consent.

Medicines and Related Substances Control Amendment Act, No. 90, § 10(a) (1997) (S. Afr.).

44. Section 10 of the Act provides that the following be inserted into Section 15C(b) of South Africa's Act 101 of 1965:

The Minister may . . . (b) prescribe the conditions on which any medicine which is identical in composition, meets the same quality standard and is intended to have the same proprietary name as that of another medicine already registered in the Republic, but which is imported by a person other than the person who is the holder of the registration certificate of the medicine already registered and which originates from any site of manufacture of the original manufacturer as approved by the council in the prescribed manner, may be imported.

Id.

45. The language of the Act is vague, restricting the Health Minister's choice of pharmaceuticals only by the phrase "The Minister of Health may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public." *Id.*

46. Even prior to the Act's passage through the South African Parliament, the governments of the United States, France, and Switzerland warned South Africa against the Act, arguing that it violated TRIPS. See Claire Bissek, *Cheaper Medicines at a Price*, FIN. MAIL (S. Afr.), Oct. 17, 1997, at 36.

47. For example, the German drug manufacturer Merck, maker of the antiretroviral Indinavir Sulfate (marketed as "Crixivan"), warned the South African government that it

antiretroviral manufacturers.⁴⁸ The USTR, in particular, alleged that the Act potentially violated TRIPS, and threatened sanctions in response to the decreased revenue that the Act would cause American pharmaceutical interests.⁴⁹ Moreover, the forty-two members of the Pharmaceutical Manufacturers Association of South Africa, composed significantly of local licensees of western pharmaceutical firms,⁵⁰ quickly challenged the Act's legality in Pretoria High Court.

II. DISCUSSION

A. Is the South African Act Valid under TRIPS?

Given its status as a developing nation, South Africa was not required to comply fully with TRIPS until January 1, 2000. With the recent passage of this deadline, the Act's validity under TRIPS is ripe and can now jeopardize South Africa's WTO membership benefits.

1. Compulsory licensing

The Act's compulsory licensing provision is not invalid per se under TRIPS, and its validity is only jeopardized by the Act's ambiguity. This is because the Act's compulsory licensing provision is less restrictive than TRIPS, and it does not specifically address the conditions required under TRIPS' compulsory licensing provision.⁵¹ So long as the Minister of

was reconsidering a fifty million Rand investment in South Africa in light of the bill even before its passage, and that it would review all future investments upon the bill's passage. *See id.*

48. On May 5, 1999, guidelines were published for the use of antiretroviral agents for HIV infection by a panel convened by the Department of Health and Human Services and the Henry J. Kaiser Family Foundation. The guidelines were updated on January 28, 2000. *See* PANEL ON CLINICAL PRACTICES FOR TREATMENT OF HIV INFECTION, GUIDELINES FOR THE USE OF ANTIRETROVIRAL AGENTS IN HIV-INFECTED ADULTS AND ADOLESCENTS (2000), available at (<http://www.hivatis.org/guidelines/adult/pdf/A&ajani.pdf>). These guidelines list ten drugs, in various combinations of three or four at a time, as the preferred agents for the treatment of established HIV infection. The thirteen Pharmaceutical companies which market these preferred agents are all American or Western European corporations.

49. The USTR report dated April 30, 1999 included the following: "We call on the Government of South Africa to bring its [intellectual property rights] regime into full compliance with TRIPS before the January 1, 2000 deadline . . . and clarify that the powers granted in the Medicines Act are consistent with its international obligations and will not be used to weaken or abrogate patent protection." United States Trade Representative, *supra* note 12.

50. *See* Simon Barber, *Drugs Patent Wrangle Nears End*, BUSINESS DAY (S. Afr.), Aug. 12, 1999, at 1.

51. *See* discussion *supra* Part I.B.

Health interprets the Act within the context of TRIPS, and abides by the conditions described in Article 31, any activity taken under the Act's compulsory licensing provision is valid under international law.

The Act's ambiguous wording can be read to permit activity which is in violation of TRIPS, however. For example, the Minister of Health could enforce a compulsory licensing provision in the absence of any prior attempt to obtain the license on reasonable commercial terms, without a licensing fee, or without the possibility of judicial review. Although such a compulsory license is arguably valid under the Act, it is in clear violation of TRIPS.⁵²

2. *Parallel importation*

Because of Article 6's failure to address the issue of exhaustion of patent rights, TRIPS offers no stance on parallel importation.⁵³ Thus, the Act does not violate TRIPS on this issue. As a matter of law, in the absence of an international treaty on this subject, parallel importation remains an entirely domestic legal concern and the South African government is free to enact any parallel importation scheme that it chooses.⁵⁴

B. **United States Response**

Despite South Africa's valid claim of sovereignty over activity within its borders, the United States is not powerless to prevent either parallel importation or unfavorable compulsory licensing schemes abroad. First, a 1988 Amendment to section 301 of the Trade Act of 1974 permits the United States President to seek the elimination of "unjustifiable or unreasonable" trade practices.⁵⁵ Second, the 1984 Trade and Tariff Act makes intellectual property protection explicitly actionable under section 301 of the 1974 Trade Act.⁵⁶ Tariffs enacted under these statutes, or the mere threat of tariffs, have convinced several countries to develop and enforce stronger intellectual property protections.⁵⁷

52. See discussion *supra* Part I.A.1.

53. See TRIPS, *supra* note 1, at 593.

54. See discussion *supra* Part I.A.2.

55. See Omnibus Trade and Competitiveness Act of 1988 § 1301, 15 U.S.C. § 2006 (1994).

56. See Trade and Tariff Act of 1984 Title V, 15 U.S.C. § 2007.8 (1994).

57. [Action under section 301] was taken against the Republic of Korea in 1985, because of complaints about the limited scope of that country's patent, trademark and copyright laws and against Brazil in the same year because of concerns about its restrictive laws dealing with the protection of computer programmes and computer software. Brazil was also the target of action under section 301 in 1987, when the United

Moreover, the Omnibus Trade and Competitiveness Act of 1988 requires an annual review by the USTR of United States' trading partners.⁵⁸ The USTR is charged with identifying foreign countries which deny "adequate and effective protection of intellectual property rights" or which "deny fair and equitable market access" to United States traders.⁵⁹ These countries are placed on either a "watch list" or a "priority watch list," the latter of which may be followed by trade retaliation consisting of increased duties and or import restrictions.⁶⁰

Under these statutes, the United States government has pressured South Africa to suspend or repeal the Act. In 1998 and 1999, the USTR placed South Africa on the "watch list" in response to the Act, citing violation of TRIPS.⁶¹ Congress reiterated this stance, making future aid to

States increased tariffs on certain Brazilian exports to procure changes in Brazil's protection of pharmaceutical patents. The section 301 actions against the Republic of Korea and Brazil were successful in procuring the desired changes to the respective countries' intellectual property regimes.

MICHAEL BLAKENEY, TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: A CONCISE GUIDE TO THE TRIPS AGREEMENT 4 (Sweet & Maxwell 1996); *see also* THE INTERNATIONAL INTELLECTUAL PROPERTY SYSTEM: PART ONE, *supra* note 8, at 331-32. In addition, during the mid to late 1980s, the U.S. pressured Thailand to provide patent protection for pharmaceuticals. Because of internal Thai politics and a desire not to capitulate to U.S. pressure, the Thai government failed to take any affirmative steps to strengthen its intellectual property regime. In 1991, the USTR identified Thailand as a "priority country" under section 301 because of Thailand's failure to enforce copyrights and its deficient protection of patented pharmaceuticals. On February 27, 1992, the Thai Legislative Assembly revised the Thai Patent Act to satisfy U.S. objections to the act as originally passed in 1979. Stefan Kirchanski, *Protection of US Patent Rights in Developing Countries: US Efforts to Enforce Pharmaceutical Patents in Thailand*, 16 LOY. L.A. INT'L & COMP. L.J. 569 (1993), *reprinted in* INTERNATIONAL INTELLECTUAL PROPERTY LAW, *supra* note 1, at 67-70. Finally,

[i]t was also found that the threat of section 301 action could have the desired result. For example, the report of the IIPA on the copyright laws of 10 selected countries had identified Singapore as the largest producer of pirated records and tapes in the world, causing the loss to the United States of some \$358 million. Following bilateral negotiations, Singapore in 1987 improved its copyright statute and manifested an intention to adhere to the principles of the UCC and to become a member of the WIPO.

BLAKENEY, *supra*, at 4.

58. *See* Omnibus Trade and Competitiveness Act of 1988 § 1301, 15 U.S.C. § 2006 (1994).

59. *See id.*

60. *See id.*

61. The United States Trade Representative Report released April 30, 1999 stated that:

South Africa dependent upon the Secretary of State's issuance of a report summarizing United States government efforts to work with South Africa to have the Act repealed.⁶² The State Department's response to Congress, dated February 5, 1999, disclosed a "watch list" designation of South Africa for 1998 and 1999 and a June 30, 1998 White House Announcement withholding preferential tariff treatment for four South African export items.⁶³

C. Settlement

Recent developments involving the United States and South Africa suggest a truce between the Act's supporters and its critics. Specifically, on September 9, 1999, the Pharmaceutical Manufacturers Association of South Africa announced that it would suspend litigation over the Act as a "goodwill gesture" while the Minister of Health considers legislative amendments that will make compliance with TRIPS unambiguous.⁶⁴ In response, the Minister of Health agreed to redraft the Act next year.⁶⁵ Eight days later, the USTR announced that the United States and South

South Africa's Medicines Act appears to grant the Health Minister ill defined authority to issue compulsory licenses, authorize parallel imports, and potentially otherwise abrogate patent rights. . . . We call on the government of South Africa to bring its IPR regime into full compliance with TRIPS before the January 1, 2000 deadline. . . . We will continue to address these issues with the South African Government and will conduct an out-of-cycle review of South Africa's progress towards addressing these concerns in September 1999.

United States Trade Representative, *supra* note 12.

62. Public Law 105-277 from the 105th Congress provides that:
[N]one of the funds appropriated under this heading may be made available for assistance for the government of South Africa, until the Secretary of State reports in writing to the appropriate committees of the Congress on the steps being taken by the United States Government to work with the Government of the Republic of South Africa to negotiate the repeal, suspension, or termination of section 15(c) of South Africa's Medicines and Related Substances Control Amendment Act No. 90 of 1997.

Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999, Pub. L. No. 105-277, 112 Stat. 2681, 2681-155 (1998).

63. United States Department of State, *U.S. Government Efforts to Negotiate the Repeal, Termination or Withdrawal of Article 15(c) of the South African Medicines and Related Substances Act of 1965* (Feb. 5, 1999) (<http://www.cptech.org/ip/health/sa/stdept-feb51999.html>).

64. See *Drug Patents: Clash Averted for Now*, FIN. MAIL (S. Afr.), Sept. 24, 1999, at 14; Neil A. Lewis, *U.S. Industry to Drop AIDS Drug Lawsuit Against South Africa*, N.Y. TIMES, Sept. 10, 1999, at A3.

65. See Lewis, *supra* note 64, at A3.

Africa had resolved their differences.⁶⁶ The United States promised to drop threats of trade sanctions against South Africa.⁶⁷ In return, South Africa agreed to enforce the Act's compulsory licensing and parallel importation provisions in compliance with TRIPS. Further details are yet unavailable.

III. FUTURE IMPLICATIONS

A. South African Perspective

Despite the apparent truce between the United States and South Africa over the Act, future negative developments could prove disastrous for South Africa. Trade sanctions by the United States in response to intellectual property violations, or even perceived ones, pose a significant threat to South Africa's economy. In 1998, South Africa exported nearly \$3.1 billion worth of goods to the United States,⁶⁸ which accounted for 11.9% of South Africa's total exports that year.⁶⁹ In comparison, U.S. exports to South Africa in 1998 accounted for only 0.39% of United States exports worldwide.⁷⁰

66. A press release from the Office of the USTR, dated September 17, 1999 included the following:

The Governments of the United States and South Africa have come to an understanding with respect to South Africa's urgent need to provide better, more affordable health care while ensuring that intellectual property rights are protected. . . . [T]he two governments have identified common ground with respect to South Africa's implementation of its so-called 'Medicines Act.' 'The United States very much appreciates South Africa's assurances that, as it moves vigorously forward to bring improved health care to its citizens, it will do so in a manner consistent with international commitments and that fully protects intellectual property rights', continued Ambassador Barshefsky.

Office of the United States Trade Representative, *U.S.—South Africa Understanding on Intellectual Property* (Sept. 17, 1999) (<http://www.ustr.gov/releases/1999/09/99-76.html>).

67. *See id.*

68. Office of the United States Trade Representative, *National Trade Estimate Report on Foreign Trade Barriers for South Africa*, (<http://www.ustr.gov/reports/nte/1999/safrica.pdf>).

69. World Trade Organization, *World Trade Growth Slower in 1998 After Unusually Strong Growth in 1997* (Apr. 16, 1999) (<http://www.wto.org/wto/intltrad/internat.htm>).

70. The United States exported \$3.6 billion worth of goods to South Africa in 1998. *See* OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 1999 NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS 379 (1999), available at (<http://www.ustr.gov/reports/nte/1999/safrica.pdf>). In comparison, total United States exports for 1998 were \$933 billion. *See* OFFICE OF THE UNITED STATES TRADE REP-

The Act may also have deleterious effects on foreign investment in South Africa.⁷¹ Given the close interactions among trade, foreign direct investment and technology transfer decisions, the general rule is that countries with stronger intellectual property rights regimes are in a better position to attract foreign investors.⁷² This effect may or may not be particularly *apropos* to the pharmaceutical industry.⁷³ If it is, however, the Act may directly antagonize the developed nations' pharmaceutical concerns. Evidence suggests that the Act has been viewed as a "disturbing omen" by foreign investors even outside of the pharmaceutical industry.⁷⁴

These risks must be considered in light of the fact that the Act is at best, only a partial solution to South Africa's AIDS epidemic. While adequate medical therapy is an obvious necessity in combating AIDS, given South Africa's poor living conditions and poorly educated population, a supply of antiretrovirals cannot be expected to address HIV infection on its own. For example, South Africa is currently experiencing 1600 new cases a day of an almost entirely preventable infection.⁷⁵ How compliant this population will be in following a rigid and often complex antiretrovi-

REPRESENTATIVE, 1999 TRADE POLICY AGENDA AND 1998 ANNUAL REPORT OF THE PRESIDENT OF THE UNITED STATES ON THE TRADE AGREEMENTS PROGRAM 19 (1999), available at (<http://www.ustr.gov/reports/tpa/1999/iii.pdf>).

71. In 1997 South Africa experienced \$1.7 billion in foreign direct investment. See OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, A COMPREHENSIVE U.S. TRADE AND DEVELOPMENT POLICY TOWARD SUB-SAHARAN AFRICA, app. 1 at A1-2 (1998), available at (<http://www.ustr.gov/reports/africa/1999/99app1.pdf>).

72. See Carlos A. Primo Braga & Carsten Fink, *The Relationship Between Intellectual Property Rights and Foreign Direct Investment*, 9 DUKE J. COMP. & INT'L L. 163, 181 (1998).

73. Regarding the effect of intellectual property protection on foreign direct investment by the pharmaceutical industry:

The success of a patented pharmaceutical product that cures a specific disease, for which there is no known substitute, and which is readily copied, may depend on strong patent protection, and in such case the presence of [intellectual property rights] protection may significantly affect a [foreign direct investment] decision based on market opportunity. Even in such a case, if the potential market size is sufficiently large and the pharmaceutical investor an efficient producer, [foreign direct investment] may be attractive even in the absence of strong patent protection.

Frederick M. Abbott, *The Enduring Enigma of TRIPS: a Challenge for the World Economic System*, 1 J. INT. ECON. L. 497, 507 (1998).

74. See Simon Barber, *Erwin Will Hear Tough Message at Business Talks*, BUS. DAY (S. Afr.), Aug. 3, 1998, at 4.

75. See CNN.com, *supra* note 41.

ral drug regimen is, at this point, only speculative.⁷⁶ In addition, as therapy currently prolongs life but is unable to eradicate the virus from an infected host, therapy will only increase the prevalence of those infected, albeit with lower viral loads and less infectious capacity.

Finally, a prior attempt at the parallel importation of drugs into Africa has already proved disastrous. On October 14, 1997, upon the Act's passage through the South African Parliament, the Director of the Kenyan National Quality Control Laboratory, Dr. Elizabeth Ominde-Ojaga, warned the South African Medicines Control Council Chairman, Peter Folb, of Kenya's failed experiment with the parallel importation of drugs.⁷⁷ Dr. Ominde-Ojaga reported Kenya's difficulty ensuring the quality of parallel imports along with an inability to recall unsafe products.⁷⁸ Moreover, Kenya found "alarming evidence" of substandard and counterfeit drugs, and experienced problems with customer confusion over multiple brands of the same product.⁷⁹ Kenya eventually outlawed the parallel importation of pharmaceuticals for safety reasons.⁸⁰

B. United States Perspective

The most obvious and worrisome effect of the Act on U.S. interests is decreased revenue for American pharmaceutical manufacturers.⁸¹ Although TRIPS requires that any compulsory licensing scheme be accompanied by "adequate remuneration," this will likely be less profitable than the contracts that the manufacturers would otherwise bargain for in a free market. Furthermore, while South Africa is a TRIPS signatory, the Act itself mentions nothing about remuneration, and it remains to be seen whether or not South Africa will actually comply with this provision.

76. Such speculation is especially relevant, however, when considering that the consequences of poor compliance are not inconsequential. See Daniel Boden et al., *HIV-1 Drug Resistance in Newly Infected Individuals*, 282 J. AM. MED. ASS'N 1135 (1999); Susan J. Little et al., *Reduced Antiretroviral Drug Susceptibility Among Patients With Primary HIV Infection*, 282 J. AM. MED. ASS'N 1142 (1999).

77. See Claire Bissek, *Beware of Counterfeit Medicines, Kenya Warns South Africa*, FIN. MAIL (S. Afr.), Oct. 24, 1997, at 40.

78. See *id.*

79. See *id.*

80. See *id.*

81. The pharmaceutical sector is among the most reliant of all industries on intellectual property protection for the discovery and development of new products. A survey showed that this sector is more than twice as dependent as the next—the chemical sector—in ranking of industries' reliance on patent protection for innovation.

Harvey J. Bale, Jr., *The conflicts between parallel trade and product access and innovation: the case for pharmaceuticals*, 1 J. INT. ECON. L. 637, 641 (1998).

To make matters worse, while TRIPS requires that any compulsory licensing scheme also be limited to domestic needs, the Act is silent on this condition as well. Pharmaceutical manufacturers could be forced into compulsory licensing schemes in South Africa at rock bottom prices, only to find that these drugs are then parallel imported into other nations where they undercut the prices of "authorized" suppliers.

In addition, the Act's own parallel importation provision is another threat to revenues. The South African Minister of Health could decide to avoid compulsory licensing and simply import antiretrovirals from other nations where they are sold more cheaply. This represents the least threatening option from the pharmaceutical manufacturers' perspective, however, as pharmaceutical manufacturers are not likely to sell antiretrovirals in other nations at prices significantly lower than the South African market would bear. As a result, parallel importation by itself may have very little appeal.

Finally, the Act may inspire other countries to enact similar legislation. Although TRIPS allows for compulsory licensing and does not preclude parallel importation, it remains to be seen how closely South Africa will comply with these provisions. Failure to comply, especially without serious repercussions, could prove contagious.

Other compelling candidates for similar legislation exist around the world. For example, while HIV infects an estimated 45 million persons worldwide, there are an estimated 1.86 billion cases of infection with *Mycobacterium tuberculosis*, the causative agent for tuberculosis ("TB").⁸² This accounts for nearly one third of the human population. While TB is not as frequently fatal as AIDS, several factors make it a profound health threat, especially in the third world.⁸³ Other candidates include malaria and the treatable sexually transmitted diseases such as syphilis, gonorrhea and chlamydia.⁸⁴

Ironically, the United States is considering adopting its own legislation similar to the Act. H.R. 2927 of the 106th United States Congress, which

82. See Christopher Dye et al., *Global Burden of Tuberculosis: Estimated Incidence, Prevalence, and Mortality by Country*, 282 J. AM. MED. ASS'N 677 (1999).

83. First of all, although typically treatable with known agents, the incidence of drug resistant strains of *Mycobacterium tuberculosis* is on the rise. Secondly, while HIV infection usually can be prevented through safe sex, clean needles and universal precautions, TB is much more problematic because it is spread through the air by respiratory aerosol. As a result, prevention requires actual isolation which is often not practical or even feasible, especially prior to diagnosis. See generally *id.*

84. See generally WORLD HEALTH ORGANIZATION, THE WORLD HEALTH REPORT 1999, at 110 (1999), available at <http://www.who.int/whr/1999/en/pdf/whr99.pdf>.

was presented on September 23, 1999, provides an amendment to Title 35 which would allow for compulsory licensing of pharmaceuticals by the United States government.⁸⁵ Unlike the Act, H.R. 2927 has no parallel importation provision and its compliance with TRIPS is unambiguous.⁸⁶ However, H.R. 2927's passage could effectively preclude future legal attacks to the Act's compulsory licensing provision. Moreover, passage of H.R. 2927 could paint the USTR's early attacks on the Act as ungrounded and premature at best, or unfair and manipulative at worst.

IV. CONCLUSION

Given its ambiguous wording, implementation of the Act may or may not comply with South Africa's obligations under TRIPS. While the situation appears to be at a stalemate, with South Africa assuring compliance and the United States no longer threatening sanctions, only time will tell.

If controversy does reignite, it will likely not center on the Act's parallel importation provision. First of all, parallel importation is permissible under TRIPS. Secondly, given Kenya's disastrous experience with parallel imported drugs and the fact that pharmaceutical manufacturers are unlikely to sell drugs cheaply enough elsewhere to make parallel importation into South Africa profitable, it is unlikely that South Africa will rely heavily on the Act's parallel importation provision.

The greatest threat to the pharmaceutical industry arises from the Act's, and even TRIPS's, compulsory licensing provisions. In one scenario, a compulsory license could be enforced granting remuneration "adequate" by South African standards,⁸⁷ but significantly less than the pharmaceutical manufacturers would otherwise bargain for in a free market. Even more threatening is the possibility that TRIPS's own compulsory licensing provision will inspire other nations to engage in widespread compulsory licensing of drugs at discount prices.

Another danger posed by the Act arises where drugs manufactured cheaply in South Africa are brought into other nations through parallel

85. H.R. 2927, 106th Cong., § 2 (1999). As of October 4 and 8, 1999, respectively, H.R. 2927 was before the Subcommittee on Courts and Intellectual Property, and the Subcommittee on Health and Environment.

86. Section 2(d) of H.R. 2927 provides that: "Regulations adopted under subsection (a) shall be consistent with provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights referred to in Section 101(d)(15) of the Uruguay Round Agreements Act." H.R. 2927, 106th Cong. § 2(d) (1999).

87. However, adequate remuneration only results from compliance with TRIPS, since the Act itself does not explicitly require this. If TRIPS is not complied with, South Africa could choose to give "inadequate remuneration," or simply none at all.

importation, causing the pharmaceutical industry to lose revenue not only in South Africa, but elsewhere as well. However, given Kenya's bad experience with parallel imported drugs, it remains to be seen whether parallel importation actually poses a real threat to the pharmaceutical industry.

Meanwhile, from a public policy point of view, the Act has the potential for tremendous humanitarian benefit. The goal of section 15(c) of the Act is to increase the availability of drugs necessary to those who could not otherwise afford them. Implementation could save or at least prolong thousands, if not millions of lives in South Africa. Unfortunately, the complexities of HIV treatment and South Africa's poor record of HIV prevention will likely make this humanitarian benefit difficult to achieve with current therapeutic modalities.

Perhaps even more menacing to South Africa, and the world in general, is the threat that if drugs are less profitable to research, develop and market, fewer firms will make new ones in the future. A discussion of the market forces behind pharmaceutical research and development is beyond the scope of this paper. That point aside, it is important to note that the major advances in health care in the past century, excluding the effect of public sanitation, were not made by new medical or surgical techniques but instead by the discovery and marketing of new drugs.⁸⁸ This observation is especially relevant to those who endorse legislative methods to increase the availability of pharmaceuticals, since new research suggests that the development of entirely new drugs will be needed to ever cure HIV infection.⁸⁹

88. Personal knowledge of the author, a physician and surgeon. *See generally* ERWIN H. ACKERKNECHT, *A SHORT HISTORY OF MEDICINE* 227-40 (1982).

89. *See* Z. Q. Zhang, et al., *Sexual Transmission and Propagation of SIV and HIV in Resting and Activated CD4⁺ T Cells*, 286 *SCI.* 1353 (Nov. 12, 1999). According to Dr. Haase, the article's co-author, we "are going to need some new therapeutic approaches altogether if we are going to talk about eradication [of HIV from an infected host]." *See* Rochelle Jones, *Scientists Discover A Curveball in Treating HIV Infection* (Nov. 11, 1999) (<http://www.cnn.com/HEALTH/AIDS/991111/hiv.hide.journal>).

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