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COMPULSORY LICENSING AND THE SOUTH AFRICAN MEDICINE ACT OF 1997: VIOLATION OR COMPLIANCE OF THE TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS AGREEMENT?

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Compulsory Licensing and the South African Medicine Act of 1997: Violation or Compliance of the Trade Related Aspects of Intellectual Property Rights Agreement?

I. INTRODUCTION

The compulsory licensing provisions of South Africa's Medicines and Related Substances Control Act (Medicine Act) and South African Medicines and Medical Devices Regulatory Act (SAMMDRA) comply with the Trade Related Aspects of Intellectual Property Rights (TRIPs) under two rationales. First, given the economic conditions in South Africa, and its rate of AIDS infections, the country cannot afford to wait for AIDS drug patents to expire. The South African laws will comply with TRIPs when: (1) South Africa declares the AIDS crisis a national emergency; and (2) the legislature rewrites the laws to reflect generic versions of patented AIDS drugs be used in times of national emergencies or when the medicine is necessary to protect human life. Second, under a broad interpretation of TRIPs, the South African laws could remain as written and still comply with TRIPs.

In 1997, South Africa amended the Medicine Act.[1] Article 15 gives the government the right to allow parallel importing,[2] which is the importation of cheaper generic versions of patented drugs from countries that do not comply with international patent agreements, namely TRIPs.[3] The Medicine Act also gives the South African Minister of Health the right to grant licenses allowing local drug manufacturers to produce patented drugs at a fraction of the patent owner's price.[4] The government may require the drug manufacturer to pay the patent holder a royalty in exchange for the right to duplicate the medicine.[5] This practice is known as compulsory licensing.[6] In 1998, the South African government passed SAMMDRA.[7] The legislature enacted SAMMDRA intending to repeal Article 15 of the Medicine Act.[8] The compulsory licensing provision, however, withstood the enactment of SAMMDRA.[9]

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1. Kathy Chenault, John Carey & Paul Magnusson, *Will The AIDS Plague Change U.S. Trade Policy?*, BUSINESS WEEK, Sept. 13, 1999, at 58.

2. *Id.; See also* Article 15C of Medicines and Related Substances Amendment Act No. 90 of 1997, 1997 SA HEALTH 90 [hereinafter Medicine Act of 1997].

3. Article 15C of Medicines Act of 1997, *supra* note 2.

4. *Id.*

5. *Id.*

6. *Id.*

7. Pharmaceutical Research Manufacturers Association, *Issues & Policy, Priority Foreign Countries, at* http://www.phrma.org/nte/safrica.html (last visited Sept. 15, 1999)[hereinafter PhRMA].

8. *Id.*

9. *Id.*

The pharmaceutical industry is in an uproar over the Medicine Act because of its alleged threat to international patent law.[10] Multinational drug companies are concerned that the Medicine Act violates TRIPs,[11] which is an extension of the World Trade Organization Agreement.[12] South Africa has halted implementation of the Medicine Act for fear of trade sanctions.[13] The United States Trade Representative legitimized South Africa's fears by placing South Africa on its "301 Watch List"[14] of countries that fail to obey international patent rights.

AIDS activists have staged various demonstrations to protest against the United States' opposition to the Medicine Act.[15] In light of his seat on the United States/South African bi-national commission, former Vice President Gore has been under attack for his advocacy on behalf of the pharmaceutical industry.[16] AIDS activists have further scrutinized the former Vice President because the pharmaceutical industry donated millions of dollars to his presidential campaign.[17] In September 1999, South African President Thabo Mbeki came to the United States with the intention of reaching an agreement on trade policy between the two countries.[18] On September 16, 1999, the United States and South Africa reached a tentative agreement requiring the United States to cease threatened trade sanctions and make AIDS drugs more affordable to South Africans in exchange for South Africa's compliance with TRIPs.[19]

South Africa is a low income Third World nation and has one of the highest HIV infection rates in the world.[20] There are specific provisions in

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10. Chenault, *supra* note 1.

11. PhRMA News Release, *PhRMA Supports USTR On South Africa,* Apr. 30, 1999, *available at* http://www.phrma.org/news/4-30-99s.html.

12. Professor Michael Blakeney, TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: A CONCISE GUIDE TO THE TRIPS AGREEMENT 8 (1996).

13. Chenault, *supra* note 1, at 58.

14. *See supra* note 11, at 1.

15. In the United States, the activist group is called ACT UP. Bob Davis, *Campaign Woes Prompt Gore to Push For AIDS Drugs Deal with Pretoria,* WALL ST. J. (Europe), Aug. 12, 1999, *available at* 1999 WL-WSJE 18411333.

16. *See id.*

17. White House Chief of Staff John Podesta and his brother Anthony, top lobbyists for the pharmaceutical industry, are an integral part of the pharmaceutical industry's movement against the Medicine Act and SAMMDRA. *See* Ed Vulliamy, *How Drug Giants Let Millions Die of AIDS*, THE OBSERVER, Dec. 19, 1999, at http://www.accessmed-msf.org/msf/accessmed/accessmed2.nsf/iwplist4/4ccca173Fab3594c1256871003e8bd?opendocument&style=content_level_2.

18. Chenault, *supra* note 1, at 58.

19. Steven Lee Myers, *South Africa And U.S. End Dispute Over Drugs*, N.Y. TIMES, Sept. 18, 1999, at A8.

20. The World Health Organization and United Nations' joint effort entitled AIDS EPIDEMIC UPDATE Report of 1998 stated that seventy percent of the HIV-infected people in the world are from Sub-Saharan Africa. In addition, it reported that South Africa accounted for one out of seven of these infections; *see* UNAIDS Joint United Nations Programme on HIV/AIDS, AIDS EPIDEMIC UPDATE: DECEMBER 1998, at 3.

TRIPs[21] that validate South Africa's compulsory licensing of AIDS drugs. Part I of this Note explains those provisions and their relation to the Medicine Act.

Part II of this Note explains the TRIPs agreement. In addition, Part II briefly compares international intellectual property restrictions under TRIPs and the Paris Convention. This section also analyzes pharmaceutical patent protection under TRIPs. Further, Part II explains compulsory licensing under TRIPs, emphasizing the national emergency exception.

Part III discusses South Africa's medical patent laws and the effect of the AIDS crisis on South Africa. Additionally, this section briefly outlines similarities between South African and U.S. patent law.

Part IV details international opposition to the Medicine Act, specifically by the Pharmaceutical Manufacturers Associations of the United States and South Africa. Part IV also outlines specific provisions in the TRIPs agreement rendering the Medicine Act valid. Further, Part IV gives a brief synopsis of South Africa's constitutional right to declare its AIDS crisis a national emergency.

II. TRIPs And Compulsory Licensing

A. *History of International Patent Law*

Patent legislation has gone through many changes.[22] Venice Patent Law of 1474 is the earliest recorded patent law[23] enacted in response to a need for talented inventors.[24] The governing body imposed time limits on patents, which were also subject to state compulsory licenses.[25]

Later, English legislators enacted the Statute of Monopolies in 1623.[26] This law banned all monopolies except those granted by the issuance of patents.[27] English legislators granted patents under the Statute of Monopolies for fourteen years, and placed price restrictions on the patents as well.[28]

The French instituted a patent law in 1791 that was very similar to the English legislation.[29] The law required patent holders to fill out affidavits

21. Articles 31, 27.1, 8.1 of TRIPs allow compulsory licensing under special circumstances, discussed further in the Note.

22. For an in depth explanation, *see* Bankole Sodipo, Centre for Commercial Law Studies, University of London, Piracy and Counterfeiting GATT TRIPS and Developing Countries, ch. 1 (1997).

23. See *id.* at 18.

24. *Id.*

25. *Id.*

26. *See id.* at 19.

27. *Id.*

28. *Id.*

29. *Id.* at 20.

ensuring that their inventions were useful and would be "worked".[30] The United States passed its first patent law in 1790.[31]

All of the above-mentioned countries passed these patent laws to maximize the level of innovation and protect inventions from piracy in a world that was experiencing an industrial revolution.[32] These countries, however, limited patent legislation to their own national borders, so international compliance was neither required nor regulated.[33]

The first international patent agreement was established in the Paris Convention of 1883.[34] The Convention included a provision providing any member of the Convention with a right of priority regarding registration of the intellectual property rights in another member's boundaries.[35] Since its inception, the Paris Convention has been revised six times.[36]

The first mention of compulsory licensing in the Paris Convention took place at the 1925 Revision Conference of the Hague (Hague Convention).[37] Article 5 of the Hague Convention laid the foundation that permitted compulsory licensing to force patentees to "work" their patented inventions.[38] Article 5 also stated that failure to work the patent could not result in forfeiture unless compulsory licensing was an inefficient remedy.[39] Therefore, compulsory licensing replaced forfeiture as the favored remedy to deter abuse by the patentee.

The Paris Convention of 1967 used phraseology similar to the 1925 Hague Convention with respect to its grant of compulsory licensing.[40] The 1967 Convention stated that compulsory licenses were granted "to prevent abuses which might result from the exercise of the exclusive rights conferred by the patent, for example failure to work."[41] Failure to work is a limitation on inactive use of the invention by the patentee.[42] The failure to work provision under Article 5 of the 1967 Convention limits the failure to use a patented invention it to four years from the date of application, or three years from the member's grant of the patent.[43] Compulsory licensing was acceptable under these conditions.[44] The 1967 Convention is analogous to the Hague Conven-

30. *Id.*
31. *Id.*
32. *Id.*
33. *Id.* at 21.
34. Michael Halewood, *Regulating Patent Holders: Local Working Requirements and Compulsory Licenses at International Law*, 35 OSGOODE HALL L. J. 243, 252 (1997).
35. *Id.*
36. *Id.* at 253.
37. *Id.* at 266.
38. *Id.* at 267.
39. *Id.*
40. *Id.*
41. Paris Convention for the Protection of Industrial Property, July 14, 1967, art. 5(A)(2), 21 U.S.T. 1583.
42. Halewood, *supra* note 34, at 245.
43. Blakeney, *supra* note 12, at 89.
44. *Id.*

tion with respect to compulsory licensing because it also includes a forfeiture clause.[45]

The Paris Convention is flawed in its approach to international intellectual property. For instance, member nations are not accountable for patents in certain industries, specifically pharmaceuticals and chemical substances.[46] This gave member nations the right to copy pharmaceuticals without any threat of legal action by the patentee.[47] Moreover, under the Paris Convention, international patents had no term limits.[48] Therefore, under the Paris Convention, if a patent is registered in country A, and country B wants to use the same invention, country B could start copying country A's invention after country B's time limit on patented inventions expired.[49] This non-uniformity gave rise to copying at different times all over the world. Another flaw of the Paris Convention is that compulsory licensees were not required to pay reasonable fees to the patentee for use of the invention.[50]

The Paris Convention's inability to effectively regulate international patents resulted in treatment of the Paris Convention's shortcomings as a trade issue.[51] For example, Section 301 of the U.S. Omnibus Trade and Competitiveness Act of 1988, allows the U.S. Trade Representative (USTR) to place non-conforming trade partners on a watch list, and threaten to halt trade if said countries fail to comply with United States' intellectual property law.[52] This watch list seems to be an alternate method of combating international piracy.

45. Paris Convention for the Protection of Industrial Property, *supra* note 41, art. 5(A)(3).
46. Sodipo, *supra* note 22.
47. *Id.*
48. *Id.*
49. *Id.*
50. *Id.* at 23.
51. *Id.*
52. Section 301 dates back to The Trade Act of 1974. Section 301(a) states: "[T]he United States Trade Representative determines under section 304(a)(1) that (A) the rights of the United States under any trade agreement are being denied (B) an act, policy or practice of a foreign country - (i) violates, or is inconsistent with, the provisions of, or otherwise denies benefits to the United States under, any trade agreement, or (ii) is unjustifiable and burdens or restricts United States commerce."; Section 301(c) lays out the actions the United States Trade Representative can take to remedy such actions, namely: "suspend, withdraw, or prevent the application of, benefits of trade agreement concessions . . .impose duties or other import restrictions on the goods of, and . . . fees or restrictions on the services of, such foreign country for such time as the Trade Representative determines appropriate." *See id.* at 23; *See also* 19 U.S.C. § 2411(a)(1).

B. TRIPs

The practice of using trade to regulate intellectual property infringement was instrumental in the creation of the TRIPs agreement.[53] Indeed, the organization that established TRIPs is the World Trade Organization (WTO),[54] which the United Nations Organization established during the Uruguay Round of the General Agreement on Tariffs and Trade (GATT).[55] The United States suggested that the GATT be the controlling body to regulate intellectual property.[56] This line of reasoning stirred controversy, because the World Intellectual Property Organization (WIPO) was already in existence.[57]

TRIPs is an extension of the WTO agreement.[58] Article IV of the WTO agreement established a Council for TRIPs, whose main functions are monitoring international compliance with TRIPs and providing counsel to settle disputes between WTO members.[59]

1. Patents and TRIPs

TRIPs introduced patent regulations that are more stringent than anything provided in the Paris Convention. As outlined above, under the Paris Convention there was a lack of uniformity regarding a minimum term for patented inventions.[60] TRIPs revolutionized international patents by assigning a universal term of twenty years from the filing date.[61] Moreover, before TRIPs came into existence many countries did not offer patent protection for pharmaceuticals and other inventions.[62]

TRIPs provides a remedy for the absence of protection of pharmaceuticals. Article 27.1 provides that "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."[63] TRIPs does, however, give developing countries the right to extend their discriminatory practices regarding pharmaceutical patents for five years from the date of the particular country's entrance into the WTO agreement.[64]

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53. The United States, which has a history of using Section 301 of the Omnibus Act to pressure countries that do not respect American patents, suggested that the GATT govern the regulation of international intellectual property.

54. Blakeney, *supra* note 12, at 22.

55. *Id.* at 29.

56. *Id.* at 3.

57. *Id.* at 4.

58. *Id.* at 8.

59. *Id.*

60. Sodipo, *supra* note 22.

61. *Id.* at 24.

62. *Id.* at 199.

63. Article 27 (1) of the Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, LEGAL INSTRUMENTS – RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 81 (1994) [hereinafter TRIPs] *also available at* http://www.wto.org.

64. Sodipo, *supra* note 22, at 200.

A developing country can also extend the term to nine years by ignoring the application until the five-year period commences, since it usually takes approximately four years for a patent application to receive a grant.[65] In fact, India, a nation known for its lax attitude towards pharmaceutical patents,[66] proposed a bill that provides that pharmaceutical patent applications will not be reviewed until December 31, 2004.[67] This continuing practice of patent discrimination gives developing countries the freedom to ignore international pharmaceutical patents.

2. Compulsory Licensing under TRIPs

A compulsory license is a governmental grant given to a local manufacturer to produce a patented invention without the permission of the patent holder, who is, however, entitled to commensurate payment.[68] The TRIPs limitations on compulsory licensing are much narrower than those of the Paris Convention.[69] Article 5A of the Paris Convention governs compulsory licensing. Its original function was to prevent inactivity by patent holders.[70] A 1975 study by the United Nations Conference on Trade and Development (UNCTAD) noted that developing countries were not using Article 5A to grant compulsory licenses because of the four year waiting period and its complexity.[71]

The WTO instituted TRIPs to simplify international compulsory licensing requirements.[72] In TRIPs, Article 31 governs compulsory licensing.[73] Article 31 provides no limitations on the grounds for granting compulsory licenses, but it omits the "failure to work" provisions integral to Hague and the Paris Conventions.[74]

TRIPs requires that any alternative use of a patent "shall be considered on its own individual merits."[75] TRIPs allows compulsory licensing only if the party has applied for permission from the patent holder under "reasonable commercial terms and conditions" and is unable to receive it within a reasonable time period.[76]

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65. *Id.*

66. The Indian Patents Act of 1970 does not provide adequate protection for pharmaceuticals. *The Effect of TRIPs on Indian Patent Law: A Pharmaceutical Perspective*, 1 B.U.J. SCI. & TECH. L. 4, at 14; *See also* Sodipo, *supra* note 22, at 200, n.41.

67. Sodipo, *supra* note 22, at 200, n.41.

68. Halewood, *supra* note 34, at 260.

69. TRIPs contains several articles that address compulsory licensing as opposed to the Paris Convention's lone Article 5. *See supra* notes 41, 63.

70. *Id.*

71. Blakeney, *supra* note 12, at 89.

72. *Id.*

73. *See id.* at 90.

74. *Id.*

75. Article 31(a) of TRIPs states: "authorization of such use shall be considered on its own individual merits."

76. TRIPs, *supra* note 63, art. 31(b).

The application requirement is waived, however, in the case of a "national emergency, or other circumstances of emergency."[77] The United States originally suggested the national emergency exception in Article 27 of the United States' draft text.[78] The application requirement is also waived in cases of public non-commercial use.[79] This provision is ordinarily used for public health or national defense.[80] Article 31 also requires the government in question to inform the patent holder immediately after using the invention for a public non-commercial use.[81] Furthermore, Article 31(c) limits the scope of the license to the purpose for which it is applied.[82] Compulsory licenses are subject to termination "if and when the circumstances which led to it cease to exist and are unlikely to recur."[83] This provision is TRIPs' method of protecting against abuse of compulsory licenses.

III. SOUTH AFRICAN PHARMACEUTICAL PATENT LAW AND THE AIDS CRISIS

A. South African Medical Patent Law

1. Medicine Act of 1997

The Medicines and Related Substances Control Act of 1965 was the first in a line of several medical-related patent laws bearing the same name.[84] The Medicine Act of 1997 repealed all earlier versions and, as such, it is the focus of this note.[85]

The insertion of Article 15C is the main source of controversy. South African legislators inserted this Article to follow Article 15B in the earlier versions. The aim of this Article is to promote affordable medicines to the South African public.[86] This is truly a broad definition of power. The South African Minister of Health governs the procedure by which patents are enforced, as a measure of ensuring public health.[87] This section also gives the

77. Article 31 (b) of TRIPs states: "This 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. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable." *Id.*

78. GATT Doc. No. MTN.GNG/NG.11/W/70, Art. 27 (May 11, 1990).

79. TRIPs, *supra* note 63, art. 27.1.

80. *Id.* art. 31(d); *See also* Blakeney, *supra* note 12, at 91.

81. TRIPs, *supra* note 63, art. 31(d).

82. Article 31 (c) states: " the scope and duration of such use shall be limited to the purpose for which it was authorized, ..." *Id.* art. 31(c).

83. *Id.* art. 31(g).

84. The History Section of the Medicine Act of 1997 lists the Act of 1965 first.

85. The History section of the Medicine Act of 1997 repeals the Medicine Act of 1965, 1976, 1978, 1979, and 1981 in whole, and the sections 1 through 22 of the 1991 Act. *See supra* note 2.

86. Article 15C of the Medicine Act of 1997 states: "The Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public." *Id.* art. 15C.

87. *Id.*

Minister the right to allow other countries to import generic versions of patented drugs into the country.[88]

Article 22C of the Medicine Act of 1997 governs the compulsory licensing of drugs in South Africa.[89] The Medicine Act of 1997 gives the South African government the right to issue compulsory licenses to local manufacturers "upon such conditions as to the application of such acceptable quality assurance principles and good manufacturing and distribution practices as the council may determine."[90]

The Medicine Act also establishes a Pricing Committee, appointed by the Minister of Health, whose main function is to recommend drug prices to the Minister.[91] Moreover, the Pricing Committee determines a uniform price for medicine sold by South African manufacturers.[92]

2. South African Medicines and Medical Devices Regulatory Act

The South African government passed SAMMDRA in response to worldwide opposition to the Medicine Act. SAMMDRA established a regulatory body to accept medical patent registration,[93] and the Act permits the regulatory body to authorize the sale of unregistered medicines.[94] The original draft of SAMMDRA repealed Article 15C of the Medicine Act.[95] However, the South African parliament reinstated the Article.[96] In fact, SAMMDRA repealed the Medicine Act in whole, but expressly retains sections 15 and 22, the main source of controversy.[97]

Neither the Medicine Act nor SAMMDRA expressly convey that AIDS drugs are the only drugs applicable to compulsory licensing.[98] Given the amount of money the patent holders stand to lose, however, and the amount of HIV infected people in South Africa, it is inferable that compulsory licensing of AIDS drugs is the primary focus of international opposition.

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88. *Id.*

89. *Id.* art. 22(C).

90. Article 22C (1)(b) of the Medicine Act of 1997 states: "the council may, on application in the prescribed manner and on payment of the prescribed fee, issue to a manufacturer, wholesaler or distributor of a medicine or medical device a license to manufacture, act as a wholesaler of or distribute, as the case may be, such medicine or medical device . . . ." *Id.* art. 22C (1)(b).

91. *Id.* art. 22G(1).

92. *Id.* art. 22G(3)(a).

93. South African Medicines And Medical Devices Regulatory Authority Act No. 132 OF 1998, 1998 SA HEALTH 132, § 24(2)(b) [hereinafter SAMMDRA].

94. *Id.* § 30.

95. PhRMA, *supra* note 7.

96. *Id.*

97. The History section of SAMMDRA says that the Medicine Act of 1978 was repealed in whole, but the 1965 and 1997 versions retained sections 1, 15, 22 in common. *See supra* note 93.

98. In both the Medicine Act of 1997 and SAMMDRA the object is referred to as "medicines" instead of AIDS medicines or AIDS drugs.

B. U.S. Patent Law Compared

In order to receive a patent on any invention in the United States, the invention must be useful, novel[99] and non-obvious to a reasonably skilled person in the field of the invention.[100] South African patent law prescribes those same requirements.[101]

The one major difference between the patent laws of both countries is in the licensing scheme. Instead of compulsory licensing, U.S. patent law utilizes a reasonable royalty scheme. This licensing scheme is a measure of damages to compensate for the infringement of a patent.[102] The reasonable rate can be determined by a jury or the court, and the court has the right to increase the determined rate up to three times.[103] This is much different from the aforementioned failure to work provisions of past compulsory licensing schemes for international patents. The reasonable royalty is also different from Section 22C of the Medicine Act, which gives the Minister of Health and the Pricing Committee the right to determine royalty rates for non- infringement purposes of compulsory licensing.

C. AIDS Crisis in South Africa

The South African AIDS crisis has reached epidemic proportions. For instance, in 1999 it was estimated that 30 percent of the young adults are HIV positive.[104] Researchers estimated that if South African conditions did not improve immediately, 45 percent of the pregnant population will be HIV infected by the year 2000.[105] Moreover, HIV infections were estimated to be increasing at a rate of 1,500 a day.[106] The total infected population was estimated at 3.6 million.[107]

South African rape figures are equally astounding.[108] South African rape incidences are among the highest in the world.[109] The rape crisis is so troubling that CGU Insurance, a South African insurance company, has recently

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99. *See* 35 U.S.C.S. § 101 (2000).

100. *See id.* § 103.

101. *See* 1978 SA COMMERCIAL LAW 57, Patents Act. No. 57 of 1978.

102. *See supra* note 99 § 284.

103. *Id.*

104. Dean Baker, *The Real Drug Crisis,* INSTITUTE FOR PUBLIC AFFAIRS, IN THESE TIMES, Aug. 22, 1999, at 19.

105. This figure is quoted from the second Global Strategies for the Prevention of HIV Transmission from Mothers to Infants Conference in Montreal, held from September 1 through 5, 1999. *One Million Additional Infants Will Be Infected With HIV by 2003 if Prevention Measures Not Taken, Announces Global AIDS Conference in Montreal,* PR NEWSWIRE, Sept. 1, 1999.

106. *Envoy Says U.S. Not A "Puppet" Of Drug Companies,* AIDS WEEKLY PLUS, Aug. 16, 1999.

107. *Activists Lock Gore Out of His Office, Criticizing SA Drug Deal,* AFRICA NEWS SERVICE, BRC-NEWS, Aug. 25, 1999.

108. Charlene Smith, *Employing the Profit Motive to Combat Rape,* FINANCIAL MAIL (South Africa), Oct. 22, 1999, at 24.

109. *Id.*

launched a rape insurance policy to offer medical and psychological treatment to rape victims.[110] Estimates put South African rape statistics at a million per year, and one of three women in their lifetime will be raped.[111] One can easily infer that the rape situation worsens an already unbearable AIDS epidemic in South Africa.

If these grave conditions persist the South African population is in danger of becoming extinct. With a low per capita income,[112] and a rising incidence of HIV infection, one can infer that the main reason for widespread opposition to the passage of the Medicine Act and SAMMDRA is the amount of money that pharmaceutical companies stand to lose.

It is well known that pharmaceutical companies depend on research to survive in a highly competitive market.[113] Patent protection and research budgets are often incorporated into the price of the drugs sold.[114] It is estimated, however, that nearly a third of the 20 billion dollars spent annually on pharmaceutical research is spent on "copycat drugs".[115] "Copy cat" drugs are produced when a company has secured a patent on a particular drug, and its competitors subsequently rush to capitalize on the market demand for said drugs by reproducing a comparable drug without infringing on the originator's patent.[116] This practice of allocating corporate earnings toward the evasion of patents costs billions, yet compulsory licensing, a cheaper alternative, is the focus of conflict.

IV. TRIPs And Opposition To The Medicine Act

A. *International Opposition*

1. South African Opposition

South Africa's attempt to secure cheaper drug prices has sparked worldwide controversy. In 1997 the Pharmaceutical Manufacturers Association of South Africa (PMA) filed suit against the South African government to suspend the Medicine Act.[117] After SAMMDRA was passed, the suit focused on repealing SAMMDRA.[118]

110. *South African Insurance Company Launches Policy for Rape Victims*, Agence France Presse, Oct. 13, 1999.

111. See *id.* This estimate is quoted from Rape Crisis, a South African non-governmental organization.

112. South Africa presently has a per capita Gross Domestic Product of three thousand dollars a year. *See* Ethel Hazelhurst, *Time to Say: I Want You*, Financial Mail (South Africa), March 24, 2000, at 50.

113. Baker, *supra* note 104.

114. *Id.*

115. *Id.*

116. *Id.*

117. Chenault, *supra* note 1. I have repeatedly tried to contact Miryenna Deeb, the CEO of the PMA to obtain a copy of the complaint, but all attempts have been unsuccessful.

118. Since SAMMDRA repealed the Medicine Act of 1997, this is inferred.

On September 9, 1999, PMA suspended their lawsuit against the South African government[119] because the South African Minister of Health agreed to redraft the Medicine Act and SAMMDRA in early 2000 to correct the "flaws" in these regulations.[120] Interestingly, the South African Department of Health asserts that their review of SAMMDRA is not due to any pressure from PMA's lawsuit.[121] The Minister of Health states that the decision is merely a result of internal discussions among the Department of Health,[122] and that the Medicine Act of 1997 is not up for review.[123] The press release further stated that the South African government is still in the process of implementing a legal strategy to defend itself against the allegations of the PMA.[124]

Mirryena Deeb, the chief executive of PMA, recently suggested that the South African government should use government funds to procure cheaper AIDS medication.[125] Ms. Deeb contends that with the aid of the State Tender System, through which the state buys 80% of all medicines, AIDS medicines can be purchased at prices lower than international aid organizations charge.[126] The plausibility of this recommendation, however, is questionable given the number of people suffering from AIDS. If there is enough capital in the State Tender to purchase AIDS medication for 3.5 million patients, then Ms. Deed's argument is with merit. If this is not the case, however, then how would the government choose who is eligible for treatment? Would the medication be rationed, or auctioned? If the solution cannot be applied to the entire infected population, the Medicine Act is a better option, provided that it is legal.

In March 2001, the PMA finally reinitiated the lawsuit in the South African High Court. Judge Bernard Ngoepe continued the confusion, however, by halting the trial. Judge Ngoepe questions the standing of the PMA to pursue this case, specifically questioning how a law that "was never put into effect and hence has no chance to cause harm" can be contested.[127]

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119. *Drug Companies Suspend Action Against South Africa*, PhRMA News Releases & Statements, *at* http://www.phrma.org/news/9-9-99.html (last visited Nov. 11, 1999).

120. *Id.* PhRMA asserts that the Minister agreed to redraft the laws because compulsory licensing and parallel importing is inconsistent with "South Africa's international obligations."

121. Press Release, South African Department of Health, Litigation Between the Pharmaceutical Manufacturers Association of SA and the Government of South Africa Regarding Act 90 of 1997, (Sept. 10, 1999) *available at* http://lists.essential.org/pharm-policy/msg00240.html.

122. *Id.*

123. *Id.*

124. *Id.*

125. *S. African Govt Should Use State Tender to Get Best Prices for HIV/AIDS Drugs: PMA*, MARKETLETTER, (London, UK), Oct. 4, 1999.

126. *Id.*

127. Henri E. Cauvin, *Trial in AIDS Drug Lawsuit Opens in Pretoria*, N.Y. TIMES, Mar. 6, 2001, at A8.

2. United States' Opposition

The United States has taken a different approach in voicing its objection to SAMMDRA and the Medicine Act.[128] On April 30, 1988, the United States Traded Representative, Charlene Barshefsky, placed South Africa on its 301 Watch List of countries that fail to give adequate protection to international patents.[129] As stated earlier, international patent regulation has shifted from an intellectual property issue to a trade issue.[130]

At least part of the USTR's decision was a direct result of political influence.[131] In fact, New Jersey Congressman Rodney Frelinghuysen is a staunch supporter of the pharmaceutical industry's efforts to repeal the Medicine Act.[132] Upon being placed on 301 Watch List, South Africa became susceptible to trade sanctions, which would further damage an already impoverished economy, thus making it more difficult to combat the AIDS crisis.[133]

On September 17, 1999, however, the USTR, through its Council of the Trade and Investment Framework Agreement, reached an agreement with the South African government regarding the Medicine Act and SAMMDRA.[134] The agreement between both countries expresses their desire to be committed to TRIPs regarding this issue.[135] Part of the agreement entails South Africa's enactment of a new law that complies with TRIPs.[136] The provisions of this agreement are confusing and vague because under both a broad and narrow reading of TRIPs, the Medicine Act and SMMDRA already comply with its provisions.

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128. Instead of suing in international court, the United States Trade Representative threatened South Africa with trade sanctions.

129. Medicine Act of 1997, *supra* note 85, art. 15(c).

130. For example, the World Intellectual Property Organization used to be the primary source of patent regulation, but the power has shifted to the World Trade Organization, which was established by the GATT, another international trade organization.

131. At the time of the USTR's decision, New Jersey Congressman Rodney Frelinghuysen introduced a provision in the Foreign Operations Bill to discontinue all aid to South Africa until South Africa repealed the Medicine Act. *See* Vulliamy, *supra* note 17.

132. Bristol Myers is based in New Jersey. *See id.*

133. PhRMA, *supra* note 11.

134. Office of the United States Trade Representative Press Release, US-South Africa Understanding on Intellectual Property (Sept. 17, 1999), *available at* http://www.ustr.gov/releases/1999/09/99-76.html.

135. The South African Department of Trade and Industry Press Release states: "This is premised on the commitment of both Governments to the Agreement on Trade Related Aspects of Intellectual Property Rights under the auspices of the World Trade Organization, as well as an appreciation of the South African Government's efforts to provide affordable health care to its people." *See* Department of Trade and Industry Press Release, JOINT UNDERSTANDING BETWEEN THE GOVERNMENTS OF SOUTH AFRICA AND THE UNITED STATES OF AMERICA, Sept. 17, 1999; The United States Trade Representative Ambassador Charlene Barshefsky stated that: "The United States very much appreciates South Africa's assurance 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". *Id.*

136. Myers, *supra* note 19.

On May 10, 2000, former President Clinton further halted any 301 activity by the USTR. Clinton accomplished this by executing an Executive Order that forbids the United States from using trade sanctions or negotiations to alter the laws of any Sub-Saharan African country, as long as the law was enacted to supply drugs to those infected with the AIDS virus. In order to receive protection, the laws must also comply with the TRIPs Agreement.[137]

B. TRIPs Provisions that validate SAMMDRA and the Medicine Act

There are many provisions in TRIPs that give the South African government the right to issue compulsory licenses for AIDS drugs.[138] Article 27.3 of TRIPs allows exceptions for drug and therapeutic treatment of animals and humans.[139] Surely, compulsory licensing of drugs, especially AIDS drugs, is instrumental to the therapeutic treatment of humans.

Article 27.2 allows compulsory licensing for inventions deemed necessary to protect human lives.[140] Indeed, there could not be a TRIPs provision more in line with the goals of the South African government to issue compulsory licenses to manufacturers to produce AIDS drugs. This article alone should silence the critics of the Medicine Act and SAMMDRA who feel that the two regulations are a direct violation of TRIPs. Furthermore, under a broad reading of TRIPs one can also validate the Medicine Act and SAMMDRA under Article 8.1, which allows grants to promote public health.[141]

Due to the amount of HIV-infected individuals in South Africa, the government can classify the AIDS epidemic as a national emergency, which would further validate the Medicine Act and SAMMDRA.[142] As stated earlier, Article 31(c) of TRIPs gives member nations the right to grant compulsory licenses in cases of national emergencies.[143] In fact, the World Health Organization has urged all African governments to declare the AIDS crisis a national emergency, which further validates the magnitude of the South African AIDS crisis.[144]

In addition, according to Section 34(1) of the South African Constitution, the South African Parliament is within its rights to declare the AIDS crisis a

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137. Exec. Order No. 13155, 65 FED. REG. 30, 521 (May 10, 2000).

138. TRIPs, *supra* note 63, arts. 8.1, 27.2, 27.3, and 31.

139. TRIPs, *supra* note 63, art. 27.3.

140. TRIPs, art. 27.2 states: "Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect public order or morality, including to protect human, animal or plant life or health to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by domestic law."

141. TRIPS, *supra* note 63, art. 8.1.

142. Article 31 of TRIPs makes it clear that one can issue compulsory licenses in times of national emergency. *Id.* art. 31.

143. *See id.*

144. *In Brief-News*, BUSINESS DAY (South Africa), June 24, 1999, (News Section), at 1.

national emergency.[145] If one looks at the legislative history behind Article 31(c) of TRIPs, it was the United States that suggested the insertion of this provision. This is ironic, considering that the United States is one of the biggest critics of the South African drug patent laws.[146] Therefore, in order to comply with the national emergency requirement of Article 31(c), the South African government must redraft SAMMDRA to state that compulsory licensing will only be used for AIDS drugs, and not aspirins or cough medicine.[147] Since many other diseases stem from HIV, the law can also be rewritten to state that compulsory licenses of medication will only be granted under circumstances of national emergency.

C. International Support of Compulsory Licensing of AIDS Drugs

In the United States, the Consumer Project on Technology, created by Ralph Nader and presently run by James Love, has been instrumental in exposing TRIPs provisions, and other instances of compulsory licensing that validate Article 15C of the Medicine Act.[148]

Thailand, a Third World country in its own right, has been under fire for its compulsory licensing practices, particularly of AIDS drugs.[149] In fact, Bristol Myers, patent holder of the AIDS drug ddI, recently rejected Thailand's attempt to issue a compulsory license for the production of ddI at a fifty percent discount of Bristol's price.[150] Dr. Tido von Schoen-Angerer, of Medicines Sans Frontiers (Doctors Without Borders), an advocate group favoring compulsory licensing of AIDS drugs, stated that the Thai movement to produce ddI is with merit because U.S. scientists at the National Institute of Health created the drug.[151] In effect, this means that Bristol Myers, a large conglomerate, is the beneficiary of a compulsory license itself, yet refuses to grant a compulsory license to a third world nation in need of remedying a national crisis.

UNAIDS, a joint effort of UNICEF, the World Health Organization, and other international organizations,[152] also supports compulsory licensing of

145. Section 34(1) of the South African Constitution states: "A state of emergency shall be proclaimed prospectively under an Act of Parliament, and shall be declared only where the security of the Republic is threatened by war, invasion, general insurrection or disorder or at a time of national disaster, and if declaration of a state emergency is necessary to restore peace and order."

146. Vulliamy, *supra* note 17.

147. PhRMA, *supra* note 7.

148. The Consumer Project on Technology was created by Ralph Nader, a worldwide recognized leader in consumer advocacy. *See* Sabin Russell, *World Trade Showdown; Activists, Industry Split Over AIDS Drugs*, S.F. CHRON., Nov. 24, 1999, at A1.

149. Thailand/USA disputes regarding compulsory licensing and AIDS drugs. Letter from James Love, Consumer Project on Technology to Thomas M. Rosshirt, Spokesman for the Vice President, (Jan. 22, 2000) *at* http://www.cptech.org/ip/health/cl/thailand/tmr.

150. *See* Russell, *supra* note 148.

151. *Id.*

152. Myers, *supra* note 19.

AIDS drugs based on the TRIPs Agreement.[153] In fact, a recent study by UNAIDS shows that most AIDS drugs are not patented in developed countries.[154] For example, Stavudine (d4T) is only patented in Egypt, South Africa, and the Philippines.[155] Moreover, Indinavir, is only patented in South Africa.[156] It is easily inferable, that these drug manufacturers applied for patents in South Africa solely because of the potential for financial reward. Further investigation by UNAIDS shows that developed countries have until 2006 to adopt legislation implementing the TRIPs agreement.[157] In light of this information, even if the Medicine Act did violate the provisions of TRIPs, the law would still be valid until 2006.

V. CONCLUSION

In light of the devastating conditions that AIDS has caused in South Africa, and South Africa's inability to purchase AIDS drugs, the Medicine Act and SAMMDRA comply with TRIPs under both narrow and broad interpretations of the agreement. The drafters of TRIPs should have written the agreement more narrowly if they were truly afraid of Third World nations issuing compulsory licenses for the production of AIDS drugs. Given the history of international patent legislation, the intent of the framers appears to be the establishment of greater restrictive conditions for compulsory licensing than those of the Paris and Hague Conventions. As written, however, any TRIPs member experiencing a major health crisis can issue compulsory licenses, or more drastically, simply ignore international patents under Article 27.2, which allows compulsory licensing for inventions necessary to protect human lives.[158]

If TRIPs is interpreted broadly, the Medicine Act and SAMMDRA comply based on Article 27.2. Under a broad interpretation, the South African medical patent laws also comply under Article 8.1, which allows grants to promote public health.[159]

Alternatively, for the Medicine Act and SAMMDRA to survive under a narrow interpretation of TRIPs, South Africa must declare their AIDS crisis a

153. The UNAIDS Secretariat has publicly stated that they support: "1) Preferential pricing of HIV/AIDS goods, including male and female condoms, and HIV/AIDS drugs and other pharmaceutical products, so that these products are priced affordably at levels consistent with local purchasing power . . . ; 4). . . that recourse to compulsory licensing may be necessary, as provided for under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), such as in countries where HIV/AIDS constitutes a national emergency." *See* J. Perriens, M.D., Compulsory Licensing and Access to HIV Drugs, Address Before the Paris 1999 Conference on Community and Home Care for People with HIV Infection (Dec. 13, 1999) *at* http://lists.essential.org/pharm-policy/msg.00355.html.

154. *Id.*

155. *Id.*

156. *Id.*

157. *Id.*

158. *See* South African Department of Health, *supra* note 121.

159. *Id.*

national emergency to fit under Article 31. Furthermore, they must rewrite their laws to indicate that the government would only issue compulsory licenses for the production of AIDS drugs. Under the current laws, South Africa could issue compulsory licenses to reproduce aspirin, cough medicine, or other drugs. If the Medicine Act and SAMMDRA are rewritten to say that compulsory licenses will only be granted in times of national emergency, and for drugs capable of curing life threatening illnesses, they should be able to survive any attack.

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