
BOTSWANA'S SUCCESS IN BALANCING THE ECONOMICS OF
HIV/AIDS WITH TRIPS OBLIGATIONS
AND HUMAN RIGHTS

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“The right of property is the guardian of every other right, and to deprive a people of this is in fact to deprive them of their liberty.”¹

I. Introduction: Botswana Leading Africa in Economics and AIDS

Botswana serves as a model for Africa and developing countries worldwide. Due to its groundbreaking response to HIV/AIDS, Botswana is a model of access to medical treatment in Southern Africa.² Botswana is the first African country to aim toward providing antiretroviral therapy to all disadvantaged citizens. It has enjoyed peace since its independence in 1966, and has become relatively prosperous,³ with a per capita income of \$11,200 in 2006.⁴ Much of Botswana's success is due to diamond mining (accounting for more than one-third of its GDP), but other key sectors include tourism, financial services, farming, and cattle.⁵ With an estimated 2006 GDP of nearly \$19 billion, the Central Intelligence Agency (“CIA”) ranks Botswana 120 out of 229 world economies.⁶

Despite such economic success, Botswana battles against HIV/AIDS.⁷ With 24.1% of its population infected, Botswana has the second highest adult HIV/

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¹ Arthur Lee, *An Appeal to the Justice and Interests of the People of Great Britain, in the Present Dispute with America*, (4th ed. 1775), available at *Citizens' Alliance for Property Rights*, <http://www.proprights.org> (last visited Apr. 1, 2007).

² 3D Three, *Trade-Related Intellectual Property Rights, Trade in Services and the Fulfillment of Children's Rights—Botswana* ¶ 1 (Sept. 2004), http://www.3dthree.org/pdf_3D/3DCRCBotswanaSept04en.pdf [hereinafter *Trade and Children's Rights*].

³ Avert, *HIV and AIDS in Botswana*, <http://avert.org/aidsbotswana.htm> (last visited April 28, 2007) [hereinafter *AIDS In Botswana*].

⁴ The World Factbook, *Botswana*, CIA, <https://www.cia.gov/cia/publications/factbook/goes/bc.html> [hereinafter *CIA Factbook*].

⁵ *Id.*

⁶ The World Factbook, *Rank Order—GDP (purchasing power parity)*, CIA, <https://www.cia.gov/cia/publications/factbook/rankorder/2001rank.html>. Actual 2006 GDP estimate is \$18.72 billion. *Id.*

⁷ “The United Nations has characterized the impact of the HIV/AIDS crisis in Africa as ‘no less destructive than that of warfare itself.’” Lissett Ferreira, *Access to Affordable HIV/AIDS Drugs: The Human Rights Obligations of Multinational Pharmaceutical Corporations*, 71 *FORDHAM L. REV.* 1133, 1133 (2002) (quoting Press Release, United Nations, In Address to Security Council, Secretary-General Says Fight against AIDS in Africa Immediate Priority in Global Effort against Disease, SG/SM/7275 AFR/200 SC/6780 (Jan. 6, 2000)).

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AIDS rate in the world.⁸ Human rights and health concerns, therefore, must be balanced against economic interests in policy making.

Botswana attempts to address both human rights and economic concerns as a signatory to the Convention on the Rights of the Child ("CRC"), the World Trade Organization Intellectual Property Agreements ("TRIPS"), and the General Agreement on Trade in Services ("GATS"). Human rights groups fear that the resulting obligations conflict with one another, and may hinder the nation's ability to fight the HIV/AIDS epidemic.⁹ One worry is that the TRIPS-mandated twenty year exclusivity rights for the developer of patented technology will artificially drive up prices of pharmaceuticals, making them unaffordable for many of Botswana's citizens.¹⁰ Unaffordable medications directly conflict with the country's obligation under the CRC to protect the life, health, survival, and development of the nation's children.¹¹

While preserving human rights, Botswana must deal with the seemingly conflicting need of ensuring economic growth. Economic growth and prosperity from diamond mining helps Botswana fight against the HIV/AIDS epidemic.¹² Economists agree that innovation plays a pivotal role in continued economic growth and development.¹³ "Over the past half century, researchers beginning with Nobel Laureate Robert Solow have established that the development and adoption of economic innovation is the most powerful factor determining a nation's underlying growth rate."¹⁴ Moreover, strong intellectual property laws encourage technology transfers and investments by foreign countries.¹⁵ For

⁸ AIDS in Botswana, *supra* note 3 at ¶ 1. In 2005, there were an estimated 270,000 people living with HIV in Botswana; the total population is about 2 million people. *Id.* Botswana has accepted a prevalence rate of 17.1%, based on people aged eighteen months and above reported to be HIV positive in 2004. *2005 Progress Report of the National Response to the UNGASS Declaration of Commitment on HIV/AIDS*, Ministry of State President, § 2.2. [hereinafter 2005 Report]. The estimate rises drastically, however, when compared to individuals 15–49 years old, 25.3% of whom were living with AIDS in 2004. *Id.* Additional statistics are frightening. Life expectancy at birth from 2000–2005 is less than forty years and 120,000 children have lost at least one parent to AIDS. AIDS in Botswana, *supra* note 3. *The Impact of Aids*, United Nations, 2004.

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⁹ See Trade and Children's Rights, *supra* note 2, ¶ 3–5.

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¹⁰ See *id.*, ¶ 8. In 2003, 30.3% of Botswana's population fell below the poverty line. CIA Factbook, *supra* note 4.

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¹¹ See Trade and Children's Rights, *supra* note 2, ¶ 8.

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¹² See CIA Factbook, *supra* note 4.

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¹³ Robert J. Shapiro & Kevin A. Hassett, *The Economic Value of Intellectual Property*, 6, (Oct. 2005), http://www.usaforinnovation.org/news/ip_master.pdf. "In the United States, the world's most successful advanced economy, an estimated 30 percent to 40 percent of the gains in productivity and growth achieved during the 20th century are attributable to economic innovation in its various forms." *Id.* Of the gains in the growth rate of U.S. productivity from 1995–2001, the development of new information technologies accounted for 28% of gains, capital investment in those technologies for 34%, research and development for 10% and response by firms in the areas of organization and worker training in response to innovation accounted for another 10%. *Id.* at 7.

¹⁴ *Id.* at 6.

¹⁵ *Id.* at 13. The strength of intellectual property protection sends an important signal to would-be investors: "It is likely that potential investors perceive the adequacy of the [intellectual property rights] regime as an indication of the government's attitude towards foreign direct investment . . ." Simon Helm, *Intellectual Property In Transition Economies: Assessing the Latvian Experience*, 14 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 119, 132 (2003) (quoting Beata Smarzynska, Composition of Foreign

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example, for every 1% increase in the degree of patent protection in a developing country, United States based investment in that country expands by .45%.¹⁶ Property rights protection also encourages multinational firms to shift research and development activity to developing countries, creating a virtuous cycle as technology is transferred and adopted by domestic citizens and firms, and the domestic rate of intellectual property development increases.¹⁷ Additional encouragement is provided for pharmaceutical firms to begin research and development of medicines necessary to fight the specific medical afflictions of each region.¹⁸ This demonstrates "that greater respect for intellectual property rights can be literally a matter of life and death in many developing countries."¹⁹

For Botswana to continue to grow and prosper it must fulfill its obligations in fighting the HIV/AIDS epidemic while ensuring that innovation is encouraged through the protection of intellectual property rights.²⁰ This article will examine whether such obligations are truly inconsistent, and suggests that both aims may be met through already existing compromises. Part II of this paper discusses the CRC and corresponding obligations. Part III explores the Agreement on Trade Related Intellectual Property Rights ("TRIPS") and the agreement's effect on drug availability and affordability. Part IV examines how Botswana worked to fulfill its obligations under both of these international agreements. Finally, Part V concludes that these obligations can be fulfilled in a manner consistent with both treaties, and that Botswana may, in the future, pave the way to combating the HIV/AIDS epidemic in Africa.

II. Convention on the Rights of the Child: Life Saving Medicines for the Whole Family

The CRC entitles all children to basic human rights protections and is considered by many as "the most rapidly and universally accepted human rights document in the history of international law."²¹ The CRC represents the first binding international human rights instrument to incorporate civil, political, economic, social, and cultural rights while managing to provide each priority with equal

Direct Investment and Protection of Intellectual Property Rights in Transition Economies 2 (Center for Economic Policy Research, Discussion Paper No. 2228, 1999)).

¹⁶ *Id.*

¹⁷ Shapiro & Hasset, *supra* note 13, at 15–16.

¹⁸ *Id.* at 16. One study found an increase in local research of anti-malaria drugs by pharmaceutical companies as a result of improved IP protection in areas prone to malaria outbreaks. *Id.*

¹⁹ *Id.*

²⁰ *See id.* at 5–6.

²¹ Lauren M. Spitz, *Implementing the U.N. Convention on the Rights of the Child: Children's Rights under the 1996 South African Constitution*, 38 VAND. J. TRANSNAT'L L. 853, 854 (2005) (quoting Barbara Bennett Woodhouse, *Recognizing Children's Rights: Lessons from South Africa*, 26 SPG HUM. RTS. 15, 15 (1999)).

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emphasis.²² Article 6 awards children the most basic of all human rights: the right to life.²³

The right to life facially creates an obligation to prevent death and illness, but some have suggested a broader interpretation.²⁴ Article 6 of the CRC states that each signatory must "ensure to the maximum extent possible the survival and development of the child."²⁵ Article 24 of the CRC creates an affirmative right to the "highest attainable standard of health."²⁶ According to the U.N. Commission on Human Rights, access to HIV/AIDS medication is "one fundamental element for achieving progressively the full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health."²⁷

Perhaps these obligations can be read to protect the child's entire family unit from the ravaging effects of HIV/AIDS. In sub-Saharan Africa, 9% of all children under the age of fifteen have lost at least one parent to the disease.²⁸ The results for these children are heartbreaking. They suffer from psychological trauma, poverty, social dislocation, and often, discrimination.²⁹ Education is significantly affected, as orphans are 13% less likely to attend school than non-orphans.³⁰ Demands on public sector services such as health care and education also begin to increase as the adult population wanes.³¹

"Botswana lost approximately 17% of its health-care workforce due to AIDS between 1999 and 2005."³² The loss created an obstacle as Botswana continues to work to provide antiretroviral therapy to all of its citizens.³³ In deciding whether to make investments, Botswana's business community also takes the loss into account, as Botswana projects that 23% of its agricultural labor force alone will be lost by the year 2020.³⁴ The children of families with HIV/AIDS, lacking resources such as education and stability, face many difficulties in attempting to fill the gaps their parents leave behind.³⁵ Any failure in fighting the HIV/AIDS epidemic, therefore, is a failure to protect the right to both the physi-

²² *Id.* at 866.

²³ M.E. Klinck, B. Iuris, D.A. Louw & B.J. Peens, *A South African Perspective on Children's Rights: Pertinent Issues In Remedial and Protection Interventions*, 19 *MED. & L.* 253, 254 (2000).

²⁴ *Id.* at 254.

²⁵ *Id.*

²⁶ *Id.* at 256.

²⁷ Access to Medication in the Context of Pandemics such as HIV/AIDS, Hum. Rts. Comm'n Res. 2003/29, U.N. ESCOR, 57th Sess., Supp. No. 3, 56th mtg. U.N. E/CN.4/2003/L.11/Add.3 (Apr. 22, 2003).

²⁸ UNAIDS, *2006 Report on the Global AIDS Epidemic*, Chapter 4 at 92, http://www.unaids.org/en/HIV_data/2006GlobalReport/default.asp [hereinafter UNAIDS Impact].

²⁹ *Id.* at 91.

³⁰ *Id.* at 92.

³¹ *Id.*

³² *Id.* at 95.

³³ World Health Organization, *Summary Country Profile for HIV/AIDS Treatment Scale-Up: Botswana* (Dec. 2005), http://www.who.int/hiv/HIVCP_BWA.pdf [hereinafter WHO Treatment].

³⁴ UNAIDS Impact, *supra* note 28, at 98, 100.

³⁵ See generally UNAIDS Impact, *supra* note 28.

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cal and productive life of the nation's children. The future stability of Botswana depends upon stabilization of both HIV/AIDS and its after-effects.³⁶

III. TRIPS, Compulsory Licenses, and the Delivery of Medication

As a signatory to the TRIPS agreement,³⁷ Botswana is required to provide minimum standards for intellectual property protection.³⁸ Botswana officially notified the World Trade Organization ("WTO") of its compliance in June 2001.³⁹ In reaching compliance, the country incorporated many of TRIPS flexibilities into its intellectual property laws.⁴⁰ It made use of compulsory licensing and government use measures, and excluded from patentability "diagnostic, therapeutic and surgical methods for the treatment of humans."⁴¹ As a result, HIV/AIDS diagnostic kits cannot be patented in Botswana and are therefore available at low cost.⁴²

TRIPS reoriented intellectual property protection as an international issue (rather than a purely national issue), setting minimum enforceable international standards.⁴³ From the outset, TRIPS represented the tension existing between the need to protect pharmaceutical patents, and the need to protect public health through access to medicines.⁴⁴ TRIPS aims to ensure that "protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation . . . in a manner conducive to social and economic welfare, and to a balance of rights and obligations."⁴⁵ Thus, the agreement intends to enhance both economic and social welfare by protecting intellectual property, which should in turn contribute to innovation and the transfer of technology.⁴⁶

³⁶ See *Id.*

³⁷ General Agreement on Tariffs and Trade-Multilateral Trade Negotiations (The Uruguay Round): Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, Dec. 15, 1993, 33 I.L.M. 81 [hereinafter TRIPS].

³⁸ Trade and Children's Rights, *supra* note 2, ¶ 9.

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ *Id.* (citing Botswana, *Industrial Property Act*, 1996, §§ 30–31, 69.)

⁴² *Id.* (citing Botswana, *Industrial Property Act*, 1996, § 9(f), as amended by *Industrial Property (Amendment Act)*, 1997.)

⁴³ See Srividhya Ragavan, *The Jekyll and Hyde Story of International Trade: The Supreme Court in PhRMA v. Walsh and the TRIPS Agreement*, 38 U. RICH. L. REV. 777, 777-78 (2004). See also TRIPS, *supra* note 37, arts. 15–18.

⁴⁴ See Peggy B. Sherman & Ellwood F. Oakley, III, *Pandemics and Panaceas: The World Trade Organization's Efforts to Balance Pharmaceutical Patents and Access to Aids Drugs*, 41 AM. BUS. L. J. 353, 363 (2004). See also World Trade Organization, *Understanding the WTO: The Agreements: Protection and Enforcement*, available at http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm (last visited Apr. 18, 2007) [hereinafter TRIPS Explanation]. "The extent of protection and enforcement of these rights varied widely around the world; and as intellectual property became more important in trade, these differences became a source of tension in international economic relations." *Id.*

⁴⁵ TRIPS, *supra* note 37, § 1, art. 7.

⁴⁶ Trips Explanation, *supra* note 44.

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Therefore, both producers and users of pharmaceuticals should enjoy the benefits of increased development.⁴⁷

This balance is the result of a compromise between the desire of developed countries to obtain strong global intellectual property protection, and the resistance of the developing world to any standards of protection.⁴⁸ Some developing nations argue that conforming their patent laws to those of developed nations causes the price of medication to rise too high for their citizens to afford.⁴⁹ On the other hand, many developed nations contend that uniform international laws promote free and balanced trade, the maintenance of a healthy economy, and the development of new medicines.⁵⁰ TRIPS is a result of a compromise between the two, in which developed countries received minimum intellectual property protections in exchange for improvements in agricultural and textile trade positions for the developing countries.⁵¹ Additionally, TRIPS allowed flexibility for developing nations, including the “exclusion of certain items from patentability, compulsory licensing under certain conditions, parallel importation, and technical and financial cooperation in favor of developing and least-developed member states.”⁵²

Two of the main objectives of TRIPS are to promote “social and economic welfare,”⁵³ and a “reciprocal balance of exchange that yields net benefit to all.”⁵⁴ Intellectual property protection benefits all participating countries, as an enhancement in such laws is analogous to removing trade barriers such as tariffs.⁵⁵ Such protection encourages investment, and allows artists and investors to remain within their own countries because they can be compensated for their work.⁵⁶ It also ensures continued incentives for pharmaceutical companies to fight specialized diseases in developing areas of the world because any newly developed medicines are subject to patents.⁵⁷

⁴⁷ *Id.*

⁴⁸ Sherman & Oakley, *supra* note 44, at 362.

⁴⁹ Jessica J. Fayerman, *The Spirit of TRIPS and The Importation of Medicines Made Under Compulsory License After the August 2003 TRIPS Council Agreement*, 25 NW. J. INT'L L. & BUS. 257, 257 (2004).

⁵⁰ *Id.*

⁵¹ See Sherman & Oakley, *supra* note 44, at 362. See also Jose E. Alvarez & Joel Trachtman, *Institutional Linkage: Transcending Trade*, 96 AM. J. INT'L L. 77, 78–79 (2002). TRIPS attempts to address the shortcomings of earlier treaties including the Paris Convention, Berne Convention, and Washington Treaty. Michelle M. Nerozzi, *The Battle Over Life-Saving Pharmaceuticals: Are Developing Countries Being TRIPed by Developed Countries?* 47 VILL. L. REV. 605, 611 (2002). Two weaknesses experienced by the Paris Convention were the lack of harmonized international patent laws, and the lack of enforcement provisions. *Id.* at 611–12. TRIPS was created to alleviate some of these problems while addressing the concerns of developing members. *Id.* at 612.

⁵² Nerozzi, *supra* note 51, at 612.

⁵³ TRIPS, *supra* note 37, art. 7.

⁵⁴ Ragavan, *supra* note 43, at 779–80 (quoting Alan O. Sykes, *TRIPS, Pharmaceuticals, Developing Countries, and the Doha “Solution,”* 3 CHI. J. INT'L L. 47, 60 (2002).)

⁵⁵ Fayerman, *supra* note 49, at 268.

⁵⁶ *Id.*

⁵⁷ *Id.*

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Furthermore, developing nations carry a high cost in prioritizing trade interests (often to the detriment of welfare), referred to as the “poverty penalty.”⁵⁸ As a result of TRIPS, countries must prioritize international obligations to avoid trade sanctions.⁵⁹ Such prioritization, however, affects the ability of signatories to fulfill national obligations.⁶⁰ At issue is the use of compulsory licensing and price control mechanisms, often utilized by developing nations to increase access to medication by the population.⁶¹

A. Patent Protection and the Public Health Exception

TRIPS extends patent protection to pharmaceuticals pursuant to Article 27.⁶² Patent protection is offered for a minimum of twenty years from the date of the filing of the patent application.⁶³ The patent holder has the exclusive rights to make, use, offer for sale, assign or transfer the patent, and to enter into licensing contracts—creating value for the patent holder.⁶⁴ Such protections, however, “can affect access to affordable medicines, which is a crucial element of fulfilling the child’s right to health and the right to life, survival and development.”⁶⁵

While the patent holder’s rights are broad, they are not without exception.⁶⁶ Before 1995, many developing countries did not recognize patent protection for pharmaceuticals.⁶⁷ Piracy, parallel importing, and the generic production of patented pharmaceuticals were common problems.⁶⁸ Patent protection aims to rem-

⁵⁸ Ragavan, *supra* note 43, at 779. The term “poverty penalty” refers to the cost born by developing nations in implementing international agreements that require prioritizing trade responsibilities to the detriment of sovereign welfare. *Id.* The poorer nations suffer a loss where they do not have the resources that allow developed nations to resort to price controls and compulsory licenses in times of crises. *Id.* at 779–80. R

⁵⁹ *Id.* at 778. *See also* TRIPS, *supra* note 37, arts. 41–50. TRIPS includes mandatory enforcement provisions. *Id.* R

⁶⁰ Ragavan, *supra* note 43, at 778. R

⁶¹ *Id.* Patrick Marc, *Compulsory Licensing and the South African Medicine Act of 1997: Violation or Compliance of the Trade Related Aspects of Intellectual Property Rights Agreement?*, 21 N.Y.L. SCH. J. INT’L & COMP. L. 109, 121–22 (2001).

⁶² Sherman & Oakley, *supra* note 44, at 363; TRIPS, *supra* note 37, art. 27. Patent protection is made clear through a cross-reference to Article 70(8). Sherman and Oakley, *supra* note 44, at 363. R

⁶³ TRIPS, *supra* note 37, § 5, art. 33; TRIPS Explanation, *supra* note 44. R

⁶⁴ TRIPS, *supra* note 37, § 5, art. 28. “1. A patent shall confer on its owner the following exclusive rights: (a) where the subject matter of a patent is a product, to prevent third parties not having [the owner’s] consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product. . . ; (b) where the subject matter of a patent is a process, to prevent third parties not having [the owner’s] consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process. 2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.” TRIPS, *supra* note 37, § 5, art. 28. R

⁶⁵ Trade and Children’s Rights, *supra* note 2, ¶ 8. R

⁶⁶ Sherman & Oakley, *supra* note 44, at 365. R

⁶⁷ *Id.* at 363.

⁶⁸ *Id.* Parallel importation results in a “grey market” where medicines sold at lower prices in less developed countries are sold in wealthier countries at below market prices. Fayerman, *supra* note 49, at 271–72. R

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edy such dilemmas while allowing governments room to protect the public health.⁶⁹

Article 27 of the TRIPS agreement contains two public health exceptions.⁷⁰ First, members may exclude from patentability inventions when exclusion is necessary for the public order or morality, including for the protection of human life or health.⁷¹ Ambiguity in this provision led some to argue that HIV/AIDS drugs should not be subject to TRIPS because they are necessary to protect the public health.⁷² In contrast, others argue that the exception simply excludes dangerous products from patentability.⁷³

Second, an exception exists for the “diagnostic, therapeutic and surgical methods for the treatment of humans.”⁷⁴ Ethical reasons and the difficulty of enforcement, however, resulted in few countries granting such patents.⁷⁵ Methods used directly on humans also do not generally avail themselves to patentability because “a method that is applied to the human body is not considered industrially applicable and so does not comply with one of the key patentability requirements of most patent laws.”⁷⁶ In the rare circumstances where such patents are offered, they negatively affect the ability of low-income patients to access treatments.⁷⁷ This is true in areas such as gene-therapy,⁷⁸ and may have more of an effect on HIV/AIDS patients as advances in medicine continue.

B. Compulsory Licenses, Circumventing the Patent?

In striking a balance between the needs of patent holders and poor nations, TRIPS includes allowances for provisions such as compulsory licenses to ensure that developing countries will gain access to life saving medicines.⁷⁹ It also makes technology building in least developed countries a goal, so the need for compulsory licenses is diminished over time.⁸⁰

“A patent is a grant issued by a national government conferring the right to exclude others from making, using, or selling the invention within the national territory.”⁸¹ Patents represent a compromise between the public interest and the

⁶⁹ See Sherman & Oakley, *supra* note 44, at 362; TRIPS, *supra* note 37, art. 7.

⁷⁰ TRIPS, *supra* note 37, § 5, art. 27(2).

⁷¹ *Id.*

⁷² Fayerman, *supra* note 49, at 260.

⁷³ *Id.*

⁷⁴ TRIPS, *supra* note 37, § 5, art. 27(3).

⁷⁵ Carlos M. Correa, *Public Health and Patent Legislation in Developing Countries*, 3 TUL. J. TECH. & INTELL. PROP. 1, 16. (2001).

⁷⁶ *Id.*

⁷⁷ *Id.* at 17.

⁷⁸ *Id.*

⁷⁹ Fayerman, *supra* note 49, at 269.

⁸⁰ *Id.*

⁸¹ Ferreira, *supra* note 7, at 1138, (quoting INTERNATIONAL INTELLECTUAL PROPERTY LAW 3 (Anthony D'Amato & Doris Estelle Long eds., 1997)).

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patentee's absolute property rights over the invention.⁸² This compromise strikes a balance between the patentee's ability to seek maximum compensation and society's need for the product.⁸³ This limited monopoly provides an incentive for pharmaceutical companies to invest in, research, and produce new drugs.⁸⁴

In contrast, compulsory licenses are an involuntary contract between a willing buyer, the government, and an unwilling seller, the patentee.⁸⁵ Such contracts affect market exclusivity directly, and market price indirectly, through the use of price controls.⁸⁶ "Direct price control is where the government restricts the market price of a product from exceeding a certain percentage above the cost of production. Indirect price control is where the government uses an incentive, a deterrent, or both to prevent the manufacturer from realizing the highest marginal profit."⁸⁷

The demand for pharmaceuticals, however, is inelastic, and it produces different results in both low and high per capita income-earning countries. In low per capita areas, the result is the need to resort to tools such as compulsory licensing.⁸⁸ This is because increasing the cost reduces affordability in the short run, but increases demand for the drugs as diseases worsen.⁸⁹

However, for patents to cause an effect on drug prices, patents must first be secured.⁹⁰ "Patents have to be secured on a country-by-country basis."⁹¹ If a particular country has not granted some form of protection, then its residents cannot be sued for copying the product, importing copies, or parallel importation.⁹² Therefore, patents alone can not be responsible for limited access to medications because most of Africa does not have patented medicine.⁹³ The Journal of the American Medical Association reported in 2001 that only 21% of antiretrovirals were patented in African countries.⁹⁴ This study, however, has

⁸² Ragavan, *supra* note 43, at 782. Rafael V. Baca, *Compulsory Patent Licensing in Mexico in the 1990's: The Aftermath of NAFTA and the 1991 Industrial Property Law*, 35 IDEA 183, 184 (1994). Compulsory licenses allow governments "to compensate for the economic shortcomings associated with not establishing a domestic industrial base when not working an invention within its borders." *Id.* at 187.

⁸³ Ragavan, *supra* note 43, at 782.

⁸⁴ Ferreira, *supra* note 7, at 1138.

⁸⁵ Sara M. Ford, *Compulsory Licensing Provisions Under the TRIPS Agreement: Balancing Pills and Patents*, 15 AM. U. INT'L L. REV. 941, 945 (2000) ("Compulsory licensing is defined generally as the granting of a license by a government to use a patent without the patent-holders permission"). Gianna Julian-Arnold, *International Compulsory Licensing: The Rationales and the Reality*, 33 IDEA 349, 349 (1993).

⁸⁶ Ragavan, *supra* note 43, at 782.

⁸⁷ *Id.* at 782-83.

⁸⁸ *Id.* at 783.

⁸⁹ *Id.*

⁹⁰ Simon Barber, *Finance, not patents, bars AIDS treatment in Africa*, Business Day: South Africa, Center for International Development at Harvard University, (Oct. 17, 2001), available at http://www.cid.harvard.edu/cidintheneews/articles/SA_Business_Day_101701.html.

⁹¹ *Id.*

⁹² *Id.*

⁹³ *Id.*

⁹⁴ *Id.* (average over all African countries).

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been criticized for its omission of crucial drugs and the lack of consideration of the effects of patents on new drug combinations of older drugs.⁹⁵

Where patents are secured in the international forum, TRIPS ensured access to medication through flexibilities written into the document.⁹⁶ Article 31 leaves open the possibility of using compulsory licenses although it does not refer to them *per se*.⁹⁷ The language, however, is sufficiently ambiguous such that it is read differently by developed and developing countries: “[w]ithout terming it such, TRIPS allows for compulsory licensing amidst several provisions in Article 31.”⁹⁸

Article 31 specifically limits the exportation of medicines under compulsory licenses outside the country that issued the license.⁹⁹ Drug companies often sell their drugs at varying prices in different countries, while each country offers varying degrees of patent protection.¹⁰⁰ When a government imports a patented drug from a country where it is sold at a discount, the practice is dubbed parallel importation.¹⁰¹

To begin manufacturing under a compulsory license, the government must first make reasonable attempts to seek permission of the patent owner.¹⁰² This requirement is waived under a national emergency, and the government has discretion in determining whether public health concerns outweigh the urgency of international intellectual property protections.¹⁰³ However, the government's use

⁹⁵ Ferreira, *supra* note 7, at 1139.

⁹⁶ TRIPS Explanation, *supra* note 44.

⁹⁷ Fayerman, *supra* note 49, at 258. Article 31 provides “Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder. . . such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. TRIPS, *supra* note 37, § 1, art. 31. 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. . . .” It also provides that members are not obligated to abide by these conditions “where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive.” *Id.*

⁹⁸ Nerozzi, *supra* note 51, at 613 (quoting Sara M. Ford, *Note & Comments, Compulsory Licensing Provisions under the TRIPS Agreement: Balancing Pills and Patents*, 15 AM. U. INT'L L. REV. 941, 949 (2000)); *See also* Robert Weissman, *A Long, Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries*, 17 U. PA. J. INT'L ECON. L. 1069, 1115 (1996) (suggesting that Article 31 authorizes the use of compulsory licensing while also creating obstacles to such programs).

⁹⁹ Fayerman, *supra* note 49, at 262.

¹⁰⁰ Ferreira, *supra* note 7, at 1140.

¹⁰¹ *Id.*

¹⁰² Fayerman, *supra* note 49, at 260. *See also* TRIPS, *supra* note 37, § 5, art. 31(b) (“such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time.”)

¹⁰³ Fayerman, *supra* note 49, at 262 (clarification made to TRIPS in 2001 at WTO meeting in Doha, Qatar, stating that AIDS and malaria would be adequate grounds for declaring a national emergency). *See* World Trade Organization Ministerial Declaration on the TRIPS Agreement and Public Health of 14 November 2001, WT/MIN(01)/DEC/2 (Nov. 20, 2001), *available at* http://www.wto.org/English/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

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is constrained, while the patent holder is protected with several measures.¹⁰⁴ Countries may not export compulsory licensed products, the patent holder must be adequately compensated, and use is non-exclusive, non-assignable and subject to judicial review.¹⁰⁵

Compulsory licenses would thus be made unreachable to countries with no manufacturing base.¹⁰⁶ However, the WTO rectified this problem by ensuring flexibility within the agreement.¹⁰⁷ Under TRIPS, countries can export medicines to an "eligible importing member," but only in a limited way designed to limit a "grey market" or parallel importation.¹⁰⁸ The importing country must state the name and expected quantity of the drug it wishes to use, must present evidence that it lacks the requisite manufacturing capacity, must comport with the compulsory license requirements of Article 31, and must remunerate the exporting country.¹⁰⁹ Exporting countries must limit the amount of drugs shipped and label the product with special colors and shapes.¹¹⁰ All WTO members are required to provide legal means by which to limit illegal importation, and all members are encouraged to transfer needed technology.¹¹¹

The flexibilities built into TRIPS enable Botswana to gain access to needed medications in the short term. To ensure continued economic success, however, Botswana must guard against too much dependence on outside assistance to combat the HIV/AIDS crises within its own borders.¹¹² As more knowledge is gained about the HIV/AIDS virus, perhaps Botswana would find it beneficial to combat the disease from its own unique perspective.¹¹³ Botswana faces unique benefits in its economic success and already existing HIV/AIDS programs, but receives less and less outside aid, which threatens to stall this fledgling economy. To encourage development of such specialized products, pharmaceutical companies require incentives and the assurance they will receive remuneration for their developments.¹¹⁴ "Some authors in favor of compulsory licensing seem to forget that without intellectual property protection there would be no medicine at all for the country to license."¹¹⁵

¹⁰⁴ Fayerman, *supra* note 49, at 260–61; *See also* TRIPS, *supra* note 37, § 5, art. 31.

¹⁰⁵ *Id.*

¹⁰⁶ Fayerman, *supra* note 49, at 262.

¹⁰⁷ *Id.*

¹⁰⁸ *Id.* at 263.

¹⁰⁹ *Id.* at 263–64.

¹¹⁰ *Id.* at 263.

¹¹¹ *Id.*

¹¹² *Id.* at 270.

¹¹³ *Id.*

¹¹⁴ *Id.*

¹¹⁵ *Id.*

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IV. The Way Ahead: Treatment and Economy

In fulfillment of the CRC, Botswana took considerable steps in fighting HIV/AIDS through its landmark national antiretroviral therapy program.¹¹⁶ Since 2001, Botswana provided free drugs to pregnant women with HIV/AIDS, all HIV positive children less than twelve-months old, and children with AIDS symptoms.¹¹⁷ As of October 2005, 55,829 people were reported as receiving antiretroviral treatment.¹¹⁸ However, in the same year, 110,000 people were reported to need such treatment.¹¹⁹ Of those receiving treatment, 85% received it free of charge from the public sector, while only 15% receiving funding through the private sector.¹²⁰ Botswana receives funding from multiple sources including international NGOs, the U.S. government, pharmaceutical manufacturers, and other agencies.¹²¹

Challenges to increasing the scope of Botswana's antiretroviral program include shortages in government staffing, the need to decentralize, and the need to involve private practitioners in continuing patient treatment.¹²² Staffing shortages resulted from a government hiring freeze to prevent future budget deficits, as much of the country's monetary resources for antiretroviral treatment come from outside.¹²³ The Bill and Melinda Gates Foundation, together with U.S. drug maker Merck, provided antiretrovirals to every citizen in need.¹²⁴ Positive results are shown in the number of AIDS-related deaths, falling from 33,000 in 2003 to 18,000 in 2005.¹²⁵ Cooperation with international pharmaceutical manufacturers, therefore, is imperative in aiding Botswana's continued struggle against HIV/AIDS.

Despite the successful implementation of HIV/AIDS prevention and treatment programs and generous outside donations, Botswana faces a lot of pressure from constraints on its economic resources.¹²⁶ In 2005, the government spent about

¹¹⁶ See Trade and Children's Rights, *supra* note 2, ¶ 6.

¹¹⁷ *Id.* Since the antiretroviral therapy program was implemented in January of 2002 at the Princess Marina Referral Hospital in Gaborone, the number of people being treated has increased steadily. WHO Treatment, *supra* note 33. In 2005 there were thirty-two public sites available within at least one of each of the country's twenty-four health districts. *Id.*

¹¹⁸ WHO Treatment, *supra* note 33.

¹¹⁹ *Id.*

¹²⁰ *Id.*

¹²¹ *Id.*

¹²² *Id.*

¹²³ *Id.* Funding has come from the Bill & Melinda Gates Foundation (\$50 million over five years), pharmaceutical manufacturer Merck & Co., Inc. (matching the Gates Foundation), the United States President's Emergency Plan for AIDS Relief (\$24.4 million in 2004 to support prevention, and close to \$51 million in 2005 to combat AIDS), the Global Fund to Fight AIDS, Tuberculosis and Malaria (\$18.6 million), and other agencies. *Id.*

¹²⁴ Joseph Hall, *Canada Breaks AIDS Pledge; Africa Still Waiting for Life-Saving Drugs Two Years After Ottawa Passed 'Breakthrough Law,'* TORONTO STAR, (Aug. 3, 2006), available at <http://www.accessmed-msf.org/prod/publications.asp?scentid=11820061738348&contenttype=&> [hereinafter *Canada Breaks Pledge*].

¹²⁵ *Id.*

¹²⁶ See 2005 Report, *supra* note 8, ¶ 4.2.

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\$165 million in HIV/AIDS-related expenditures (excluding recurrent indirect costs such as development of infrastructure, drug procurement, training costs, hospital budgets, and others).¹²⁷ Recently, many donor agencies started to shift their focus on poorer nations as Botswana is now classified as an upper-middle class country.¹²⁸

Criticisms aside, TRIPS may help to save developing countries such as Botswana. Article 7 of the agreement "calls for international intellectual property protection to be instituted 'in a manner conducive to social and economic welfare.'"¹²⁹ Therefore, TRIPS calls on the international community to give a helping hand to nations faced with both the devastating HIV/AIDS crises and limited resources, which would ensure far more success than the mere use of compulsory licenses.¹³⁰ By encouraging technology investment both domestically and internationally, the TRIPS agreement widens the scope of prospective pharmaceutical development.¹³¹

Viable alternatives to compulsory licenses may also be utilized. These measures include bulk procurement, voluntary donation, and publicly funded research and development schemes.¹³² Bulk procurement involves a group of developing countries pooling its resources to obtain large quantities of needed drugs.¹³³ This method results in regional cooperation and innovation while guaranteeing high demand, reliable payment, straightforward pricing-negotiations, and overall pharmaceutical profits in the developing world.¹³⁴ Voluntary donations by wealthy countries of excess drug supplies have been successful in both Haiti and India.¹³⁵ Such schemes, however, risk large fluctuations in supply, and do not further the goal of promoting technology transfers and investment.¹³⁶ Publicly funded research projects resulted in improved nutrition in agriculture, but again relied on wealthier donations and non-governmental organizations.¹³⁷

While Botswana has been highly successful in implementing its ARV program, the financial cost is staggering.¹³⁸ In 2003, the drugs alone cost the gov-

¹²⁷ *Id.* The country's office exchange rate GDP in 2006 is estimated at approximately \$9.7 billion; despite positive growth rates, HIV/AIDS and an expected leveling off in diamond mining production threatens long-term economic growth. CIA Factbook, *supra* note 4.

¹²⁸ See 2005 Report, *supra* note 8, ¶ 4.2.

¹²⁹ Fayerman, *supra* note 49, at 269.

¹³⁰ *Id.*

¹³¹ *Id.* at 268.

¹³² *Id.* at 272-74.

¹³³ *Id.* at 273.

¹³⁴ *Id.* Critics of the bulk procurement method often point to the fact that the poorest nations may not be able to afford medicines even on such a large scale. *Id.* at 274. As an upper-middle class country, Botswana can utilize its position without this setback. 2005 Report, *supra* note 8, ¶ 4.2.

¹³⁵ *Id.* at 273.

¹³⁶ *Id.*

¹³⁷ *Id.* at 274.

¹³⁸ U.N. Office for the Coordination of Humanitarian Affairs, *Botswana: More than Money Needed for Successful AIDS Programme* (Aug. 4, 2003), <http://www.irinnews.org/report.aspx?reportid=45306> (listing the costs of drugs, clinics, and equipment per year, per patient).

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ernment between \$1,200 and \$3,000 a year per patient; the price jumps to between \$7,000 and \$10,000 a year per patient when the price of clinics and equipment is included.¹³⁹ Much of this success, therefore, can be attributed to the fact that Botswana's market-led economy is among the freest economies in the world.¹⁴⁰ Current laws serve to encourage investment, and an independent judiciary provides a sufficient framework for conducting secure commercial dealings.¹⁴¹ However, obstacles remain for investors, as a backlog of cases is increasingly preventing investors from obtaining timely trials.¹⁴² An additional problem exists in the fact that starting a business in Botswana takes 108 days compared to the world average of only forty-eight days.¹⁴³

Further obstacles could arise if the flexibilities of TRIPS are undermined. For example, currently the United States is quietly entering into bilateral and regional trade agreements around the world.¹⁴⁴ The United States signed and ratified the TRIPS agreement "in order to create a broader framework for regulating world trade."¹⁴⁵ However, the agreement is non-self-executing which gives it no force in U.S. courts.¹⁴⁶ Actions brought against the United States would be before a WTO panel.¹⁴⁷ If implemented, the resulting bilateral and regional agreements would limit the conditions under which United States pharmaceutical companies' patents could be broken in exchange for lucrative trade benefits.¹⁴⁸ Negotiations have begun with several nations in the heart of the fight against HIV/AIDS, including Botswana, South Africa, and Thailand.¹⁴⁹

The United States argues that stronger patents will save lives by assuring pharmaceutical companies that their rights will be protected.¹⁵⁰ According to an assistant United States trade representative, "It is crucial to public health . . . to promote the innovation of drugs and to make sure research and development of drugs continues."¹⁵¹ Although the United States promises to exempt AIDS drugs from tightened protections, the promise remains absent from the text of the

¹³⁹ *Id.*

¹⁴⁰ See Heritage Foundation, *2007 Index of Economic Freedom: Botswana*, <http://www.heritage.org/index/country.cfm?id=Botswana> [hereinafter 2007 Index] (stating that Botswana's economy is ranked the 38th freest economy in the world). This score, however, has fallen since 2006 when Botswana was ranked 30th and the most free of Africa's economies. See *South Africa economically freer*, International Marketing Council of South Africa, available at http://www.southafrica.info/doing_business/economy/fiscal_policies/freedom-090106.htm.

¹⁴¹ 2007 Index, *supra* note 140.

¹⁴² *Id.*

¹⁴³ *Id.*

¹⁴⁴ Anand Giridharadas, *U.S. Pushes to Limit Generic Drug Rights*, INT'L HERALD TRIB., Apr. 19, 2006, available at http://www.bilaterals.org/article.php3?id_article=4458.

¹⁴⁵ Helen A. Christakos, *WTO Panel Report On Section 110(5) of the U.S. Copyright Act*, 17 BERKELEY TECH. L.J. 595, 597 (2002).

¹⁴⁶ *Id.*

¹⁴⁷ *Id.*

¹⁴⁸ Giridharadas, *supra* note 144.

¹⁴⁹ *Id.*

¹⁵⁰ *Id.*

¹⁵¹ *Id.*

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agreement.¹⁵² The new agreements would prolong patents beyond the twenty-year mark where the developing country shows “unreasonable delays” in approving a patent.¹⁵³ They would also require retesting of generics, exclude forced competition of branded products with generics, and limit the situations under which patents may be broken.¹⁵⁴ All these measures threaten affordability as well as the ability for the world's nations to operate cohesively to fight HIV/AIDS. The carefully orchestrated compromises of the TRIPS agreement could therefore be rendered null.¹⁵⁵

In hopes of taking advantage of compulsory licensing in the TRIPS agreement, Canada took the opposite approach in May 2004.¹⁵⁶ Passing the Jean Chrétien Pledge to Africa Act (later renamed Canada's Access to Medicines Regime), Canada is aiming to compel its pharmaceutical companies to offer some patented drugs to generic producers.¹⁵⁷ The act requires that impoverished countries first request such drugs, and then that generic producers contract to charge the countries only 25% of the cost of the brand-name counterpart.¹⁵⁸ Generic drugs, however, have not reached poor countries under the act because negotiations between patent holders and the generic producers proved difficult and unsuccessful.¹⁵⁹ Accordingly, the forced-agreement attempt utterly failed.¹⁶⁰

V. Continued Compromise

The need for price-effective drugs will mostly likely become more urgent in the near future.¹⁶¹ Many successful HIV/AIDS programs have been effective because of the lower cost of generic drugs.¹⁶² “Most AIDS patients eventually need to switch to second-line treatment because of the side-effects and drug resistance.”¹⁶³ For example, one new antiretroviral combination therapy does not need refrigeration and would be useful in Botswana, where as recently as 2002,

¹⁵² *Id.*

¹⁵³ *Id.*

¹⁵⁴ *Id.*

¹⁵⁵ See Sherman & Oakley, *supra* note 44, at 362.

¹⁵⁶ Canada Breaks Pledge, *supra* note 124.

¹⁵⁷ *Id.*

¹⁵⁸ *Id.*

¹⁵⁹ *Id.*

¹⁶⁰ See *id.*

¹⁶¹ Jacqui Wise, *Access to AIDS Medicines Stumbles on Trade Rules*, Bulletin of the World Health Organization (May 1, 2006), available at <http://www.who.int/bulletin/volumes/84/5/news10506/en/index.html> [hereinafter Wise] (explaining that although first-line antiretrovirals are available as inexpensive generics, patients will eventually need to switch to second-line antiretrovirals which are less widely available at affordable prices).

¹⁶² *Id.*

¹⁶³ *Id.*

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only 24% of households had access to electricity.¹⁶⁴ However, according to Medecins Sans Frontieres, this drug is not available in Africa at all.¹⁶⁵

In addition to health conditions, social, economic, and psychological problems threaten to become much worse before the HIV/AIDS epidemic subsides.¹⁶⁶

The impact of AIDS is still not fully understood, particularly when the long term is considered. The epidemic comes in successive waves, with the first wave being HIV infection, followed several years later by a wave of opportunistic diseases, and later still by a wave of AIDS illness and then death.¹⁶⁷

Botswana has not yet been hit by the peak of the third wave, and has not advanced very far into the fourth wave of illness and death.¹⁶⁸

Yet hope is prompted by falling death and infection rates.¹⁶⁹ Additionally, Botswana has been successful in complying with TRIPS obligations while maintaining the use of flexibilities inherent in the agreement; this balance included the use of compulsory licenses.¹⁷⁰ Its antiretroviral therapy program has been highly successful and is a model for all developing countries dealing with the threat of HIV/AIDS.¹⁷¹ Forcing negotiations between pharmaceutical manufacturers does not work, as firms have no incentive to enter into unprofitable contracts.¹⁷² On the other hand, circumventing the flexibilities and compromises inherent in TRIPS threatens the ability of developing nations to protect property rights while serving their citizens in emergency and epidemic situations.¹⁷³ Such actions would threaten the very "broad framework" for regulation of world trade, as opportunities for negotiation and compromise would be destroyed.¹⁷⁴

The use of TRIPS flexibilities in Botswana could be the answer to ensuring such drugs continue to reach the hands of needy citizens.¹⁷⁵ Botswana shows that participation in the world market and participation in TRIPS need not result in dismissing health and other human rights concerns. This model, therefore, can serve to aid other nations in battling life-threatening illness while maintaining a growing economy. After all, Botswana will provide many heralded opportunities

¹⁶⁴ *Id.* Helio International, *2002 Energy and Sustainable Development in Botswana*, <http://www.helio-international.org/reports/2002/botswana.cfm>.

¹⁶⁵ Wise, *supra* note 161.

¹⁶⁶ UNAIDS Impact, *supra* note 28, at 80–81.

¹⁶⁷ *Id.* at 80.

¹⁶⁸ *Id.* (explaining that none of the highly affected countries in Africa have hit the peak of the third wave).

¹⁶⁹ See Canada Breaks Pledge, *supra* note 124. This hope is evidenced by the fact that AIDS related deaths dropped by nearly 50% between 2003 and 2005. *Id.* Such deaths fell from 33,000 to 18,000. *Id.*

¹⁷⁰ Trade and Children's Rights, *supra* note 2, ¶ 9.

¹⁷¹ See Trade and Children's Rights, *supra* note 2, ¶ 6.

¹⁷² See Canada Breaks Pledge, *supra* note 124.

¹⁷³ See Giridharadas, *supra* note 144.

¹⁷⁴ *Id.*

¹⁷⁵ See *id.*

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for both medical and economic researchers¹⁷⁶ as the HIV/AIDS epidemic carries out its course. Secure investments by private medical companies can provide a plethora of information regarding the disease. Resulting pharmaceutical developments could help patients and drug companies throughout the world fight and eliminate the disease.

All such possibilities, however, depend upon the protection of invaluable intellectual property rights. Secure intellectual property rights lead to better developments in healthcare, which leads to a stronger economy. Botswana has shown the world that human rights and economic concerns are not independent; rather both objectives can be obtained in building a stronger, healthier nation.

¹⁷⁶ See Shapiro & Hasset, *supra* note 13, at 15–16; Fayerman, *supra* note 49, at 268.
