COMPULSORY LICENSING PROVISIONS
UNDER THE TRIPS AGREEMENT:
BALANCING PILLS AND PATENTS

SARA M. FORD*

INTRODUCTION .............................................. 942
I. BACKGROUND ............................................ 945
   A. Compulsory Licenses .................................. 945
   B. The Emergence of the Agreement on Trade Related
      Aspects of Intellectual Property (TRIPS) .......... 946
   C. Current Confusion Over Compulsory Licensing:
      Example of the Recent South Africa-United States
      Trade Dispute ......................................... 949
      1. Overview ............................................ 949
      2. South African Perspective ........................ 950
         a. Overview of National Health Crisis ............. 950
         b. Medicines & Related Substances Act .......... 952
      3. United States' Perspective ........................ 953
         a. General Objections to Compulsory Licensing ... 953
         b. Confusing Legal Objections With Policy Objections
to Compulsory Licensing ................................ 954
      4. A Negotiated Settlement, Absent the Influence of the
         WTO .................................................. 955
II. ANALYSIS OF COMPULSORY LICENSING IN TRIPS ... 956
   A. Paris Convention .................................... 957

* J.D. Candidate, May 2001, American University, Washington College of
  Law; B.A., Government & International Relations, University of Notre Dame,
  May 1996. Special thanks to Professor Ala’i and the staff of the American University
  International Law Review who provided thoughtful guidance and insight on
  my Comment. I also thank my fellow participants on the summer 1999 legal studies
  program in Cape Town, South Africa who opened my eyes to new perspectives.
  Finally, I am grateful to my friends and family, especially Greg Burstein, who always
  provide encouragement and support as I seek to expand my horizons.
INTRODUCTION

Diverging perspectives are emerging on the issue of compulsory licenses amidst an array of controversy surrounding the recent dispute between the South African Parliament and the United States Trade Representative ("USTR"). The confusion centers around the interpretation of the World Trade Organization's ("WTO") Agreement on Trade Related Aspects of Intellectual Property Rights

---

1. *See* discussion *infra* Part III (discussing the opposing views between developing nations like South Africa and developed nations like the United States).

on the issuance of compulsory licenses of pharmaceutical patents by governments in developing nations. While disputes between the governments of developed nations holding critical patents and governments with most of the pharmaceutical needs are not new, the issue of compulsory license remains an unresolved matter.

Although some commentators assert that TRIPs needs to be amended to clarify confusion on compulsory licensing, a unique aspect of the WTO is that there already exists a conflict resolution body, the Dispute Settlement Body ("DSB"), established through the Understanding on Dispute Settlement ("DSU"), to resolve issues


4. See Review of TRIPs, Int'l Trade Daily News (BNA) (Int'l Trade Rep.) at D7 (June 9, 1999) (highlighting the recent controversy surrounding the interpretation of compulsory licensing in TRIPs).


7. See Richard H. Marschall, Note, Patents, Antitrust, and the WTO/GATT: Using TRIPs as a Vehicle for Antitrust Harmonization, 28 LAW & POL'Y INT'L BUS. 1165, 1190 (1997) (calling for amendments to TRIPs that would limit the broad escape clause permitting developing nations to use compulsory licenses in favor of more narrow antitrust or anticompetition justifications).

arising under TRIPs.9 The primary problem, however, arises when nations in a dispute fail to involve the DSB in resolving their problem because they are either wary of damaging relations with an important trading partner10 or fearful that their position will not withstand the TRIPs.11 Yet, as the WTO gains legitimacy through increased involvement in dispute settlements,12 the probability is high that the issue of compulsory licensing will arrive before the DSB.13

Accordingly, for the sake of future dispute resolutions on the matter of compulsory licensing, this Comment seeks to review the WTO treatment of compulsory licenses in Article 2, Section 5 of TRIPs. While this Comment’s basic premise is that nations can save time and resources by resolving intellectual property disputes through the WTO’s dispute resolution system,14 it also recognizes

---


10. See Hizon, supra note 9, at 126 (noting the existence of threatening bilateral trade measures that enforce dispute settlement outside of the WTO’s DSB).

11. See infra note 68 and accompanying text (quoting the statement of Rep. Sanders suggesting that the United States hesitated in bringing the issue before the WTO due to the uncertainty of its success).

12. See Hizon, supra note 9, at 120 (showing that the DSU has thus far been successful in attracting and serving the needs of countries in all stages). Of the 157 requests made to the DSB, 88 were filed by developed nations and 29 were filed by developing nations. See id. But see Kim Van Der Borght, The Review of the WTO Understanding on Dispute Settlement: Some Reflections on the Current Debate, 14 AM. U. INT’L L. REV. 1226, 1242 (noting recent criticisms of the DSM including how the Appellate Body is involved in too many Panel reviews and how an over-emphasis on free trade subordinates other worthy causes like the environment and consumer rights).

13. See Review of TRIPs, supra note 4, at D7 (reporting that the nations of Kenya, Jamaica, Pakistan, Tanzania, Uganda, and Zambia recently submitted a joint paper to the WTO calling for a review of TRIPs provisions to ensure that their nations retain access to pharmaceutical products through compulsory licensing).

14. See Hizon, supra note 9, at 118-19 (offering a pessimistic perspective on the ability of GATT dispute resolution mechanisms to succeed amidst a lack of agreement on the values and rules being enforced).
that this will not always be a certain option as long as ambiguities in the TRIPs language exist. This Comment endeavors to alleviate some of the confusion surrounding compulsory licensing and to recommend an interpretation of the Article 31 language in TRIPs that would satisfy broad interests.

Part I of this Comment introduces compulsory licenses and the emergence of the TRIPs Agreement. In addition, Part I examines the recent trade dispute between South Africa and the United States by exemplifying how recent confusion over the meaning and purpose of compulsory licensing can present a complicated issue for trade partners. Next, Part II examines relevant provisions in the TRIPs Agreement concerning compulsory licensing, amidst the backdrop of the Paris Convention. Part III briefly explores contrasting policy objectives for the use of compulsory licensing by comparing the perspectives of developing nations and developed nations. Finally, Part IV recommends that future DSB panels strike a balance between the needs of both perspectives to ensure the continued legitimacy of the DSB and the WTO.

I. BACKGROUND

A. COMPULSORY LICENSES

Compulsory licensing is defined generally as the granting of a license by a government to use a patent without the patent-holder's permission. As applied to international intellectual property rights, it allows governments to grant licenses for patent use in situations where the patent-holder is either not using the patent within the country or is not using it adequately. Although compulsory licensing is not a new concept, it recently has received considerable attention.

15. See infra Parts II.B.2 and III (examining ambiguous terminology in TRIPs and the vast spectrum of potential interpretations thereof).
16. See infra Part IV.B.2-3 (opining that balancing the interests of both developed and developing nations will provide the broadest legitimacy to the DSB decision).
17. See Review of TRIPs, supra note 4, at D7 (defining compulsory licenses).
18. See Beeby Lewis, supra note 5, at 845 (applying the definition of compulsory licensing to intellectual property concerns).
19. See Weissman, Symposium, supra note 2, at 3 (noting that compulsory li-
attention as pharmaceutical companies and activist groups seek to advance their respective political agendas over the right to drug access for life-threatening diseases.  

When governments issue compulsory licenses, the result is often a sharp decrease in prices, similar to the introduction of other competitive forces like generic drugs. For this reason, many developing nations argue for the right to issue compulsory licenses for pharmaceuticals that are normally very expensive for their citizens. During the negotiations for the TRIPs agreement, however, most developed nations argued for harsh restrictions on compulsory licenses to safeguard their domestic industries. Thus, an ostensible tension among developing and developed nations is mounting over the use of compulsory licenses.

B. THE EMERGENCE OF THE AGREEMENT ON TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY (TRIPS)

Following many years of uncertainty and discomfort concerning intellectual property, the General Agreement on Trade & Tariffs ("GATT") established jurisdiction over international enforcement licensing is common practice around world, even in the United States). When patent holders apply for and obtain patents, they are aware of the use of compulsory licenses. See id.


21. See AIDS Drugs Policy: Africa Policy Information Center, Afr. News Serv. (BRC) (Sept. 7, 1999) (estimating that compulsory licensing can lower prices of medicines by more than 75%). But see Gianna Julian-Amold, International Compulsory Licensing: The Rationales and the Reality, 33 IDEA 349, 364 (1993) (arguing that a more likely result of issuing compulsory licenses is an increase in profits to the local generic pharmaceutical industry and no decrease in prices for consumers).

22. See Review of TRIPs, supra note 4, at D7 (noting the apprehension of developing nations on losing their right to issue compulsory licenses).


of intellectual property rights in a declaration to promote multilateral negotiations on the topic. Reaching a consensus was not easy. Developing nations consistently questioned the need for an additional multilateral intellectual property agreement, while developed nations aggressively argued the need for a multilateral enforcement body. Many United States pharmaceutical companies closely monitored the negotiations, raising issues and protests whenever patent language did not seem to reinforce their "rights." Influenced by the powerful pharmaceutical lobby, the United States noted its position on pharmaceutical patents by simultaneously punishing nations it believed were lacking intellectual property provisions through the use of the Special 301. Under the Special 301 threat, the United


25. See BLAKENEY, supra note 5, at 3 (providing a historical account of the adoption of the TRIPs agreement).

26. See id. at 4 (noting the many complicating layers involved in constructing the TRIPs agreement).

27. See id. (highlighting the disagreements set forth by India and Brazil for the need of another intellectual property organization aside from the existing World Intellectual Property Organization ("WIPO")).

28. See id. at 7 (outlining the development of the negotiations from the insistence of developed nations, led by the United States).

29. See id. (noting the influence of pharmaceutical companies in the negotiation process); see also Robert Weissman, A Long Strange TRIPs: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Alternatives Available to Third World Countries, 17 U. PA. J. INT’L ECON. L. 1069, 1086-87 (1996) [hereinafter Weissman, A Long Strange TRIPs] (illustrating how pharmaceutical companies characterized pharmaceutical patents as "rights" during legal discussions, thus successfully elevating their status to new moral highs).

30. See Omnibus Trade and Competitiveness Act of 1988, Pub. L. No. 100-418, 102 Stat. 1107 (1988) (codified in multiple sections of 19 U.S.C.). Compare Y. Kurt Chang, Special 301 and Taiwan: A Case Study of Protecting United States Intellectual Property in Foreign Countries, 15 NW. J. INT’L L. & BUS. 206, 228 (1994) (noting the United States policy to use Special 301 and disagreeing with the utility of such unilateral actions), and Weissman, A Long Strange TRIPs, supra note 29, at 1078 (noting the United States primarily has used Special 301 against developing nations that have developed threatening pharmaceutical industries in their own nations), and Robert J. Pechman, Note, Seeking Multilateral Protection for Intellectual Property: the United States "TRIPs" Over Special 301, 7 MINN. J. GLOBAL TRADE 179, 202-03 (1998) (commenting on how, despite the need for the United States to use Special 301, due to the inadequacies in TRIPs, its use violates the WTO Agreements), with Alan C. Swan, "Fairness" and "Reciprocity." in the
States either threatens to or does revoke a nation's Most Favored Nation ("MFN") status until appropriate changes are made to their intellectual property safeguards. Amidst all of the special interests, the TRIPs agreement was adopted at the conclusion of the Uruguay Round in Marrakesh in April 1994.

Creating the WTO and entering into the TRIPs Agreement was a major accomplishment for the reconciliation of trade priorities among both developing and developed nations. Although TRIPs emerged from vivid negotiations, there were high hopes for multilateral methods to trump bilateral bullying. At the onset, it was apparent that TRIPs initially would cost developing countries money, but it also was speculated that the long-term benefits would help nurture the emergence of pharmaceutical industries in developing countries to ultimately reduce the cost of pharmaceuticals.

International Trade Section 301 and the Rule of Law, 16 Ariz. J. Int'l & Comp. L. 37 (1999) (discussing recent changes in Section 301 that make it less of an intrusive instrument and more of an instigator of an open global economy).

31. See Chang, supra note 30, at 206 (noting how the United States uses Section 301 as a stick amidst the carrot of trade privileges).

32. See Blakeney supra note 5, at 7 (pointing out the final signing of the TRIPs agreement).


34. See Marschall, supra note 7, at 1188 (noting high hopes for multilateralism to limit the need for bilateral actions). The author also postulates that the vague and broad exceptions under the TRIPs agreement may have provided incentive for the developing nations to sign the agreement. See id. at 1189.

35. See World Trade Organization-Committee on Trade and Development, supra note 9, at 17 (warning developing nations of new requirements in the text of the TRIPs, which will increase the prices of certain goods, such as pharmaceuticals and agricultural products).

Although TRIPs incorporates portions of the Paris Convention, the Berne Convention, the Rome Convention, and the Treaty on Intellectual Property in Respect of Integrated Circuits,\textsuperscript{17} the patent provisions are notably new to international intellectual property law.\textsuperscript{18} Without terming it such, TRIPs allows for compulsory licensing amidst several provisions in Article 31.\textsuperscript{19}

C. CURRENT CONFUSION OVER COMPULSORY LICENSING: EXAMPLE OF THE RECENT SOUTH AFRICA-UNITED STATES TRADE DISPUTE

1. Overview

Since the inception of the TRIPs Agreement, increasing numbers of intellectual property disputes have been brought before the dispute settlement mechanism.\textsuperscript{40} One issue that has not been argued before into TRIPs and generally enforced by other unilateral acts actually have enabled United States pharmaceutical companies to gain a stronger monopoly on pharmaceutical products and processes around the globe).

37. See TRIPs, supra note 3, Part I, art. 2, sec. 1-2 (noting that members of TRIPs should comply with the Paris Convention and that nothing in TRIPs takes away from existing obligations in the other international treaties); see also Robert J. Gutowski, Comment, The Marriage of Intellectual Property and International Trade in the TRIPs Agreement: Strange Bedfellows of a Match Made in Heaven?, 47 BUFF. L. REV. 713, 720-24 (1999) (discussing the uncertainties inherent in the Paris Convention and the Berne Convention).

38. See McCabe, supra note 23, at 43 (noting the new patent provisions introduced in the TRIPs).

39. See TRIPs, supra note 3, Part II, sec. 5, art. 31 (authorizing laws of a member nation that allow "for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government" under certain conditions); see also World Trade Organization-Committee on Trade and Development, supra note 9, at 18 (articulating to developing countries that, "[d]etailed conditions are laid down for compulsory licensing or governmental use of patents without the authorization of the patent owner").

40. See Robert E. Hudec, The New WTO Dispute Settlement Procedure: An Overview of the First Three Years, 8 MINN. J. GLOBAL TRADE 1, 17 (1999) (finding that the number of disputes brought before the WTO during the first three years of its existence was ninety percent higher than the number of cases brought before the old GATT dispute settlement mechanism). Furthermore, during the first three years of its inception, the number of cases brought against developing nations as defendants has tripled. See id. at 24.
the DSB is that of compulsory licenses. Thus, when South Africa recently introduced legislation to allow the Health Minister to issue compulsory licenses for pharmaceuticals, the United States interpreted those actions to be in violation of intellectual property standards in TRIPs, and threatened trade sanctions. Although the South African government never conceded to any violation of TRIPs, the two governments finally did settle the matter quietly, without the involvement of the WTO’s DSB.

2. South African Perspective

a. Overview of National Health Crisis

Although South Africa has come a long way since its conversion into a new democracy in April 1994, the nation still faces tremendous obstacles in the areas of economic disparities and health care.

41. See World Trade Organization-Committee on Trade and Development, supra note 9, at 18 (declaring that compulsory licensing is allowed under TRIPs). This official declaration supports the view by many that compulsory licensing is clearly legal and need not come before the DSB. But see Review of TRIPs, supra note 4, at D7 (noting that several nations have recently called for a review of TRIPs to clarify the rights of nations on this matter).

42. See Consumer Project on Technology, U.S. Department of State Report: U.S. Government Efforts to Negotiate the Repeal, Termination, or withdrawal of Article 15(c) of the South African Medicines and Related Substances Act of 1965 (visited Sept. 21, 1999) <http://www cptech.org/ip/health/sa/stdeptfeb51999.html> [hereinafter State Department Report on South African Act] (finding that the United States “joined with other USG agencies with trade responsibility to insist on this [Special 301 Watch List] designation in the hope that this special attention would spur South Africa to change or withdraw Article 15(c)”).

43. See infra notes 51, 64 and accompanying text (noting how the two nations resolved their trade perspectives by diplomatic means). But see Simon Barber, U.S. Remains Hostile to South Africa Drugs Act, AFR. NEWS SERV. (BRC) (Sept. 27, 1999) (reporting that the South African Trade and Industry Minister, Alec Erwin, told interviewers that, while an agreement was reached between the two nations concerning the trade policy objectives, the United States has not accepted the trade practices used to achieve those policies).

44. See U.S. Department of State, Background Notes: Republic of South Africa-Released by the Office of Southern African Affairs, Bureau of African Affairs (last modified Feb. 1998) <http://www.state.gov/www/background_notes/southafrica_0298_bgn.html> (noting that in South Africa, “economic disparities between population groups are expected to persist for many years” and “violence against women and children is a serious problem”); see also AIDS Coalition to
One of the greatest threats to the South African population is Auto Immune Deficiency Syndrome (AIDS), currently affecting one-eighth of its citizens.\(^45\) Even more troubling is the lack of advanced medicines available to those affected.\(^46\) Although AIDS-infected citizens in developed nations can receive an array of medicines to delay the onset of symptoms, many physicians in South Africa do not mention those remedies to their patients because they know that the patients cannot afford the drugs.\(^47\)


45. See AIDS Drugs Policy: Africa Policy Information Center, supra note 21 (noting statistics on the infection rate of AIDS in South Africa); see also Peter Hawthorne, A Blighted Generation Southern Africa Has Been Most Severely Hit by AIDS, Leaving Children Orphaned and the Workforce Depleted, TIME INT'L, July 26, 1999, at 57 (reporting that almost twenty percent of South Africa's workforce will likely be HIV positive by the year 2000).

46. See ACT-UP, supra note 44 (explaining that the South African Health Minister came under attack by AIDS activists when she cancelled pilot projects for AZT at prenatal clinics due to a lack of funding). While the epicenter of the AIDS epidemic is occurring in Third World nations, most people there cannot afford the sophisticated drugs used to treat the disease. See id.

47. See PhRMA, More Than 120 New Medicines in Development for AIDS: AIDS Death Rate Down 16 Percent from '95 to '96 (last modified Nov. 1997) <http://www.phrma.org/facts/phfacts/11_97a.html> [hereinafter PhRMA: New Medicines] (reporting that the new breakthroughs in AIDS medications are enabling sufferers in the United States to live longer lives with fewer infections). According to PhRMA, the number of AIDS-related deaths plunged twenty-six percent from 1995 to 1996 due to new combination drug therapies and better access to health care. See id. Cf. William Dowell, Ethics and AIDS Drugs: Some Countries Want to Suspend Patent and Trade Laws to Get Lower-cost Medications to the Poor, TIME MAG., July 12, 1999, at 49 (speculating that the AIDS virus may soon be reduced to a chronic disease instead of a deadly disease, due to the influx of pioneering pharmaceutical breakthroughs).

48. See Debra Rosenberg & John Barry, No Money, No Meds: South Africa Needs Access to Cheap AIDS Medicine, But Drug Companies Want a Say in What They Get and How They Get It, NEWSWEEK, July 12, 1999, at 32 (reporting how doctors at Rietvlie Hospital in the Eastern Cape do not disclose the availability of AIDS treatments, as a gesture of kindness to their dying patients who would not be able to afford the pharmaceuticals on their meager incomes); see also ACT-UP, supra note 44 (estimating that the average South African income nears $2600/year while the cost of the pharmaceuticals manufactured in the United States is near $12,000/year); Claire Bisseker, SA in Race to Develop an Affordable Vaccine: AIDS Research, FINANCIAL MAIL at 38 (Feb. 5, 1999) (reporting that the triple cocktail therapy is not affordable to the South African population).
b. Medicines & Related Substances Act

Responding to the AIDS crisis in 1997, the South African Parliament proposed the Medicines and Related Substances Control Amendment Act,\(^49\) which would allow the South African Health Minister to override patent rights to allow compulsory licensing and parallel importing.\(^50\) By issuing compulsory licenses, the Health Minister hoped to reduce the price of influential AIDS pharmaceuticals and make them more affordable to the population.\(^51\) Notably, the stated purpose of the Amendment was to reduce the cost of pharmaceuticals to protect the health of the public.\(^52\)

South Africa had good reason to believe that the issuance of compulsory licenses would cause prices to decrease for desperately needed pharmaceuticals.\(^53\) Several other nations have used this

---


The Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular may―(a) notwithstanding anything to the contrary contained in the Patents Act, 1978 (Act. No. 57 of 1978), determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine, or with his or her consent.

\(^{50}\) See State Department Report on South African Act, supra note 42 (describing the effect of the proposed South African Amendment on patent rights for pharmaceuticals).

\(^{51}\) See Governments of South Africa and the USA Reach Joint Agreement, South African Press Association (Sept. 18, 1999) (quoting Tshediso Matona, Director for Bilateral Trade Relations in the Department of Trade and Industry, as saying that the agreement would enable ordinary people to buy medicines cheaply).

\(^{52}\) See Republic of South Africa, supra note 49 (stating that the Minister may decree situations where cheaper drugs are needed).

\(^{53}\) See Nathan Ford & Daniel Berman, AIDS and Essential Medicines and Compulsory Licensing 2 (visited Oct. 15, 1999) <http://www.cptech.org/march99-cl/report1.html> (finding that the AIDS drug AZT costs $239 per month in the United States while costing only $48 per month in India, where pharmaceutical production currently is unregulated).
method successfully, even at the disapproval of highly industrialized nations.\textsuperscript{54}

3. United States' Perspective

a. General Objections to Compulsory Licensing

However, the United States strongly opposes the issuance of compulsory licenses for many reasons.\textsuperscript{55} The United States has discouraged the use of compulsory licenses for various altruistic reasons, including the promotion of scientific research and development industries in developing nations, the protection of the sick population from inappropriate administration of potent pharmaceuticals,\textsuperscript{56}

\textsuperscript{54} See BLAKENEY, supra note 5, at 4-6 (noting many nations who have infringed on patent restrictions to enable the use of expensive pharmaceuticals); see also Beeby Lewis, supra note 5, at 859-64 (noting that multiple nations are in dispute with the United States for violating pharmaceutical patent provisions); cf. Vicente, supra note 36, at 1132 (noting how discarding its ability to use compulsory licenses drove up the cost of pharmaceuticals in Canada, estimated to cost the nation an extra $7 billion by the year 2010).

\textsuperscript{55} See infra notes 56-59 and accompanying text (highlighting the wide array of excuses, both protectionist and altruistic).

\textsuperscript{56} See Vicente, supra note 36, at 1131 (noting how the United States has justified its position against compulsory licenses by referring to the need to help develop a science and technology infrastructure for pharmaceuticals in developing nations). But see Aphaluck Bhatiasevi, Experts Fear Impact From WTO Terms: Poor Could Be Denied Access to New Drugs, BANGKOK POST, Aug. 19, 1999, at 4 (noting that the TRIPs agreement has not encouraged transfer of technology of pharmaceutical companies into Thailand, but instead encouraged importing of expensive drugs from monopolies in Western societies); cf. DOMINIQUE FORAY, Knowledge Distribution and the Institutional Infrastructure, in INTELLECTUAL PROPERTY RIGHTS AND GLOBAL COMPETITION: TOWARDS A NEW SYNTHESIS 85-87 (Horst Albach & Stephanie Rosenkranz eds., 1995) (noting that any patent policy based entirely on creating vast new innovations, without acknowledging the importance of collaborating existing knowledge to develop smaller steps along the path, automatically leads to re-enforcement of the patent-holder's protection).

\textsuperscript{57} See REP. CALLAHAN, FOREIGN OPERATIONS, EXPORT FINANCING, AND RELATED PROGRAMS APPROPRIATIONS BILL, H. REP. NO. 105-719, at 33 (1998) (expressing the concerns of the House Appropriations Committee that the compulsory licensing scheme of Section 15(c) of the Medicines and Related Substances Act threatens the health of South Africans by potentially allowing sub-standard and counterfeit products to be placed on the market). But see ACT-UP, supra note 44 (acknowledging the issue of pharmaceutical safety and noting that it is better monitored as a regulatory issue instead of a trade issue).
and the allegiance to international treaties enforcing the policy of intellectual property rights. Yet, the most consistent complaint by the United States is that compulsory licenses violate international intellectual property law proscribed in the TRIPs agreement.

b. Confusing Legal Objections With Policy Objections to Compulsory Licensing

The USTR's response to South Africa's proposed amendment confirmed the United States' opposition to compulsory licensing. On the one hand, threatened sanctions were not surprising given the immense financial threat that compulsory licenses present to United States pharmaceutical companies. Nonetheless, the manner in which the USTR set forth its objections revealed how the pharmaceutical industry has exerted pressure on the United States to adhere to a different standard other than that agreed in the international TRIPs agreement. As a result rampant confusion currently exists in

58. See 145 Cong. Rec. H6027 (daily ed. July 21, 1999) (statement of Rep. Gilman) (asserting that the implementation of section 15 (c) would put the United States in violation of TRIPs for failing to "seek the strengthening of intellectual property laws").

59. See Actions by United States Trade Representative, 19 U.S.C. sec. 2411 (d)(3)(i)(II)(1994) (authorizing the United States Trade Representative to take actions to protect against unreasonable acts, which "denies fair and equitable provision of adequate and effective protection of intellectual property rights notwithstanding the fact that the foreign country may be in compliance with the specific obligations of the Trade Related Aspects of Intellectual Property..."); see also State Department Report on South African Act, supra note 45 (stating that "Nevertheless, United States Government experts determined that provisions of Article 15 (c) authorize action clearly inconsistent with South Africa's obligations under TRIPs").


61. See Weissman, A Long Strange TRIPs, supra note 29, at 1075-1077 (highlighting the aggressive nature of the pharmaceutical industry's lobbying in Washington, D.C. and the numerous government bureaucrats with prior experience in powerful positions of pharmaceutical companies).

62. See Ford & Berman, supra note 53, at 2 (quoting Lois Boland of the United
United States Government agencies over the legality of compulsory licensing in TRIPs.\textsuperscript{63}

4. A Negotiated Settlement, Absent the Influence of the WTO

Recently, the United States and South Africa resolved their trade disagreement through bilateral political negotiations,\textsuperscript{64} attracting unflattering claims that the United States was using its economic power to bully the developing nation.\textsuperscript{65} In the agreement, the United States

\textsuperscript{63} See Intellectual Property: U.S. Cites Problems with India’s Patent Law; No Plans to File Complaint, 16 Int’l Trade Rep. 759 (BNA) (May 5, 1999) (quoting United States Ambassador to the WTO, Rita Hayes as saying, “[t]he United States believes that the TRIPs agreement does not permit WTO members to grant compulsory licenses or impose other exceptions or limitations on exclusive marketing rights”); see also CPT’s Letter to Cong. Black Caucus, supra note 60 (quoting Lois Boland of the United States Patent and Trademark Office, “[A] compulsory licensing provision in a given law that would affect certain categories of inventions, such as pharmaceuticals, would not be consistent with Article (a) of Article 31, which requires that ‘authorization . . . shall be considered on its individual merits.’”). But see id. (quoting the text of a letter from Vice President Gore to James E. Clyburn, which states that South Africa’s efforts to enhance health care for its population may include compulsory licensing as long as they comply with international agreements).

\textsuperscript{64} See Department of Trade and Industry, Joint Understanding Between the Governments of South Africa and The United States of America (visited Sept. 18, 1999) <http://vww.polity.org.za/govdocs/pr/1999/pro9176.html> (noting that the resolution to the trade dispute between South Africa and the United States was resolved through the exchange of views of both governments); see also Office of the United States Trade Representative, Executive Office of the President, United States-South Africa Understanding on Intellectual Property (visited Sept. 18, 1999) <http://vww.ustr.gov/releases/1999/09/99-76.html> (highlighting the new understanding between the governments and asserting that the United States is committed to helping South Africa solve its AIDS problem). But see Activists Look Gore Out of His Office, Afr. News Serv. (BRC) (Aug. 25, 1999) (noting the speculations by AIDS activists that the Clinton Administration insisted upon compulsory licensing concessions only for AIDS drugs and not for other needed pharmaceuticals, despite the fact that the exact trade agreement arrangements have not yet been disclosed).

\textsuperscript{65} See Int’l Trade Daily News, supra note 6, at D8 (reporting the condemnations of the United States and the EU by Medecins Sans Frontiers Health Action International, ACT-UP for adopting provisions to prevent developing nations from implementing compulsory licensing schemes).
agreed to relax its trade pressures on South Africa by acknowledging the special circumstances inherent in the AIDS epidemic. While both nations reaffirmed their policy objectives to mutual satisfaction, it is unclear if the United States' position actually acknowledged the legality of compulsory licensing or whether it merely backed down due to harsh political pressure. Consequently the higher authority of the DSB did not resolve the question of whether compulsory licenses are legal under the TRIPs and no precedent was set for future disputes.

II. ANALYSIS OF COMPULSORY LICENSING IN TRIPS

To fully appreciate the current debate ensuing about compulsory licensing for pharmaceuticals, it is necessary to analyze the treatment of the subject in the international agreement, TRIPs. A full analysis includes a summary of the relevant portions of the Paris Convention as it applies to the compulsory licenses provision in TRIPs and the language describing the use of compulsory licenses finally adopted in TRIPs.

---

66. See Barber, supra note 43 (noting the mutual policy goals of upholding intellectual property rights and achieving affordable health care).

67. See Activists Look Gore Out of His Office, supra note 64 (reporting that AIDS activists accused Vice President Al Gore of implementing a political face-saving measure by allowing South Africa to use compulsory licensing, while raising questions of how this issue may be applied to other nations). During a Congressional Hearing, Joe Popovich, a representative from the USTR, stated that the administration was willing to relax the trade policy against compulsory licensing for only AIDS drugs. See id. See also James Love, Five Common Mistakes by Reporters Covering the US/South Africa Disputes Over Compulsory Licensing and Parallel Imports 1 (last modified Sept. 23, 1999) <http://www.cptech.org/ip/health/sa/mistakes.html> (finding that among several mistakes made by the press was the idea that South Africa backed down and abandoned plans to permit compulsory licensing, when it was the United States that ended its trade pressures).


69. See DSU, supra note 8, art. 3(2) (noting the role of the DSB is "... to preserve the rights and obligations of Members under the covered agreements, and to clarify the existing provisions of those agreements in accordance with customary rules of interpretation of public international law"); see also Vienna Convention on the Law of Treaties, art. 31.2, opened for signature May 23, 1969, 1155 U.N.T.S. 331 (entered into force Jan. 27, 1980) [hereinafter Vienna Convention] (specifying
A. PARIS CONVENTION

The TRIPs Agreement notes that its patent provisions must comply with the Paris Convention of 1967.70 Under the Paris Convention,71 the term "patent" is interpreted broadly to encompass all forms of patent laws created within its member nations.72 At the outset, the Paris Convention sought to eliminate unequal treatment by any nation's domestic laws toward foreign patent holders through the "National Treatment" provision in Article 2.73 For example, the Convention promulgated that it be necessary to treat foreign patent holders equally for patent fees, patent terms, and the time period within which the patent holder must work the patent to avoid the granting of compulsory licenses.74

In addition, the Paris Convention contains limited and controver-

70. See TRIPs, supra note 3, Part I, art. 2, secs. 1-2 (noting that the Paris Convention applies to Parts I, III, IV of the agreement).


72. See id. at 20 (defining patent in Article 1, sec.4 as including "various kinds of industrial patents recognized by the laws of the countries of the Union"); see also STEPHEN A. BENT ET AL., INTELLECTUAL PROPERTY RIGHTS IN BIOTECHNOLOGY WORLDWIDE 400-01 (1987) (noting that the definition is purposely broad to include all types of industrial patents).

73. See Paris Convention, supra note 71, at 20 (stating that in Article 2 that nationals of any member country of the Convention shall enjoy the rights included under any other member nations' laws); see also Gutowski, supra note 37, at 718 (distinguishing the concept of "national treatment" from the concept of "reciprocal treatment," where foreign parties in a nation only receive equal treatment as compared to how foreigners are treated in their own nation).

74. See BENT ET AL., supra note 72, at 401-02 (finding that these were the very concepts for which developing nations did not want to provide equal treatment for foreign patent holders). But see Mayer, supra note 36, at 382 (asserting the negative role of the national treatment provision in the Paris Convention). National treatment allowed member nations to implement very low levels of intellectual property protection as long as foreigners were treated similarly, thus opening the door for nations like Brazil to eliminate all domestic patent protection. See id. at 382.
sional terms for the regulation of compulsory licenses. Under the Paris Convention, compulsory licenses are permitted to solve the problem of underutilized patents. Notably, the Convention creates time restrictions before an application for a compulsory license can be submitted and creates limitations of licenses when the patentee can justify insufficient usage. Yet, the language concerning the justifications for inaction is vague, leaving room open for alternative interpretations.

B. WTO TRIPS DOCUMENT

Complementing the language in the Paris Convention, TRIPS never mentions the phrase "compulsory license" throughout its text. Yet, Article 31 describes an allowable exception to patent enforcement in language implying compulsory licensing.

75. See BLAKENEY, supra note 5, at 89 (noting that Article 5A of the Paris Convention was one of the most controversial parts of the agreement).
76. See Paris Convention, supra note 71, at 24 (stating in Article 5, sec. A(3) that the problem of misuse also can be addressed by forfeiture of the patent, but only after the compulsory licenses process has been attempted).
77. See id. at 24. Article 5, sec. A(4) states:

A compulsory license may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four years from the date of filing of the patent application or three years from the date of filing of the grant of the patent, whichever period expires last; it shall be refused if the patentee justifies his inaction by legitimate reasons. Such a compulsory license shall be non-exclusive and shall not be transferable, even in the form of the grant of a sub-license, except with that part of the enterprise or goodwill which exploits such license.

Id.; see also BLAKENEY, supra note 5, at 89 (defining the legitimate reasons as those pertaining to legal, economic, or technical hurdles to utilizing the patent).
78. See BLAKENEY, supra note 5, at 89 (finding that the provisions are unclear).
79. See CPT's Letter to Cong. Black Caucus, supra note 60 (noting that while TRIPS do not contain the phrase compulsory license in its terminology, trade experts agree that it allows for compulsory licensing in Article 31); see also BLAKENEY, supra note 5, at 90 (noting that there is no specific reference to the reasoning of inadequate use of patent, as made in the Paris Convention).
80. See TRIPS, supra note 3, Part II, sec. 5, art. 31. The relevant text reads:

Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following
1. Conditions for Compulsory Licensing

Article 31 sets forth a series of guidelines member nations must respect prior to implementing compulsory licenses.\(^8\) Section (a) notes that authorization of compulsory licensing should be considered on its merits.\(^8\) Section (b) conditions the granting of compulsory licenses on an initial attempt to obtain authorization by the patent holder through commercial terms and failure to obtain an agreement within a reasonable amount of time.\(^8\) Furthermore, this provision permits waivers in situations of national emergency or extreme urgency.\(^8\) Section (c) limits the use of the compulsory licensing scheme to the purpose for which it was initially authorized.\(^8\) Section (d) notes that the compulsory license will not be exclusive\(^8\) and Section (e) notes that it will not be assignable.\(^8\) Section (f) prescribes that use of the license shall be predominantly for domestic market use.\(^8\) Section (g) authorizes use of compulsory licenses only during the time that the circumstances for its creation still exist, and “competent authority” shall have the power to review the continuation of the compulsory licenses.\(^8\) Section (h) ascribes proper payment to the patent holder, based on the economic value of the compulsory licensing scheme.\(^9\) Section (i) notes that the decision to authorize compulsory licenses is subject to judicial review\(^9\) and Sec-

---

\(^8\) See id. art. 31(a)-(l).
\(^8\) See id. art. 31(a).
\(^8\) See id. art. 31(b).
\(^8\) See TRIPs, supra note 3, Part II, sec. 5, art. 31(b).
\(^8\) See id. art. 31(c).
\(^8\) See id. art. 31(d).
\(^8\) See id. art. 31(e).
\(^8\) See id. art. 31(f).
\(^8\) See id. art. 31(g).
\(^9\) See TRIPs, supra note 3, Part II, sec. 5, art. 31(h).
\(^9\) See id. art. 31(i).
tion (j) explains that the payment to the patent holder is also subject to judicial review by a "distinct higher authority in that member". Finally, Section (k) comments that special consideration should be given in cases where the patent holder is engaged in anti-competitive acts.

2. Ambiguous Terminology

Essentially, Article 31 provides for a distinct balancing act, establishing a government's right to issue compulsory licenses, while attempting to safeguard the rights of the patent-holder whenever possible. Some analysts have suggested that Section (h) set forth the greatest controversy in the Article 31 language due to its ambiguity on the issue of determining the proper economic value of the compulsory license. While this Section arguably necessitates the strongest use of the balancing test to weigh the economic concerns of the patent holder against the economic capabilities of the license grantor, it is not beyond the ability of the DSB to do so.

Yet, the ambiguous language in Article 31 that is likely to cause most of the debate over compulsory licensing is the vague use of the

---

92. See id. art. 31(j).
93. See id. art. 31(k). Article 31 concludes with provision (I), which applies to second patent issues. See id. art. 31(I).
94. See Weissman, A Long Strange TRIPs, supra note 29, at 1113 (commenting that the conditions in Article 31 provide little difficulty for establishing an efficient compulsory licensing scheme).
95. See TRIPs, supra note 3, Part II, sec. 5, art. 31(c), (d), (e), and (g) (outlining strict restrictions for use of compulsory licenses, notification procedures, and royalties to benefit the patent holder).
96. See Weissman, A Long Strange TRIPs, supra note 29, at 1114 (finding that provision (h) provides a critical obstacle to adopting a compulsory licensing program for a developing nation).
97. See id. (noting that there is no single economic value of a compulsory license).
98. See World Trade Organization-Committee on Trade and Development, supra note 9, at 19 (highlighting the features of the new dispute settlement mechanism as contributing to the impartiality and legitimacy of the DSB). The DSB uses a negative consensus approach so that a consensus is needed to halt the proceedings instead of continuing them, and there is also the opportunity for an appellate review of any decision before the panel's decisions become binding. See id.
terms "circumstances" in Sections (b) and (g) and "purpose" in Section (c). First, the requirement to obtain permission from the patent holder is waived in cases of national emergency or "other circumstances of extreme urgency." Section (g) notes that the licencing scheme should end when the "circumstances which led to it" conclude. Similarly, Section (c) limits the duration and scope of the compulsory license to the "purpose for which it was authorized."

The essential problem is that the factors contributing to the legitimate need to issue compulsory licenses are not fully developed within the text of Article 31. Without clarity in the language, nations are likely to evade the issue of compulsory licensing, fearful of the unknown.

While the WTO has yet to consider the issue of compulsory licenses for patents in relation to Article 31, it has mentioned the term in two panel decisions regarding the marketing of patents in Pakistan and India on other matters. As the WTO endeavors to es-

99. See TRIPs, supra note 3, Part II, sec. 5, art. 31(b) and (g).
100. See id. art. 31(c).
101. See id. art. 31(b) (emphasis added).
102. See id. art. 31(g) (emphasis added).
103. See id. art. 31(c) (emphasis added).
104. See Marschall, supra note 7, at 1188-89 (characterizing the ambiguous language in TRIPs as nebulous and full of loopholes).
105. See id. at 1193 (demonstrating how one drawback of a flexible approach to TRIPs language is that it may create uncertainty for member nations).
106. See TRIPs, supra note 3, Part VI (providing for additional time allotments to developing nations to pass appropriate legislation and regulations to meet the TRIPs agreements). Yet, under Article 65, a nation is obliged to ensure that any changes its government undertakes do not result in a lesser degree of complicity with the TRIPs agreement. See id. TRIPs Part VI, art. 65(5); see also Weissman, A Long Strange TRIPs, supra note 29, at 1084 (implying that the immense frustration regarding the delay exhibited by the developing nations evidenced their victory in the negotiations).
107. See First Submission of the United States of America: India Patent Protection for Pharmaceutical and Agricultural Chemical Products, 1997 WL 113721, at *1 (W.T.O. Mar. 6, 1997) (finding that India modified some of its legislation concerning compulsory licenses for marketing of pharmaceuticals at the urging of the United States); see also Gutowski, supra note 37, at 742 (noting that the India-United States case was a landmark case because it was the first case to go through the entire dispute resolution process of the WTO); Notification of a Mutually-
tablish itself as a legitimate multilateral body, capable of impartial
dispute resolution mechanisms,\textsuperscript{108} it would be a great mistake for the
DSB to yield to pressure from the pharmaceutical companies on
matters of compulsory licensing.\textsuperscript{109} Yet, the WTO cannot assist a de-
developing country to justify its issuance of compulsory licenses if the
developing nation maintains a submissive disposition toward harsh
political pressure from developed nations.\textsuperscript{110} Therefore, the time is
ripe for the WTO's dispute settlement mechanism to decipher the
ambiguous terms that outline the legality of compulsory licenses un-
der TRIPs, Article 31.\textsuperscript{111}

---

Agreed Solution: Pakistan Patent Protection for Pharmaceutical and Agricultural
Chemical Products, 1997 WL 371039, at *1 (W.T.O. Mar. 7, 1997) (noting that the
United States and Pakistan arrived at a settlement on granting patents to relevant
pharmaceuticals and agricultural products). The United States convinced Pakistan
to prohibit the use of compulsory licenses for exclusive marketing rights under
certain criteria in that country. See id. at *2. The agreement materialized only after
Pakistan requested further consultations when the United States requested a WTO
panel investigation. See Gutowski, supra note 37, at 739.

\textsuperscript{108} See Hizon, supra note 9, at 122 (highlighting the new more litigious
method invoked by the WTO's DSU). The author notes that to ensure compliance
by Members to its decisions, the DSU has adopted a judicial quality of formality
and finality. See id. at 123; see also supra note 87 (stating the enhanced procedures
under the new DSB).

\textsuperscript{109} See Steve Charnovitz, Participation of Nongovernmental Organizations in
that, while NGO's are not allowed to participate in the work of the World Trade
Organization currently, they should be allowed to present the interests of the entire
world).

\textsuperscript{110} See Vicente, supra note 36, at 1108-10 (commenting on how the imposition
of unilateral sanctions by the United States under "Special 301" of the 1988 Trade
Act required Argentina to change its pharmaceutical patent policies above and be-
{}yond what TRIPs requires); see also Chang, supra note 30, at 230 (concluding that
the success of the TRIPs and the WTO depends upon whether developed nations
can abstain from imposing unilateral sanctions on nations to meet their standards
of intellectual property rights). But see John M. Wechkin, Comment, Drug Price
Regulation and Compulsory Licensing for Pharmaceutical Patents: The New Zea-
solution to reduce the cost of pharmaceuticals in developing nations by imple-
menting price control measures).

\textsuperscript{111} See Review of TRIPs, supra note 4, at D7 (reporting that several developing
nations have called for clarifications of TRIPs by the WTO on the issue of compul-
sory licensing).
III. THE POTENTIALLY WIDE RANGE OF INTERPRETATION OF AMBIGUOUS LANGUAGE IN ARTICLE 31

Without expressly defining the perimeters of the categories in Article 31, there is great room for different interpretation of the ambiguous terms surrounding the issuance of compulsory licenses. A brief review of the specific objectives favored by the parties most likely to bring the issue of compulsory licenses before the DSB could help illuminate the possible scope of interpretation of the language in TRIPs. While developing countries are likely to favor a broad and open interpretation of the conditions in Article 31, this perspective will likely clash with the more narrow and restrictive interpretation by developed nations.

A. DEVELOPING NATIONS

Amidst the backdrop of multiple urgent problems present in developing nations, the leaders must develop a unique approach to compulsory licensing. Taking into account their domestic laws concerning intellectual property rights, it is realistic to expect that the actions of developing nations will support the immediate concerns of

112. See Marschall, supra note 7, at 1189-90 (noting that the current TRIPs agreement allows broad interpretation of compulsory licensing justifications due to its ambiguous language).

113. See Gutowski, supra note 37, at 748-50 (setting forth the human rights debate over intellectual property between developing nations and developed nations). While developed nations believe that intellectual property indeed is a human right, the perspective of many developing nations rejects that idea. See id. at 747. The history in many developing nations encompassed a more communal approach to development, allowing other pressing community concerns to trump individualistic intellectual property rights. See id. at 747, 749.

114. See Chang, supra note 30, at 214-15 (noting the different intellectual property values held by developing nations and developed nations). In many developing nations, the short-term benefits of compromising high intellectual property standards are more apparent than any long-term benefits. See id. at 214.

their population’s needs in formulating a new policy.\textsuperscript{116}

Developing nations are likely to argue for a broad interpretation to pave the way for easier implementation of compulsory licensing.\textsuperscript{117} The arguments of developing nations facing staggering health challenges support the idea of morality in international trade practices.\textsuperscript{118} Developing nations generally believe that the economic injury complained of by the pharmaceutical companies in developed nations should have no bearing on the right to receive adequate health care.\textsuperscript{119} For these nations, compulsory licenses should be available for any health concern where there exists a pharmaceutical capable of either curing or postponing the disease.\textsuperscript{120} Thus, they believe that the moral exception argument should dictate the broad use and implementation of compulsory licenses under the TRIPs Article 31.\textsuperscript{121}

\textsuperscript{116} See Chapter 2, sec. 27 Bill of Rights of Constitution of the Republic of South Africa Act 108 of 1996 (ensuring the right to have access to health care services for South African citizens and mandating that the government must take reasonable measures to realize this right). By placing health care within the Bill of Rights, the South African government has an affirmative duty to protect the health concerns of its population. See id.

\textsuperscript{117} See discussion supra Part.C.1 (noting that developing nations have many other challenges to concern themselves besides patents).

\textsuperscript{118} See Rosemary J. Coombe, Intellectual Property. Human Rights & Sovereignty: New Dilemmas in International Law Posed by the Recognition of Indigenous Knowledge and the Conversation of Biodiversity, 6 IND. J. GLOBAL LEGAL STUD. 59 (1998) (discussing the social justice implications of intellectual property rights). But see Weissman, A Long Strange TRIPs, supra note 29, at 1088 (noting how the pharmaceutical industry created their moral twist on the intellectual property debate by characterizing patents as "rights").

\textsuperscript{119} See Ford & Berman, supra note 53, at 3 (pronouncing the strong distaste that physicians in developing nations have for the manipulated trade laws seeking to place economic value of drugs over health of their patients); see also supra note 49 and accompanying text (outlining the language in the proposed South African legislation, which notes that the main purpose behind the Amendment is to provide adequate health services to its citizens).

\textsuperscript{120} See World Health Organization, Essential Drugs (visited Nov. 17, 1999) <http://www.who.org/aboutwho/en/ensuring/essential.htm> (finding that the WHO Essential Drug Programme endeavors to “... ensure that all people, wherever they may be, are able to obtain the drugs they need at the lowest possible price; that these drugs are safe, effective, and of high quality; and that they are prescribed and used rationally”).

The justification for the developing nation's perspective would likely arise out of the exclusions noted in Article 27 of TRIPs. Article 27 provides exceptions for patents in cases where Members wish to protect public order and morality, including the protection of human life. In this case, the purpose for utilizing compulsory licenses for AIDS pharmaceuticals is as simple as saving lives.

In fact, this was the position that the South African government adopted in the recent dispute. As mentioned earlier, the express purpose of the Medicines and Related Substances Control Amendment Act was to protect the health of the public. Thus, as phrased, it is impossible to divorce the Act's economic implications from its moral imperative.

---

122. See TRIPs, supra note 3, Part II, sec. 5, art. 27 (providing exceptions to the patent enforcement outside of compulsory license provisions).

123. See id. TRIPs Part II, sec. 5, art. 27. This provision reads:

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

Id.

124. See PhRMA: New Medicines, supra note 47 (highlighting the vast number of new AIDS drugs being investigated for FDA approval and the effects of such drugs on the lives of sufferers).

125. See supra notes 50-52 and accompanying text.

126. See supra Part I.C.2.b (discussing the South Africa's recent attempts to legalize compulsory licensing).

127. See Henry Anrys, Medical Ethics and Human Rights, in THE HUMAN RIGHTS, ETHICAL AND MORAL DIMENSIONS OF HEALTH CARE: 120 PRACTICAL CASE STUD. 55, 57 (European Network of Scientific Co-operation on Medicine and Human Rights, 1998) (showing that a right to health often encompasses an economic right to access to adequate resources by illustrating the ethical conflict in the current AIDS epidemic). But see Garcia, supra note 121, at 52 (arguing that tension between rigid moral entitlements and flexible economic rights presents an increasing danger of undoing human rights-based justice).
B. DEVELOPED NATIONS

On the other side of the debate, developed nations are likely to argue for a narrow interpretation to limit the use of compulsory licenses, especially for pharmaceuticals.\(^{128}\) Developed nations may be fearful that even seemingly minor health risks will be interpreted as extremely urgent, allowing for a wave of compulsory licenses for pharmaceuticals.\(^{129}\) A massive tide of licenses certainly would adversely impact the profits for the pharmaceutical industry,\(^{130}\) arguably hurting the ability of those companies to research and develop any new drugs.\(^{131}\) Again, this is the position that the United States adopted during the recent dispute with South Africa.\(^{132}\) Yet, no developed nation wants to be placed in the situation of arguing that an easily treated health concern is not an urgent concern for all of humanity.\(^{133}\) Again, without knowing if “circumstances” or “purpose”

---


129. See id. at 33 (quoting Rep. Callahan who asserts that the proposed amendment, Section 15 (c) of the South Africa Medicines & Related Substances Act, creates a disturbing precedent for the deterioration of intellectual property rights in South Africa).

130. See PhRMA, Backgrounders: What’s At Stake in Seattle (visited Nov. 18, 1999) <http://www.phrma.org/facts/bkgrndr/seattle.html> (estimating that the American pharmaceutical industry loses somewhere from $6 billion to $9 billion each year due to international trade barriers like government intervention in the marketplace and failure to protect intellectual property).


132. See discussion supra Part I.C.3 (discussing the many reasons that the United States opposes compulsory licenses for pharmaceuticals, including the notion that allowing them would undermine the traditional cycle of the pharmaceutical industry).

133. See Indonesia-Death Refugees: At Least 294 E. Timorese Died in East Nusatenggara, ANTARA INDON. NAT’L NEWS AGENCY (Nov. 11, 1999) [hereinafter E. Timorese] (reporting that diarrhea and respiratory infections were the cause of numerous deaths).
are meant to include broad concerns or very specific concerns, the application of these provisions is difficult to ascertain.\textsuperscript{134}

In addition, it is essential to note that the United States government would not want to seem hypocritical by making blanket assertions that compulsory licensing is illegal.\textsuperscript{135} In the United States, the Government reserves the right to issue compulsory licenses for products, including drugs, that it funds.\textsuperscript{136} In addition, it allows for some types of patent infringements under the doctrine of misuse.\textsuperscript{137}

\textbf{IV. RECOMMENDATIONS}

Amidst the recent confusion, there is hope for solving the compulsory licensing dispute. With the DSB established to form legitimate and binding decisions regarding TRIPs issues,\textsuperscript{138} an interpretation of Article 31 could provide a compromise solution between both sides.

\begin{footnotes}
\item[134] See discussion \textit{supra} Part I.C (debating the vast possibilities in interpreting the TRIPs language).
\item[135] See \textsl{CPT's Letter to Cong. Black Caucus}, \textit{supra} note 60 (suggesting that the United States and the EU would be hypocritical by insisting on an unconditional rejection of compulsory licenses under Article 27 of TRIPs because both have codified their own compulsory licensing schemes).
\item[136] See March-in Rights, 35 U.S.C. sec. 203(1)(b) (1984) (limiting the scope of patents created with federal assistance by reserving the right to grant a compulsory license for the patent if it is necessary to alleviate health or safety needs which are not being met by the patent-holder); see also 17 U.S.C. sec. 115 (1984) (outlining the provisions for issuing compulsory licenses for phonorecords).
\item[137] See \textsl{Mallinckrodt v. Medipart}, 976 F.2d 700 (Fed. Cir. 1992) (holding that the criteria for applying the doctrine of misuse depends on whether the patentee's "restriction is reasonably within the patent grant, or whether the patentee has ventured beyond the patent grant and into behavior having an anti-competitive effect not justifiable under the rule of reason"); see also \textsl{Note, Is the Patent Misuse Doctrine Obsolete?}, 110 HARV. L. REV. 1922 (1997) (debating whether the equitable doctrine of misuse should be replaced by reliance on antitrust laws, ultimately postulating that a greater reliance on the misuse doctrine is preferred). But see Theo Bodewig, \textsl{On the Misuse of Intellectual Property Rights, in INTELLECTUAL PROPERTY RIGHTS AND GLOBAL COMPETITION: TOWARDS A NEW SYNTHESIS}, 247 (Horst Albach & Stephanie Rosenkranz eds., 1995) (establishing that, according to the European Court of Justice, the denial of a license alone does not constitute misuse). Yet, when a company participates in discriminatory practices designed to prevent competitors from market access, the Court effectively has issued compulsory licenses for IBM products. See \textit{id.} at 248-49.
\item[138] See discussion \textit{supra} note 12 (acknowledging recent criticisms of the DSM).
\end{footnotes}
by balancing the scope of its application between broad moral interests and narrow protectionist interests.\textsuperscript{139} Although the trade tensions between developed and developing nations may never fully be eliminated, a resolution of the compulsory licensing issue in Article 31 of TRIPs may restore trust and encourage stronger trade relationships between both sides.

A. THE NEED FOR DISPUTING PARTIES TO BRING THE ISSUE OF COMPULSORY LICENSING BEFORE THE DSB

Because of the high stakes and increasing confusion involving compulsory licensing, the time has come for disputing parties to bring the issue of compulsory licensing before the WTO’s DSB.\textsuperscript{140} It is essential that parties debating the issue of compulsory licensing bring the dispute before the DSB instead of continuing to rely on diplomatic measures to resolve their disputes.\textsuperscript{141} Realistically, it is apparent that developed nations have a much easier time relying on their unilateral trade sanctioning measures to achieve their desired results.\textsuperscript{142} Developed nations are not likely, therefore, to risk a bind-

\begin{itemize}
\item \textsuperscript{139} See discussion infra Part IV.B.2 (opining that striking a balance between the needs of all nations is the best solution to maintain legitimacy for the WTO and resolve future disputes).
\item \textsuperscript{140} Compare TRIPs, supra note 3, Part VI, art. 65, sec. 4 (suggesting that developing nations are immune from dispute settlement procedures for five years from the signing of the Treaty), with \textit{id.} art. 65, sec. 5 (mandating that a Member who categorizes itself under the immunity in sec. 4 “shall ensure that any changes in its laws, regulations and practice made during that period for not result in a lesser degree of consistency with the provisions of [TRIPs]”). Thus, if the United States truly believes that South Africa is breaching its obligations under TRIPs, it could bring the matter before the DSB even if South Africa claimed its status was a developing nation. \textit{See id.} But see Pechman, supra note 30, at 202 (asserting that by invoking unilateral measures through the Special 301, the United States may violate the WTO Agreements). Thus, South Africa could bring the matter before the DSB to allege illegal use of threatened unilateral trade sanctions of a matter falling under the jurisdiction of the WTO. \textit{See generally id.} at 206-07 (speculating on the case of the United States being a defendant before the DSB).
\item \textsuperscript{141} See Nicole Telecki, Note, \textit{The Role of Special 301 in the Development of International Protection of Intellectual Property Rights After the Uruguay Round}, 14 B.U. INT’L L.J. 187, 215-18 (1996) (discussing how the United States assured members of the DSU negotiations that it would utilize the DSB for resolution of WTO issues, in exchange for the drafters to leave out a provision to prevent nations from using unilateral means like the Special 301 to resolve WTO issues).
\item \textsuperscript{142} See Beeby Lewis, \textit{supra} note 5, at 853-54 (exploring the success of bilat-
ing negative decision by bringing the disputes before the DSB.\footnote{144} Indeed, developing nations present the best chance for challenging those unilateral measures.\footnote{144} By bringing a compulsory licensing dispute before the DSB, they stand to gain legitimacy in their compulsory licensing schemes and international recognition for paving the road for other developing nations and potential trading partners to create similar mechanisms.\footnote{144} The only potential harm in bringing the matter before the DSB is the potential risk of damaging their relationships with important trading nations.\footnote{146} Nonetheless, developing nations have strong motivation for taking the lead on the compulsory licensing issue.

B. THE DSB MUST REVIEW AND CLARIFY THE LANGUAGE IN ARTICLE 31 OF TRIPS

The most practical method the WTO could implement to resolve the current atmosphere of uncertainty surrounding compulsory licensing is for the DSB to clarify the language of the compulsory licensing provisions for short term dispute settlements). The author cites a study by the Institute for International Economics, reporting that the use of Special 301 has yielded at least partially successful outcomes in almost half the instances when it was invoked. See id. at 853.

\footnotetext[143]{143. See id. at 854 (noting how bilateral negotiations are usually more efficient, more timely, more flexible, and generally more beneficial for the United States).}

\footnotetext[144]{144. See Pechman, supra note 30, at 206 (noting that under a stronger dispute resolution system, developing nations may not be as intimidated from bringing cases against developed nations before the DSB).}

\footnotetext[145]{145. See Van Der Borght, supra note 12, at 1223, 1225 (relating how most WTO members articulate their general overall satisfaction with the DSM). The author notes how nations have found the system to be credible, predictable, impartial, and objective, thus legitimizing the DSB’s decisions for all parties involved in international trade. See id. at 1225.}

\footnotetext[146]{146. See Carlos A. Primo Braga, Industrial Property Rights and Private Sector Development: Lessons for Developing Countries, in STRATEGIC ISSUES OF INDUSTRIAL PROPERTY MANAGEMENT IN A GLOBALIZING ECONOMY: ABSTRACTS & SELECTED PAPERS 23, 29 (Thomas Cottier et al., eds. 1999) (suggesting that compliance with high standards of intellectual property protection will foster increased trade in developing nations). Conversely, risking political relationships may adversely affect trade relations between developing nations and their developed nation trading partners. See also discussion supra note 30 (exploring the United States’ liberal use of Special 301 and trade sanctions). But see Hizon, supra note 9, at 126 (noting that although unilateral mechanisms still exist, that their use will only undermine the philosophy of the multilateral WTO).}
censing provisions in Article 31 of TRIPs. In doing so, the DSB could either define the language in Article 31 as bright line language, which sets a rigid standard of either a broad or narrow interpretation for justifying the licenses, or it could devise a compromise between both sides by basing its interpretation of the ambiguous language in Article 31 on the concept of “inadequate usage,” enshrined in the Paris Convention. This would focus the DSB’s decision on procuring a strong definition of “inadequate usage” and would allow subsequent decisions to be decided on a case-by-case analysis.

1. The Legitimacy of the DSB May Be at Risk by Assuming an Extreme Position

The first option is to take an extreme position by implementing a hard line approach, which would encourage criticism over the DSB’s role as an impartial multilateral agency. Under the first option, the WTO could implicate a very strict interpretation of Article 31 and rule that any exceptions for compulsory licenses must not prejudice the rights of the patent holder, as deemed reasonable by the patent holder. This would likely trigger the denunciation of TRIPs by many developing nations. On the other side, the WTO liberally could allow compulsory licensing under Article 31. Additionally,

147. See Hizon, supra note 9, at 124 (noting how the member nations of the WTO have legitimized the DSB by bringing a substantial number of trade disputes before it to be settled).

148. See Vienna Convention, supra note 69 (noting the exact manner in which treaty language should be interpreted). But see Marschall, supra note 7, at 1190 (opining that the best solution to resolving the problem of ambiguous language in Article 31 is to limit the use of compulsory licensing to instances of antitrust or anticompetition violations).

149. See supra notes 77, 78 and accompanying text (exploring the room for interpretation of “inadequate usage” in the Paris Convention).

150. See discussion infra Part IV.B.2 (discussing the need for a strong, but balanced approach to defining “inadequate usage”).

151. See infra note 157 and accompanying text (examining how the narrow interpretation of language like “inadequate usage” that outlines the purpose of issuing compulsory licenses may affect the broader decision regarding the legality of compulsory licenses).

152. See BLAKENEY, supra note 5, at 4 (noting the fragile acceptance of TRIPs by developing nations).

153. See WTO Appellate Body Report on the United States-Standards For Re-
this would risk its stance as a multilateral agency, for developed nations would likely pursue other bilateral options rather than allow the WTO to decide matters.  

2. Striking a Balance Between the Needs of Both Developing and Developed Countries is the Best Approach

The best alternative for the DSB in determining limits for allowing compulsory licenses is to first suggest specific criteria that it will use in calculating the legitimacy of a nation’s purpose for using compulsory licensing, by balancing the interests of both developed and developing nations. As noted earlier, the Paris Convention allowed compulsory licenses in situations where the patent-holder was inadequately utilizing those rights within another country. If this is still the case under TRIPs, then the WTO needs to define what it considers to be “inadequate usage.” The question remains whether “in-
adequate usage” includes instances when a patent holder, like a pharmaceutical company, does not market a drug in a specific country because the cost-benefit analysis would not yield a favorable result and would harm the company. In addition, it is unclear whether “inadequate usage” includes instances where the pharmaceutical company does market a drug in a developing country, but keeps the prices high and unaffordable to a majority of the population. Without guidelines for interpretation, the meaning of “inadequate usage” remains unclear.

A compromise between these definitions suggests the best option is to balance the interests of both developed and developing nations. The WTO should permit compulsory licenses for cases of “inadequate usage” of all pharmaceutical patents for drugs used to treat life-threatening diseases, which affect a significant portion of a nation’s citizens and are not available to those affected through the current market practices. Although this may raise questions concerning what constitutes a life threatening disease, the burden will be on the license-seeking nation to prove the relevant circumstances. Furthermore, using this definition of “inadequate usage” would define the concepts of “national emergency” or “case of extreme ur-

158. See The North American Free Trade Agreement Implementation Act-Chapter Seventeen: Intellectual Property, A(5) (1993) (defining the requirement to “work” a patent under NAFTA as satisfied when a patented product is merely imported into a country). Thus, it is likely that developed nations would take a conversely narrow approach to what constitutes “inadequate usage.”

159. See infra note 167 and accompanying text (highlighting the need for the DSB to devise a compromise in the spirit of keeping a “proper balance between the rights and obligations of members”).

160. See Garcia, supra note 121, at 63 (opining that international economic law must defer to international human rights on some levels, including rights involving life and freedom).

161. See E. Timorese, supra note 133 (describing how many E. Timorese died of respiratory illness and diarrhea). But see World Health Organization, The World Health Report 1999: Mortality By Sex, Cause, and WHO Region (visited Nov. 16, 1999) 1 <http://www.who.org/whr/1999/en/pdf/mortality.pdf> (calculating that 4.8% of the population of low and middle income WHO member states died of diarrhea in 1998, and that only .1% of the population in high income member states died of the same disease). This shows that what may be considered a dangerous and deadly disease in one nation may not be considered a threat in another nation, due to access to medications. See id.
gency” noted in Article 31 (b).  

3. Approaching Royalties Through Consensus is the Most Realistic Approach

To satisfy developed nations and their industries that stand to lose a great deal of money from such practices, the WTO should require a consensus from both sides as to the duration of the license and the royalties to be paid to the patent-holder. While some scholars have asserted that it only makes sense for the sum of royalties to be determined by the developing nation, this is an idealistic approach. In order to satisfy the concerns of politically powerful pharmaceutical companies in developed nations, it is imperative to offer some concession. In order to prevent the risk of negotiations wasting valu-

162. See Blakeney, supra note 5, at 91 (noting that it was initially suggested by the United States that the exception should read “declared national emergency”). While this would make the definition more clear-cut, it would still be subject to the decisions of each nation’s government whether such a declaration was necessary. See also Chapter 2, sec. 37 Bill of Rights of Constitution of the Republic of South Africa Act 108 of 1996 (restricting the invocation of a declared state of emergency). It is important to note that some nations, like South Africa, restrict the declaration of a state of emergency to protect its citizens from the human rights abuses that were allowed historically under such a declaration. See Nicholas Haysom, Emergency, in FUNDAMENTAL RIGHTS IN THE CONSTITUTION: COMMENTARY & CASES 321, 325 (Nicholas Haysom et al. eds., 1997) (articulating how specific provisions for declared states of emergency under the new South African Constitution were necessary to protect citizens from arbitrary acts, such as martial law and extra-judicial killings).

163. See AIDS Drugs Policy: Africa Policy Information Center, supra note 21 (pointing out that whether the pharmaceutical companies stand to lose money in developing countries is arguable, since they do not profit much with their current high prices).

164. See Bodewig, supra note 137, at 249-50 (noting that the European Court of Justice has interpreted excessively high royalties and royalties extending for an excessive time period to be a violation of intellectual property rights under the misuse doctrine). This may serve as a deterrent to patent-holders attempting to spoil negotiations by insisting on unreasonably high royalties.

165. See Weissman, A Long Strange TRIPs, supra note 29, at 1114 (noting that logic dictates the developing country, or the country in need of the license, should dictate the value of the compulsory license because if it were the other way around, the patent holder would issue the license without compulsion).

166. See AIDS Drugs Policy: Africa Policy Information Center, supra note 21 (noting that pharmaceutical companies urgently insist that they require cash flows to fuel the research and development schemes to develop more pharmaceuticals).
able time and money to both sides, the final decision on royalties will be left with the WTO’s DSB. Thus, if the sides do not quickly come to a resolution on the matter within a specific time restraint, each side should be required to submit a proposal to the DSB. At that juncture, the WTO would formulate a fair decision.

CONCLUSION

While the framers of TRIPs may have believed at the time that the issue of compulsory licenses was well defined, the opposing perspectives are bound to face off at some point in the near future. It is essential that the WTO is prepared to handle the matter quickly and efficiently, as the issue of compulsory licenses is of great concern to those standing to lose immense sums of money in the pharmaceutical industry and, more importantly, by those who await medical treatments for life-threatening diseases in developing nations. Although the recent tensions between the United States and South Africa have been temporarily resolved, it took two and a half years for both sides to settle the dispute. Now is the time for the WTO to embrace the issue of compulsory licensing and take necessary steps to assure both sides of the debate that reasonable solutions can be made through the DSU.

Interestingly, the article notes that the two most controversial AIDS pharmaceuticals to be considered for compulsory licensing were created at the National Institute of Health with taxpayer funds. See id.

167. See DSU, supra note 8, art. 3(3). The DSU provision notes that regarding the resolution of disputes:

The prompt settlement of situations in which a Member considers that any benefits accruing to it directly or indirectly under the covered agreements are being impaired by measures taken by another Member is essential to the effective functioning of the WTO and the maintenance of a proper balance between the rights and obligations of members.

Id.

168. See John H. Jackson, The WHO Dispute Settlement Understanding-Misunderstandings on the Nature of Legal Obligation, in DISPUTE RESOLUTION IN THE WORLD TRADE ORGANIZATION 69, 73 (James Cameron & Karen Campbell eds., 1998) (noting that while a decision by the DSB may not necessarily be “binding” in the traditional sense, the decisions by the DSB do create an international law obligation to perform the act proscribed in the decision).