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# Shifting the Power to Define Intellectual Property Rights: The 1998 South African Case, Developing Nations and TRIPS

## Introduction

The *Agreement on Trade Related Aspects of Intellectual Property* (TRIPS) was incorporated into the World Trade Organization (WTO) in 1994 at the request of developed nations who argued that intellectual property rights were not properly protected in the emerging globalized business world. Developing nations did not want intellectual property rights (IPRs) to be included in the WTO, but were won over by concessions in other trade areas. The TRIPS agreement does three main things: 1) it established minimum international standards on the protection of intellectual property: 2) it prescribes procedures and solutions that are to be available within Member states to enforce these rights: and 3) it extended the basic GATT principles of transparency and non-discrimination to IPRs[1]. Unlike most multinational agreements, according to point 2) above, TRIPS provides positive prescriptive changes that nations must make to domestic practices and procedures. This has made the agreement "the most comprehensive international agreement on intellectual property to date" because of its breadth and "its near-universal applicability"[2] and surrounded it in controversy. In recent years, the TRIPS agreement has undergone some important changes. Though its inception was closely tied to the interests of the developed world and powerful

[1] Bernard M. Hoekman & Michel M. Kostecki. *The Political Economy of the World Trading System: The WTO and Beyond*. ( Oxford, New York: Oxford University Press, 2001), 285

[2] Jayashree Watal "Implementing the TRIPS Agreement" in *Development, Trade, and the WTO: A Handbook*. Editors: Bernard Hoekman, Aaditya Mattoo & Philip English (US: The World Bank, 2002), 359

multinational companies in the pharmaceutical and film industries, since 2001 the agreement has evolved to become more responsive to the needs of the developing world over the wants of the developed.

Since 2001 the power structure of the members of TRIPS has arguably shifted from the developed to the developing world. This shift is largely the result of the dropping of a high profile lawsuit filed against the South African Government in 1998 by 39 major Pharmaceutical Companies, lead by the Pharmaceutical Manufacturers Association of South Africa (PMA). The lawsuit attempted to argue that the newly enacted South African *Medicines and Related Substances Control Amendment Act* (*Amendment Act*) had violated the TRIPS agreement. A close examination of the *Amendment Act*, the lawsuit and the TRIPS Agreement reveals that not only is the *Amendment Act* not in violation of the TRIPS Agreement but that the lawsuit has little to no basis within it. The dropping of the case by the pharmaceutical industry was recognition that there was no basis to their allegations. The failure of the pharmaceutical companies[3] to win the lawsuit led to a shift in the 'power to define' terms within the

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[3] The 39 Pharmaceutical companies, mostly subsidiaries of multinational pharmaceutical companies, are: The Pharmaceutical Manufacturers' Association of South Africa, Alcon Laboratories (S.A.) (Proprietary) Limited, Bayer (Proprietary) Limited, Bristol-Myers Squibb (Proprietary) Limited, Byk Madaus (Proprietary) Limited, Eli Lilly (South Africa) (Proprietary) Limited, Glaxo Wellcome (South Africa) (Proprietary) Limited, Hoechst Marion Roussel Limited, Ingelheim Pharmaceuticals (Proprietary) Limited, Janssen-Cilag Pharmaceutica (Proprietary) Limited, Knoll Pharmaceuticals South Africa (Proprietary) Limited, Lundbeck South Africa (Proprietary) Limited, Merck (Proprietary) Limited, MSD (Proprietary) Limited, Novartis South Africa (Proprietary) Limited, Novo Nordisk (Proprietary) Limited, Pharmacia & Upjohn (Proprietary) Limited, Rhone-Poulenc Rorer South Africa (Proprietary) Limited, Roche Products (Proprietary) Limited, Schering (Proprietary) Limited, Schering-Plough (Proprietary) Limited, S.A. Scientific Pharmaceuticals (Proprietary) Limited, SmithKline Beecham Pharmaceuticals (Proprietary) Limited, Universal Pharmaceuticals (Proprietary) Limited, Wyeth (Proprietary) Limited, Xixia Pharmaceuticals (Proprietary) Limited, Zeneca South Africa (Proprietary) Limited, Bayer AG, Boehringer-Ingelheim International GmbH, Boehringer-Ingelheim KG, Bristol-Myers Squibb Company, Byk Gulden Lomberg, Chemische Fabrik GmbH, Dr. Karl Thomae GmbH, Eli Lilly and Company, F. Hoffman-LaRoche AG, Merck KGaA, Merck & Co., Inc., Rhone-Poulenc Rorer S.A., SmithKline Beecham

newly implemented and vaguely worded TRIPS Agreement from the developed members of the WTO to those in the developing world. This shift in power produced the *Doha Declaration on TRIPS and Public Health* (*Doha Declaration*) and the 2003 waiver of Article 31 (f). In this thesis, I argue that this shift codified a new way of interpreting the TRIPS agreement in favor of developing nations. This codification will affect future disputes regarding developed and developing nations within the TRIPS agreement.

## Brief Background on the South African Case, the TRIPS Agreement and North-South Relations

In order to examine the South African case and its implications, it is necessary to understand some fundamental developments. In 1997, the Government of South Africa passed the *Amendment Act*. The Act was passed in an attempt to utilize the safeguards in the TRIPS agreement for the production or purchasing of cheaper drugs if needed for national health crises. This new legislation sparked heated protest among the world's pharmaceutical companies who felt it was a violation of the TRIPS agreement, of which South Africa was a signatory. In 1998 thirty-nine pharmaceutical companies launched a lawsuit against the government of South Africa and the *Amendment Act*. South African state law prohibits the enacting of legislation that is involved in litigation. Thus, until the lawsuit was settled the *Amendment Act* could not be enacted within domestic law. The major point of contention for the pharmaceutical companies was the addition of Article 15C, which gave the Minister of Health the power to supply "more affordable medicines in certain circumstances"[4] deemed worthy by the Minister. The lawsuit claimed that this degree of Ministerial power was in direct conflict with Article 27 of TRIPS. The

[4] *Medicine and Related Substances Control Amendment Act (Amendment Act*). Section 10 introducing Section 15C, 10 Available: http://196.36.153.56/doh/docs/legislation/acts/1997/act90.pdf last accessed December 12, 2005

governments of the developed nations supporting the PMA argued that more sections than just 15C were in violation of TRIPS. Between the lawsuit brought by the pharmaceutical industry and complaints made by the US, France, Switzerland and Germany, the entire act came under fire as a violation of intellectual property rights.

The case against the *Amendment Act* in the High Courts of South Africa rested on the pharmaceutical companies' ability to prove that the act threatened a patent holder's ability to regain financial investments. In 2001, the case was postponed and subsequently dropped. The dropping of the case occurred after the Treatment Action Campaign (TAC) was named *amicus curiae* ("friend of the court"). TAC is a non-governmental organization that whose main objective is to campaign for more affordable HIV/AIDS medicine for South Africans living with the disease. In 2001, TAC was ready to release publicly, as evidence, a report on the financing of research and development (R&D) of major pharmaceutical companies. This report would have undermined the PMA's claim that they received no subsidization for the creation of HIV/AIDS medication. The report would have also made obvious the extent of which prices were inflated by the pharmaceutical companies from the price of production.

There are two main issues surrounding compliance to the TRIPS agreement for developing nations. Implementation costs of enacting the TRIPS agreement is the first. These costs are often seen as being two-fold. The first part is the cost of domestic restructuring in order to bring domestic laws into conformity with the agreement and the strengthening of domestic institutions to handle the new regulations. The second cost is the rent-transfer that occurs, which is expected, especially in the short- term, to amount to a considerable amount of money transferred from developing to developed nations in the

form of royalties and rent-costs paid to copyright and patent holders in developed countries[5]. Disagreement over what is to be covered under patents is the second major issue regarding developing nations and TRIPS. The developing world argues that the definition of things allowed to be patented is too broad within the TRIPS agreement. The breadth of the current wording has meant that many processes and products vital to the developing world for health, industry and trade have been patented. A related issue is the debate as to whether or not some WTO countries or regions should be allowed to remain outside the TRIPS agreement, at least until they have accomplished a certain specified level of development. While many scholars have discussed the above issues of TRIPS compliance for developing nations, none had foreseen the potential for developing countries to redefine the agreement in terms beneficial to themselves, thus creating an agreement more sensitive to developing nations' needs. In general, there are two broad schools of thought regarding the relationship between TRIPS and developing nations. The first is that exemplified by Michael P. Ryan, who argues that indigenous "innovation and expression activity could be better encouraged by protection of intellectual property rights than by piracy and other violations"[6]. This is what I call the liberal economic optimist perspective, which relies on the idea that TRIPS, as it was intended by developed countries, will eventually bring about innovation and invention in the developing world.

The second school of thought generally believes there is no hope for positive revision or growth of TRIPS to make it applicable or beneficial to developing nations and their problems. Constantine Michalopoulos argues that the "TRIPS agreement poses

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[5] Hoekman & Kostecki, 290

[6] Michael P. Ryan *Knowledge Diplomacy: Global Competition and the Politics of Intellectual Property*. (Washington, D.C., US: Brookings Institution Press, 1999), 142

serious problems for many developing countries"[7] in that it restricts them and hinders development rather than encouraging it. A variant of this approach is Donald G. Richards' argument, that opposition to the TRIPS agreement and the international order it supports has caused, and will continue to cause, developing countries to work together to create a common critical voice of the developed world. Thus, according to Richards the good of the TRIPS agreement is not found in the ability of developing nations to work within it, but in the cooperation between these nations resulting from its opposition. These authors both agree that the dismantling of the TRIPS agreement is in the best interest of the developing world.

The TRIPS agreement, like other WTO agreements, is a legal framework whose implications "will be decided by the resolution of disputes"[8] and legal cases involving it. One of the most important legal cases regarding the TRIPS agreement was the lawsuit against the South African government. Some authors have recognized the importance the South African case has had on North-South relations dealing with IPRs[9]. However, none have fully acknowledged that the case was about defining concepts and setting precedents, and that the pharmaceutical industry's loss of the case was a major turning point in who had the ability to define key concepts and set important precedents within TRIPS. For example Debora Halbert and Christopher May argue that some sort of shift or evolution has occurred due to the South African case. They view the South African case as a watershed which has ultimately brought to the forefront deep questions regarding the legitimacy of an international IPR regime such as TRIPS. According to

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[7] Constantine Michalopoulos. *Developing Countries in the WTO*. (N.Y., US: PALGRAVE, 2001), 131, 148
[8] K. Balasubramaniam "Access to medicines and Public Policy Safeguards Under TRIPS" in *Trading Knowledge: Development Perspectives on TRIPS, Trade and Sustainability*. Edited Christophe Bellman, Graham Dutfield, and Ricardo Meléndez-Ortiz. (US: Earthscan Publications, 2003), 139
[9] Authors such as Debora Halbert & Christopher May, and David Barnard

these two authors the AIDS crisis in general has "fundamentally weakened the legitimacy of the TRIPS Agreement"[10]. Halbert and May see the *Doha Declaration* as a sign that the neo-liberal view of the role of IPRs in international economic relations is shifting. This shift, according to them, is towards a recognition and establishment of issues of health care and human rights within the IPR framework. Their argument is partially correct in that the shift that has occurred has had a greater emphasis on issues of health care and human rights within the TRIPS agreement. However, I will argue that they fail to recognize how fundamental the shift really was.

David Barnard takes a view more in line with the argument in this thesis. He argues that the South African case was a watershed in that the pharmaceutical companies were afraid of the precedent the *Amendment Act* would present to other developing nations. Thus if they wished to maintain control they had to set a legal precedent. According to Barnard, the legal issues underlying the case were never truly tested and it was the negative publicity and cooperation of the developing world that led to the collapse of the lawsuit. While he does argue that the PMA's position was at best weakly supported by TRIPS, he does not view the dropping of the lawsuit itself as a victory or precedent in favor of South Africa and developing nations. Barnard instead views the *Doha Declaration* as the "resounding and unambiguous legal victory"[11] solely for the South African government. Nonetheless, Barnard's argument that the legal issues underlying the case were never tested is also only partially correct. Because the case was dropped, there was no decisive court ruling that could be used as a legal precedent in the

[10] Debora Halbert & Christopher May. "AIDS, Pharmaceutical Patents and the African State: Reorienting the Global Governance of Intellectual Property" in *The African State and the AIDS Crisis*. Edited by Amy S. Patterson (England: Ashgate Publishing Limited, 2005), 197
[11] Barnard, 166

future. However, a careful examination of the texts of the *Amendment Act* and the lawsuit's Notice of Motion in comparison to the relevant sections of the TRIPS agreement, will show that there was no basis for the suit to have been won. Dropping the lawsuit was recognition by the pharmaceutical companies' that it had no basis. This recognition has led to a greater shift in principle and practice than Barnard acknowledges, as we discuss in the final 2 sections of this thesis.

## The South African *Amendment Act* and Lawsuit: Alleged Challenges to the TRIPS Agreement

To demonstrate that the pharmaceutical companies had no basis to their lawsuit within the TRIPS agreement, this thesis will show that no part of the *Amendment Act* was in violation of the TRIPS agreement. If that is true, then the lawsuit filed could not have any solid basis in claiming that a specific section of the act was in violation of the agreement. This examination will be done in two sections; the first examining the *Amendment Act* and its compliance with TRIPS, the second section will examine the Notice of Motion and its claims that the *Amendment Act* violated the TRIPS agreement.

Before examining the *Amendment Act* and the Notice of Motion and their connections to the TRIPS agreement it is important to define some key terms; exhaustion, parallel importing, and compulsory licensing. Exhaustion refers the ending of an IPR right upon first sale of the object of the IPR on the market. In other words "once the IPR-holder has sold the product covered by the IPR, the IPR-holder cannot thereafter have any control on the later stages of the marketing of the product" or the sale, or exportation of the product[12]. Parallel importing is when a country imports a patented medicine, not a

[12] Bhagirath Lal Das. *The World Trade Organization: A Guide to the Framework for International Trade*. (NY, US: Zed Books Ltd, 1999), 360

generic, from someone other than the patent holder or person authorized. Products imported in this fashion are seen as having been purchased off of the grey market, a market that is not illegal but is not fully covered by the law either. Parallel importing is only possible with right exhaustion, because it is the exhaustion of rights that allow the buying of patented medicines from a third party without it still being under the control of the patent holder. Compulsory licensing is when a country forces the authorization of a patent holder for a product. Thus, instead of using the product illegally the country forces the patent holder to authorize its use.

There are many sections of the original *Medicines and Related Substances Control Act of 1965* that the *Amendment Act* amended. This thesis focuses on the sections that directly relate to issues of IPR protection and, in particular, to the three main issues of exhaustion, parallel importing, and compulsory licensing. These were the big issues at the heart of the dispute between the pharmaceutical Companies, the developed nations backing them, and the South African Government. This narrows the examination to four sections of the *Amendment Act*, namely these are Sections 1, 15, 22, and 35. While the lawsuit filed only specifically mentions Section 15C as being in violation of the TRIPS agreement it is important to examine the other sections due to their connection to 15C, and because developed nations backing the lawsuit claimed the entire *Amendment Act* as being in violation of TRIPS.

Though the amendments made to section one deal mainly with the redefining of terms in the domestic context, there are two amendments in this section that relate to the international IPR regime laid out by TRIPS. The first is the amendment made to subsection *(j)* (2), which stipulates that the subsection shall be subject to the provisions of

Section 15C. Subsection *(j)* (2) basically states that two medicines, though they may be identical in components, physical characteristics, quantity and quality, will not be considered the same medicine if the holder of the certificate of registration (patent) for one of the medicines has not applied for "registration issued in respect of [the] other medicine"[13]. In other words, an identical version of a patented medicine will not be considered the same as the patented medicine unless the patent holder has registered it as such, thus identical generic medicines would not be automatically considered the same medication as the patented version, and this is subject to the terms of Section 15C which will be discussed later. The TRIPS agreement itself lays out that a person or persons who wishes to hold a patent in more than one country, must register and obtain patents in each individual country. Thus, Subsection *(j)* (2), without reference to Section 15C, is not in violation of TRIPS.

The second amendment in connection with IPRs is the addition of subsection (*k)* to Section 1. Subsection *(k)* states that "International tendering for medicines shall be allowed in the prescribed manner and on the prescribed conditions"[14]. This means that the selling, purchasing, and importation of medicines is allowed in certain conditions, which are not specified in the Act. The addition of this subsection also does not appear to be in opposition to the TRIPS regime. The way in which the TRIPS agreement is implemented into domestic law is up to the individual member, and according to most scholars there is considerable flexibility regarding the selling and acquisition of patented items through such legitimate means as price differentiation, parallel importing and

[13] *Amendment Act*, Section 1 Subsection *(j)* (2), 4
[14] Ibid, Subsection (*k*), 4

compulsory licensing[15]. Due to the fact that subsection *(k)* does not specify what is meant by 'prescribed manners' or 'prescribed conditions' it is difficult to evaluate its compliance with TRIPS except that it does not specifically lay out terms in opposition to the agreement.

Amendments made to Section 15 of the *Medicines Act* are the most controversial in terms of their relation to the TRIPS Agreement. Subsection (2) *(b*) states that the registrar shall:

> ensure that such an application in respect of medicine which appears on the latest Essential Drug List or medicine which does not appear thereon but which, in the opinion of the Minister, is essential for national health is subject to such procedures as may be prescribed in order to expedite the registration[16]

In essence, this amendment simply states that medicines thought necessary to national health would be given priority for licensing and registration for their importation or domestic production. This may mean that the medicines are forcibly registered or licensed. Article 8 (1) of TRIPS allows Members to "adopt measures necessary to protect public health and nutrition"[17]. Thus, enabling the registrar to hurry along the process of registration, or licensing, for reasons of national health is in line with the TRIPS agreement.

Section 15C is the most pertinent section for showing that the *Amendment Act* is in compliance with TRIPS due to the fact that it was specifically mentioned in the lawsuit as violating the agreement. Broadly stated, Section 15C declares that the Minister of Health may "prescribe conditions for the supply of more affordable medicines in certain

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[15] Michalopoulos, 134
[16] *Amendment Act*, Section 15 subsection (2) *(b)*, 10
[17] *Agreement on Trade Related Aspects of Intellectual Property Rights* (TRIPS), Article 8 (1), 323 Available: http://www.wto.org/english/docs_e/legal_e/27-trips.pdf last accessed December 12, 2005

circumstances so as to protect the health of the public"[18]. More specifically, Section 15C codifies terms of exhaustion of patent rights in subsection *(a)* by stating that the Minister of Health may determine that rights with regards to medicines under patent within the Republic of South Africa shall not extend to "acts in respect of such medicine which has been put onto the market by the owner of the medicine"[19] or with their consent. In other words, the Minister of Health may determine that medicine bought off the market, not directly from the patent holder, may be resold at a value determined by the South African government, in the name of public health. It also means that the South African Government is able to buy patented medicines from a country other than the patent holder at a lower cost, because the medicine was already placed on the market with the permission of the patent holder and thus their rights had been exhausted.

Article 6 of the TRIPS Agreement addresses the issue of exhaustion. It states that "subject to the provisions of Article 3 and 4 nothing in this Agreement shall be used to address the issue of exhaustion of intellectual property rights"[20]. Article 3 stipulates National Treatment and Article 4 extends the GATT principle of Most-Favored Nation Treatment. Thus, as long as a nation abides by Articles 3 and 4 they are free to have their own provisions in regards to exhaustion of rights[21]. Subsection (*a*) does not discriminate between national or international sales, or between specific countries, thus as long as it used in a non-discriminatory way it is not in violation of TRIPS.

Section 15C subsection *(b)* creates the legal framework for parallel importation, a key point of tension between developed nations, multinational corporations and the

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[18] *Amendment Act* Section 10 introducing Section 15C, 10
[19] Ibid, Section 15C Subsection *(a)*, 10
[20] TRIPS, Article 6, 323
[21] Das, 360

developing world. The section allows for the importation of medicine "which is identical in composition, meets the same quality standard and is intended to have the same proprietary name as another medicine already registered in the Republic… and which originates from any site of manufacture of the original manufacturer"[22] by someone other than the holder of the registration certificate, with approval of the council. In layman's terms it allows for someone other than the person licensed by the patent holder, to import the patented medicine. For instance, if a medicine is created and produced in the US and is also patented in South Africa the Minister of Health can allow for the importation of the medicine from another country, such as India, through a non-licensed importer. As was already mentioned parallel importing is not prohibited within the TRIPS framework.

Subsection *(c)* of Section 15C states that the Minister of Health may "prescribe the registration procedure for, as well as the use of, the medicine referred to in paragraph *(b)*"[23]. In other words the Health Minister may prescribe how a medicine acquired by parallel importation is classified and used within the Republic. Section 15C is, in general terms, entirely dependent on the idea of exceptions to patent laws based on national health needs. The wording of the TRIPS agreement is not specific as to what exceptions are considered acceptable "to protect public health", in cases of "national emergency" or "circumstances of extreme urgency" [24], nor are there definitions given for these key terms. There is however, some flexibility provided by the fact that these terms are included at all, and because they are not defined within the text.

Section 22G of the *Amendment Act* introduces the idea of a transparent pricing system, a particularly sore spot for multinational corporations who do not want their

[22] *Amendment Act*. Section 10 introducing Section 15C subsection *(b*), 10-11
[23] Ibid, Section 15C subsection *(c)*, 12
[24] TRIPS Article 8 (1), Article 31 (b), 323 & 333

financial systems open to the public. Many pharmaceutical companies lobbied the US government for trade sanctions against South Africa on this point. Subsection (2) *(a)* gives the Minister of Health the ability to introduce a "transparent pricing system for all medicines…sold in the Republic"[25]. This transparent pricing system shall include, according to the *Amendment Act*, a single exit price that would "be the only price at which manufacturers shall sell [the] medicines"[26] to anyone other than the state. This exit price would be openly published for consumer knowledge. So, while pharmacists would be allowed to charge a dispensing fee, manufacturers could be forced to sell at a price established by the Health Minister in conjunction with the pricing committee appointed by the Minister.

While TRIPS does not specifically address transparent pricing systems, and while most scholars agree that the TRIPS regime allows for individual members to create their own adequate pharmaceutical regimes[27], it is also true that most abuses of IPRs relate to selling and licensing restrictions[28]. A transparent pricing system with a set exit price for manufacturers could be deemed anti-competitive behavior, as it is de facto price setting. Anti-competitive practices are generally frowned upon within the TRIPS agreement. This can be seen in the fact that the need to correct them is taken into consideration when determining the amount of compensation to be given to a right holder whose exclusivity has been violated. However, the actual wording of Section 22G of the *Amendment Act* does not formally set up a transparent pricing system, it simply states that the Minister,

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[25] *Amendment Act*, Section 14 introducing Section 22G Subsection (2) *(a)*, 26
[26] Ibid, Section 22G Subsection (3) *(a)*, 26
[27] Balasubramaniam, 138-39
[28] Keith E. Maskus. "Benefiting from Intellectual Property Protection" in *Development, Trade, and the WTO: A Handbook*. Editors Bernard Hoekman, Aaditya Mattoo & Philip English. (Washington D.C., US :The World Bank, 2002),375

on recommendation of the pricing committee, *may* make regulations on the introduction of such a system. The allowance for such a system to be created is neither anti-competitive, nor in direct opposition to TRIPS.

Section 22H of the *Amendment Act* specifies the source of medicines wholesalers are to access. Subsection (1) *(a)* states that no "wholesaler shall purchase medicines from any source other than from the original manufacturer or from the primary importer of the finished product"[29]. Subsection (3) of Section 22H stipulates an exception to this rule by laying out that a wholesaler "may in the prescribed manner and on the prescribed conditions be exempted by the Director-General from the provisions of subsection (1)"[30]. Rather than violate the TRIPS agreement, Section 22H instead appears to strengthen it by requiring that major purchasers of medicines buy directly from the original manufacturer or primary importer. Both of which, except under special conditions, are required to have a patent registration or authorization. Subsection (3) simply allows for the already established legitimate exceptions granted by the Minister of Health or the Director-General.

Section 35 (1) of the *Amendment Act* also underwent heavy amendments. Broadly speaking Section 35 (1) lists out the regulations the Minister of Health may make in consultation with the council. A number of the subsections relate to issues of patent rights. According to Section 35 (1) the Minister may make regulations regarding: the classification of persons applying for registration of medicines and transfer of certificates of registration (i), classifications of medicines for the purpose of the *Amendment Act* (iii), providing the circumstances, conditions and persons or categories of persons to which

[29] *Amendment Act* ,Section 14 introducing Section 22H Subsection (1) *(a)*, 26
[30] Ibid, Section 22H Subsection (3), 28

medicine may be sold to (vii), the importation of medicines (xxiv), the conditions in which medicines may be sold (xxxiv), and the safety and quality of imported medicines (xxxviii)[31].

All of the issues discussed above, have an impact on the use of patents and their right holders. Section 35 also allows for the Minister to add, change, appeal or amend any of the subsections in Section 35 and it states that the Minister may make regulations "generally for the efficient carrying out of the objects and purposes of [the] Act"[32] that shall not be restricted by the subsections of Section 35. It has already been shown that the creation of domestic legislature that looks after issues of public health is not in opposition to TRIPS. As long as the legislature abides by Articles 3 and 4, National Treatment and Most-Favored-Nation Treatment respectively, and it does not unfairly interfere with the rights held by the patent holder then it is in compliance with the TRIPS agreement.

After a careful examination of the *Medicines and Related Substances Control Amendment Act* it must be concluded that, with the possible exception of potential for anti-competitive practices, the sections of the Act relevant to IPR protection are in compliance with the TRIPS Agreement. It is repeatedly stated in the TRIPS agreement that Members are allowed exceptions and to create their domestic legislation around concerns for public health. The suspension of rights is also allowed in circumstances of 'national emergency', which at the time of the lawsuit remained an undefined term. Within South African legislation, the *Amendment Act* sets up a framework for dealing

[31] *Amendment Act*. Section 23 substituting Section 35 (1) subsections (i), (iii), (vii), (xxiv), (xxxiv), (xxxviii), 32-36
[32] Ibid. Section 35 (1) subsection (xli), 36

with national health crises. The broad wording in the Act enables flexibility in the government's response depending on the situation

## Part 2: The Lawsuit

A close look at the Notice of Motion's claims and the wording of the TRIPS agreement will show that the pharmaceutical industry had no backing in TRIPS for its claim of violation. The lawsuit against the Government of South Africa was filed on February 18th, 1998 and dropped on April 9th, 2001. The original Notice of Motion had forty-two applicants and ten respondents with the fourth respondent being the Minister of Health (Dr. Zuma, at the time). The majority of the lawsuit focuses on the unconstitutionality of sections of the *Amendment Act*. This study will not discuss these sections and their constitutionality but will instead focus on the part of the lawsuit that specifically mentions the *Amendment Act* as being in violation of the TRIPS agreement.

Section 2.4 of the Notice of Motion declares that Section 10 of the Amendment Act, which introduces Section 15C, claims that the *Amendment Act* is not in compliance with the TRIPS Agreement. It states that Section 15C of the *Amendment Act:*

> is discriminatory in respect of the enjoyment of the patent rights in the pharmaceutical field which discrimination is in conflict with the provisions of Article 27 of the Trade Related Aspects of Intellectual Property Rights Agreement…an international agreement binding the Republic and to which Parliament has given effect by the promulgation of the Intellectual Property Laws Amendment Act, No. 38 of 1997[33]

In other words, the Republic of South Africa as a signatory of the TRIPS Agreement had amended its intellectual property laws in compliance with the agreement but with the

[33] *Notice of Motion*. Section 2.4, 6 Available: http://www.cptech.org/ip/health/sa/pharmasuit.html last accessed December 12, 2005

introduction of Section 15C by the *Amendment Act* had violated the Agreement and domestic law.

In order to show that there is no validity to this charge, it is necessary to take a closer look at Section 15C introduced in the *Amendment Act* in relation to Article 27 of the TRIPS agreement. As has already been shown, Section 15C allows the Minister of Health to determine regulations for exhaustion, and parallel importation. In fact, the South African Government had repeatedly stated that the *Amendment Act* was geared towards parallel importation and not compulsory licensing or exhaustion, though South African Governmental officials began to see the potential for such use as the case wore on[34]. The main focus of the lawsuit, however, was the issue of the allowance of parallel importing in Section 15C.

The PMA attempted to argue that Section 15C created discrimination against a patent holder's rights, which was in violation of Article 27 of the TRIPS agreement. Section 15C allowed for the Minister of Health to shop around and find cheaper drugs through parallel importing, or the importation of medicines "imported by a person other than the person who is the holder of the registration certificate"[35]. This meant that the state did not have to purchase directly from the patent holder but could purchase and import from another country once the medicines had been placed on the market. This has the potential to undercut the patent holders' right to sell or export to whom they wish at a price they wish and to maintain a monopoly on the product's sale and trade. Article 27 of the TRIPS Agreement states that patents and patent rights shall be available "without discrimination as to the place of the invention, field of technology and whether products are imported or locally produced"[36]. Thus, the PMA argument attempted to say that

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[34] James Love. *Report on Court Case over South Africa Medicines Act*. March, 4th 2001, Available Online: http://lists.essential.org/pipermail/pharm-policy/2001-March/000740.html Last Accessed December 7, 2005

[35] *Amendment Act*. Section 10 introducing Section 15C Subsection *(b)*, 12

[36] TRIPS, Section 5 Article 27 (1), 331

parallel importing creates discrimination and undercuts the above-stated rights of the patent holder.

As David Barnard states, the PMA's position was "at best weakly supported, by a close reading of the TRIPS agreement"[37]. While it may be arguable that Section 15C does in fact allow the Minister to discriminate towards importing medicines from an unauthorized source, the PMA argument fails to take into account the effect that Article 6 of TRIPS as well as subsequent articles within Section 5 on Patents, has on their argument. Article 6 of the TRIPS agreement clearly lays out that nothing in the agreement shall address the issue of exhaustion, thereby allowing members to have their own provisions in regards to rights exhaustion. Section 15C subsection *(a)* introduced in Section 10 of the *Amendment Act* clearly lays out the provisions for exhaustion. It states that the Minister may "determine that the rights with regard to any medicine under 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"[38]. In other words, if someone holds a patent for a medicine either imported directly from the manufacturer or an authorized importer into South Africa, and that medicine is sold in another country then the patent holder no longer has rights regarding it. For example if a medicine is manufactured in the United States, and the company holds a patent for it in South Africa, but they sell the patented medicine to a company in India. Then South Africa may buy and import from India, though the Indian distributor may not have any authorization to sell or export the product, because the rights of the patent holder ended with the first sale of the product to the Indian company. This ultimately can allow a

[37] Barnard, 164
[38] *Amendment Act*. Section 10 introducing Section 15C subsection *(a)*, 10

country to buy a product at a price lower than the patent holder may charge for it in their region.

Exhaustion has implications in regards to the limitations on the exclusive rights of right holders[39]. A right holder no longer has control over their product once it has been placed on the market. This could be construed as discrimination against the patent holders rights, which would be in opposition to Article 27. However, Article 6 clearly states that nothing in the agreement shall be used to determine exhaustion, therefore Article 27 cannot be considered in any way as a guideline or restraint on the terms of rights exhaustion.

Thus, in simply examining the complainant's claim that Section 15C violates Article 27 it is a weak claim. While there may be some sort of discrimination against a patent holders' rights in setting up the provisions for a parallel importation system, the allowance of individual Members to set the terms for rights exhaustion negates any discrimination, as the patent holder's rights ended with the first sale of the item according to South African legislation.

The lawsuit continues to lose standing when the claim against Section 15C is examined in the wider context of Section 5 on Patents as a whole. Articles 30 and 31 of the TRIPS agreement allow for exceptions to be made in allowance for patentability. A member state is allowed to create domestic law to use the 'subject matter' of a patent without the patent holder's permission. The guidelines for doing so are laid out in Article 31. Of particular relevance is the exception laid out in Article 31 subsection (b). It states that the state, or the authorized third party, must have made efforts at obtaining "authorization from the right holder on reasonable commercial terms" and that these

[39] Das, 360

efforts must not have "been successful within a reasonable period of time", this requirement, however, may be waived in the event of "a national emergency or other circumstances of extreme emergency" [40]. Section 15C of the *Amendment Act* states that the Minister may determine rights not to be extended, and prescribe conditions for importation and registration in order to "protect the health of the public"[41]

So Article 31 "recognizes the government's right, not only to use [a patent], but also to authorize use by a 'third party'", thereby making the exclusive rights of patent holders laid out in Article 28 non-absolute[42]. The article also specifically mentions cases of national emergency and other circumstance of extreme emergency in which this may be done. Section 15C simply allows the Minister of Health to take steps permitted in the TRIPS agreement to protect public health.

To sum up, the claim against the *Amendment Act* does not have a basis in the TRIPS Agreement. There are many places within the TRIPS Agreement that allow for exceptions based on 'public health', 'national emergency', or other 'extreme emergency'. It is also a fact that the exhaustion of IP rights is left to domestic legislature which is not to be restrained or guided by any article within the TRIPS Agreement. Thus, a claim that Section 15C discriminates against a right holder by laying out the requirements for exhaustion and a system of parallel importing specifically for the protection of public health cannot have a basis in the TRIPS Agreement.

## **How the Case was Decided and the Precedent Set**

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[40] TRIPS. Article 31 (b), 333
[41] *Amendment Act*. Section 10 introducing Section 15C, 10
[42] Narendra B. Zaveri "The TRIPS Agreement and Generic Production of HIV/AIDS Drugs" in *Trading Knowledge: Development Perspectives on TRIPS, Trade and Sustainability*. Edited Christophe Bellman, Graham Dutfield, and Ricardo Meléndez-Ortiz. (US: Earthscan Publications, 2003), 149

Prior to the court case the TRIPS agreement had been defined in terms of what the United States, the global pharmaceutical industry and film industry wanted, as the TRIPS agreement was their initiation. When the PMA dropped the lawsuit, it was because they could not prove that Section 15C set up a system that would discriminate against patent holders' rights beyond what is allowed within the TRIPS Agreement. This was a loss of principle. The PMA had attempted to define the rights of patent holders and Member states in terms of Article 27 as the predominant ideal that other Articles must submit to. In other words they attempted to argue that Articles 6, 8, 30 and 31, which made allowances for Members to safeguard public health, were only to be used in so far as they did not create the discrimination that was prohibited in Article 27. This loss of principle ultimately allowed the developing countries to define the TRIPS Agreement in terms of a Member's rights to utilize the safeguards within the Agreement, and to define explicitly what those safeguards are in the *Doha Declaration*.

In order for the Pharmaceutical Companies to prove that the South African legislation was in violation of TRIPS it had to be proved that the rights of the patent holders would be violated beyond acceptable limits. In terms of patents it is widely accepted that the exclusive rights of the patent holder are granted in order to allow the person or corporation to regain the R&D costs that went into the original creation to begin with, before opening the market to competitors. Thus, the PMA attempted to argue that the discrimination set up by Section 15C was in violation of Article 27 and would ultimately lead to an undercutting of the patent holders' rights to regain R&D costs because purchasers would not be paying the price placed upon the product by the rights

holder. In essence they had to prove that there would in fact be a long and sustained loss of profit if South Africa was able to legitimately parallel import medicine.

Due to the fact that the pharmaceutical industry as a whole is the most dependent on intellectual property and patent protection, the lawsuit was fueled by concern of "the threat to the overall worldwide linkage between patent protection, market share, and long-term profitability" that the South African legislation seemed to pose[43]. In fact, the case that was brought against South Africa was not about immediate loss of profits, as Africa in general only accounts for around 1 % of pharmaceutical sales world wide[44], but about precedent and the power to define in the new IPR regime set up by the TRIPS agreement. If a precedent was set that a country was entitled to parallel import and compulsory license in the name of public health in compliance with the TRIPS Agreement, it may cause numerous more financially relevant countries to enact their own version of the *Amendment Act*. On the other hand if the PMA could prove that this type of legislation was in fact in violation of the TRIPS agreement it would keep the hands of many Member governments tied, making them unable to purchase cheaper medicine from the grey or black markets that provide generic and parallel imported medicines.

The South African Government argued that the *Amendment Act* was simply codifying the flexibility already in place in regards to the TRIPS Agreement for developing nations to utilize safeguards like parallel importing, compulsory licensing and domestically determined rights exhaustion. They also argued that these safeguards were necessary due to the "common universal experience that patents for drugs and medicines

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[43] David Barnard. "In the High Courts of South Africa, Case No. 4138/98: The Global politics of Access to low-Cost AIDS Drugs in poor Countries" *Kennedy Institute of Ethics Journal*. 12 (2 ): 2002, 165
[44] Ibid, 164-5

are [often] grossly abused by right holders", particularly multinational corporations[45]. It is estimated that the price increases for patented drugs range from 5-67% and are variable depending upon the region[46]. The principle they were arguing for was the right to take steps to create systems that allowed for public and national health to supersede patent holder rights.

The pharmaceutical companies, backed by developed nations, countered that an 'Article 30' approach to the TRIPS agreement, allowing for exceptions of patents and suspension of patent rights, would ultimately undermine the Agreement and deter R&D in the developing world[47]. Instead of a full suspension of patent rights for medicines chosen by governments the pharmaceutical industry preferred a temporary waiver solution for some of the diseases[48]. Instead of allowing individual Member governments to decide which medications were vital enough to warrant suspension of patent rights to ,the pharmaceutical industry would create a waiver list within an international agreement specifying the medicines with temporarily waived patents. The pharmaceutical industry and developed nations argued that in principle only very narrow, internationally accepted, and specifically-defined exceptions should be granted in regards to patent rights.

It was also argued by the PMA that a minority of HIV/AIDS suffers were being used by the South African government to justify broadly worded legislation that would violate the TRIPS agreement by allowing parallel imported medicines to be sold in the private sector. Mirryena Deeb, the CEO of the PMA, stated that South Africa had the cheapest drugs of anywhere and that it was not expensive drugs keeping medicine from

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[45] Zaveri, 154
[46] Blasubramaniam, 137
[47] Ruth Mayne. "The TRIPS Agreement and Access to Medicines: an NGO Perspective" in *The WTO and Developing Countries*. Editors: Homi Katrak & Roger Strange (US: Palgrave Macmillam, 2004), 152
[48] Ibid, 152

the sick but government inaction[49]. The PMA also argued that in fact Section 15C would not result in cheaper medicine for a large number of people because the legislation was geared towards the private sector and that in fact the need for cheaper medicine was already being met by price reduction offers from manufacturers. This was evidence, according to the PMA, that the pharmaceutical industry had the know-how and drive to solve the problem of access to medicine and that it should be left in their hands and not in the hands of the developing countries.

On March 6th 2001 the Treatment Action Campaign (TAC) was named *amicus curiae,* and was to supply statements from patients and health care workers to the effect that medicine was not available in the system due to the price. The court was adjourned until April 8th 2001 at the request of the PMA so that they could gather more evidence to counter that given by TAC. When the court resumed, a replying affidavit was given by Theodora Steele, a member of the TAC National Executive Committee, on April 10th 2001. In her statement Steele argued that Section 15C of the *Amendment Act* is "rational, based upon clear government policy and public need" and has a "precedent in other jurisdictions and will have an impact on the price of medicines"[50]. Steele also states that the PMA and TAC agreed that the number of people living with AIDS in South Africa was estimated to be around 4.7 million[51]. A number that does not seem to be the small 'minority' that the PMA accused the South African government of using as an excuse for violating IPRs.

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[49] Zackie Achmat. *A Summary of the Parliamentary Hearings.* TAC Website Available: http://www.tac.org.za/, last accessed December 8, 2005

[50] Theodora Steele. Treatment Action Campaign: Replying Affidavit. April 10th, 2001, Available: http://www.tac.org.za/. last accessed: December 8, 2005, 7

[51] Theodora Steele. "Areas of Agreement". *Treatment Action Campaign: Replying Affidavit*. April 10th, 2001, Available: http://www.tac.org.za/. last accessed: December 8, 2005, 9

The PMA dropped the lawsuit after TAC threatened to publicly release the amount of financial support for the development of AIDS-related drugs that came from the public sector[52]. This would have disproved the claim by the PMA that the brunt of the costs of creating new drugs came from capital investment by the company and that without the monopoly patent rights granted they could not recover R&D costs to be re-invested in the creation of more new drugs.

The PMA had support not only from other members of the Pharmaceutical Industry but also many developed nations, most importantly the US. Thus, when the PMA dropped the case it was not only the Pharmaceutical industry that lost the principle and precedent at stake in the case, it was also the developed nations backing them. In February of 1998, the Pharmaceutical Research and Manufacturers of America (PhRMA) lobbied, along with one of the world's largest pharmaceutical multinational companies, Bristol-Myers Squibb, and the United States Trade Representative (USTR), to designate South Africa as a Priority Foreign country under Special 301 Review. PhRMA argued that "South Africa [had] become a 'test case' for those who oppose the US government's long standing commitment to improve the terms of protection for all forms of American intellectual property including pharmaceutical patents"[53]. Special 301 is a part of US Trade Law that deals specifically with issues of American intellectual property rights and violations in the international market. Countries placed on the Special 301 list may receive trade sanctions against them in the name of IPR violations. On May 1st 1998, South Africa was placed on the Special 301 'watch list' for the *Amendment Act*. In June

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[52] Barton

[53] *APPENDIX B: Time-line of Disputes over Compulsory Licensing and Parallel Importation in South Africa.* August 5th 1999. Available: http://www.cptech.org/ip/health/sa/sa-timeline.txt Last Accessed: December 10, 2005

of the same year US Embassy officials traveled to Midrand, South Africa to express the US's strong negative views on Section 15C.[54]

In February of 1999 the US Department of State sent a report to the US Congress entitled '*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*'. This report described the American issue over Section 15C as a 'bilateral trade conflict' with South Africa. It also states that the provisions in Section 15C are "inconsistent with South Africa's obligations and commitments under the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)"[55]. Thus, the White House through Special 301 and reports such as these was making it quite clear that it did not support South Africa's attempts to utilize the public safeguards within the TRIPS agreement. It was later learned that it was not only the US that had been pressuring the South African government on the *Amendment Act*. France and Germany had both discussed the issue with the South African government privately in an attempt to pressure them into reforming the act.

Due to the fact that the developing world has had issues regarding Article 27 since the inception of the TRIPS agreement, many key terms in the agreement were left undefined in order to conclude the initial negotiations. This meant that Members were given flexibility in their interpretation of the TRIPS Agreement, especially in relation to patents, and the way the agreement was implemented into national law[56]. From the

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[54] *APPENDIX B: Time-line of Disputes over Compulsory Licensing and Parallel Importation in South Africa.* August 5th 1999

[55] *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.* Available: http://legalminds.lp.findlaw.com/list/info-policy-notes/msg00072.html Last Accessed December 10, 2005

[56] Das, 362

beginning, the G-10 had argued that "developing countries should be free to exclude pharmaceuticals…from patent protection"[57], but were persuaded to agree with the promise of safeguards and transition periods. The late 1990s proved to be the first tests of these supposed 'safeguards' with the lawsuit against South Africa's parallel importation scheme and the trade dispute between Brazil and the US over compulsory licensing. When the PMA dropped the case unconditionally it set the precedent that developing nations could utilize the safeguards within the TRIPS agreement. It also shifted the power to define terms within the agreement to developing nations because the terms disputed, such as parallel importing and exhaustion as well as what constituted a national emergency, were central to the South African lawsuit. Thus, when the pharmaceutical companies backed down they capitulated to the South African interpretation of these key terms.

In April of 2001, the pharmaceutical companies dropped the case unconditionally, with assurances from the South African government that the *Amendment Act* would be implemented in compliance with the TRIPS Agreement and that they would be consulted in the implementation process. By this point the lawsuit had become a global debate over the right of developing countries to utilize the undefined flexibility within the TRIPS agreement to create national systems with safeguards in the name of public health. The capitulation of the pharmaceutical Industry was a great victory for South Africa and all developing nations. In short, the South African government had enacted legislation which took advantage of the supposed safeguards present in the TRIPS agreement, had been challenged by big business and developed nations, and had won. The win had not been a legal victory, as the case had been dropped, but the pharmaceutical companies and

[57] Ryan, 110

developed nations involved had lost in principle and a precedent had been set that developing nations were entitled to utilize public health safeguards and to define key terms in favor of themselves.

## Implications for the Future of Developing Countries and the TRIPS Agreement

The shift in the power to define from the developed to developing nations within the WTO and the TRIPS agreement has produced two important documents that codify rules and norms for the interpretation of the TRIPS agreement and disputes within it. The Doha Declaration is perhaps the most important in that it was initiated by the developing world. The second important document is the 2003 Waiver of Article 31(f) of the TRIPS agreement. Together these two documents provide a powerful principle and precedent that has been set by the developing nations of the WTO.

The call for the *Doha Declaration* was lead by the African Group of WTO members, including South Africa and headed by Kenya, as well as sixteen other developing nations. There were four main demands that developing nations forwarded. The first was that TRIPS should not interfere with measures for public health, a condition that was already worded into the original Agreement but which many developing nations felt needed to be reiterated, especially after the challenges it had had in the late 1990's. The second demand was that the transition period for Least Developed Countries be extended to 2016. The third and fourth conditions were that Members be free to determine grounds for compulsory licensing and establish regimes for parallel importing

through exhaustion. These demands were not specifically mentioned in the original text of the TRIPS Agreement but are explicit in the *Doha Declaration* itself.[58]

In early November of 2001, the *Doha Declaration* was finally adopted by the WTO. Adoption of the declaration came after concerns and alternative suggestions, such as the medicine waiver list, were heard from the pharmaceutical industry. The declaration "asserts a member's right to use to the fullest extent the flexibility" found within the TRIPS Agreement in regards to public health[59]. It is also credited with "*reasserting* the rights of developing countries to use parallel importation and compulsory licensing" to deal with health threats[60]. The *Doha Declaration* specifically states that Members have a "right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted" and that each Member is "free to establish its own regime for …exhaustion without challenge" as long as it abides by Articles 3 and 4[61]. Although there is no specific mention of parallel importation, if a country can determine its own guidelines for exhaustion then it can parallel import.

Another key point that the *Doha Declaration* attempts to clarify is that a "Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency"[62]. The PMA had attempted to say that the South African government was using the infection of a minority of people with AIDS as a 'national emergency' to justify the suspension of patent rights, implying that it was not in fact a justifiable 'national emergency' or circumstance of 'extreme urgency'. In effect

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[58] Watal, 362-368
[59] Ibid, 365
[60] Halbert & May, 196
[61] *Doha Declaration on the TRIPS Agreement and Public Health.* Section 5 (*a)*-(*d*)
[62] Ibid, Section 5 *(a)-(d)*

the PMA was attempting to qualify what was to be considered a national emergency worthy of suspension of patent rights.

The fact that developing countries within the WTO banded together and were able to get a declaration adopted that specifically laid out a Member's rights to compulsory license and to determine exhaustion shows a very significant shift in power within the TRIPS agreement. Especially considering that the demands regarding these declared rights were the subject of major legal suits between the developing and developed world during the late 1990's. The *Doha Declaration* now provides official rules for interpreting future WTO agreements and for deciding future disputes in a way that is sensitive to issues of public health, particularly in the developing world[63]. These are rules that were brought into being through calls from the developing world. The fact that the US, as well as other developed nations, had backed the PMA in the South African lawsuit, and that they had lost set a powerful precedent that the developed world was not invulnerable.

Some may argue in opposition to what has been said here on the grounds that the *Doha Declaration* is in fact, for the most part, beneficial to all Members of the WTO and that is why it was adopted, not because of any shift in the power structure. Some scholars have even argued that the Anthrax scare in the US during 2000-2001 led to the US pulling support from the South African case and accepting the *Doha Declaration*. This is a fair rebuttal to make. After all, compulsory licensing is only useful if the country forcing the license has the resources to produce the product itself[64]. Also, the world's largest pharmaceutical producers would all be required to have fully implemented TRIPS by January 2006. This would mean that the generic and illegal productions of cheap

[63] Balasubramaniam,150
[64] Mayne, 150-51

medications that occur in places like India and Thailand would cease because Article 31 stipulates that the compulsory licensing of a patent "shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use"[65]. Therefore, they would not be allowed to export their medicines after January 2006 when their pharmaceutical industries came under the TRIPS patent regulations. So it may be argued that the developed world had nothing to lose. In a few years, the largest producers of medicines would have to fully implement the TRIPS agreement, which would make it illegal to sell to least developed countries medicines they produced even under compulsory licensing, and least developed countries could compulsory license but could not afford to produce their own medication.

Were it the case that the developed world was simply capitulating because of negative attention and because they had nothing to lose, then the agreement of 2003 which allowed for the waiver of Article 31 *(f)* would have never been supported by the West. A major critique of the *Doha Declaration* is that while it recognized the importance of compulsory licensing and exhaustion in producing cheaper medicines it did not provide an answer to the problem that was presented by Article 31 *(f*). Countries utilizing compulsory licensing are only supposed to do so to supply their domestic markets and as was explained above this leaves least developed countries without a way to access cheaper pharmaceuticals.

However, on August 30th 2003 the General Council agreed to waive section (f) until Article 31 had undergone a more complete revision. This would allow countries to compulsory license with the intent to export to least developed countries. While many countries as a gesture of good faith vowed either not to use the system or to use it only in

[65] TRIPS. Article 31 (*f*), 333

cases of extreme emergency the agreement itself is quite a reversal in policy from the original intent of the TRIPS Agreement. It was further announced on December 6th 2005 that Members had approved an initiative to make the waiver of 2003 a permanent change of the TRIPS agreement, amending a core WTO agreement for the first time[66].

While the TRIPS agreement may have originally "rested on the economic power and diplomatic aggressiveness of the United States"[67] today the Doha Declaration and the 2003 Waiver codify a way of interpreting the TRIPS agreement that is in line with the concerns and wishes of the developing world. These two documents define terms and accept precedents that the developing world has called for since the TRIPS agreement's beginning. This shift in power within the TRIPS agreement members has great potential for up and coming issues in regards to IPR protection.

There are two related issues regarding developing nations that are becoming the focal point of discussion within the TRIPS agreement: the issues of Genetic Resources and Traditional Knowledge. Genetic resources refers to the issue of the use of genetic material from a country for the development of a product, which is then patented by the inventor of the product with no recognition of where the genetic material came from to begin with. This issue is also related to pharmaceuticals, who gather genetic material for research from developing nations, create a new patented medication and then sell the medication back to the developing country at the inflated monopoly price. Traditional knowledge is the issue of a practice or method being patented that may be a widely used method in a developing country but is patented in a developed nation under the pretext

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[66] WTO Press Release. *Members OK Amendment to Make Health Flexibility Permanent*. December 6th 2005. Available: http://www.wto.org/english/news_e/pres05_e/pr426_e.htm, Last Accessed: December 18, 2005

[67] Ryan, 93

that the method is new or innovative, thus forcing the people who use the method to pay royalties. Developing countries are home to more than 90% of the world's genetic resources and traditional knowledge[68], thus these issues have particular pertinence for them.

Within intellectual property right history there is a long standing principle that IP rights cannot be granted for things found in nature[69]. However, with the shift in the power to define and interpret key terms and phrases within the TRIPS agreement this long standing principle may be overturned by the desires of the developing world. Proposals have already been made by developing countries for "assurances that patents deriving from resources of a particular country" will result in the patent holder sharing the economic benefits with that country[70].

A proposal has also been made in regards to protection of traditional knowledge. Developing countries would like "restrictions placed on patents on items that are already available to the public by virtue of use"[71]. While there is no long standing principle in opposition to this request, the TRIPS agreement has not set up an international system of verification that is thorough enough to prevent the patenting of widely known methods or practices. The patenting of such things is also not prohibited by the TRIPS agreement.

These two issues are particularly important to developing nations, especially as their deadline to bring domestic legislature in line with TRIPS by January 1st, 2006 (January 1st, 2016 for least developed Members) draws near. The power to define and

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[68] Avrind Subramanian. "Propriety Protection of Genetic Resources and Traditional Knowledge" in *Development, Trade, and the WTO: A Handbook*. Editors Bernard Hoekman, Aaditya Mattoo & Philip English. (Washington D.C., US :The World Bank, 2002),382
[69] Ibid, 386
[70] Michalopoulos, 144-45
[71] Ibid, 144-45

codify principles and precedents by which an international agreement is to be understood and interpreted is a powerful force to wield in today's international world. This power is shifting within the TRIPS agreement, and the WTO, from the developed nations who created the organization and agreement to the developing nations who wish to restructure and amend the organization and agreement in their favor. Valentina Delich argues that IPRs may become developing countries "most effective means of exerting pressure and eventually retaliating" against abuses or unwanted agreements forced upon them by the developed world[72]. She is right to argue this. As the power continues to shift in favor of developing nations the IPR framework laid out within the TRIPS agreement will continue to favor the developing world in future disputes, such as those of genetic resources and traditional knowledge.

[72] Valentina Delich "Developing Countries and the WTO Dispute Settlement System" in *Development, Trade, and the WTO: A Handbook*. Editors Bernard Hoekman, Aaditya Mattoo & Philip English. (Washington D.C., US :The World Bank, 2002), 76

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