TRIPS and the WTO August 2003 Deal on Medicines: Is it a Gift bound in a Red Tape to Developing Countries?

A mini thesis submitted in partial fulfillment of the requirement for the LLM Degree in International Trade and Investment, University of the Western Cape.

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DECLARATION

I, ENGA KAMENI INNOCENT, hereby declare that this work is original and the result of my own research and effort. It has never on any previous occasion been presented in part or whole to any Institution or Board for the award of any degree.

I further declare that every secondary information used has been duly acknowledged in the work. I am responsible for any error whatever the nature, in this work.

Student

Signed……..
Date……

Supervisor

Signed…….
Date……

DEDICATION

To

My father, Enga Alphonse and step mother, Enga Margaret, all of blessed memory.

To

My loving and caring mother, Enga Elisabeth, the source of my strength throughout the programme

And to

My very good friend, Foncham Festus, of blessed memory.

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ACRONYMS

AIDS ……. Acquired Immune Deficiency Syndrome

ARV…….. Anti-retroviral

AZT ……. Zidovudine

EC ……. European Commission

EU ……. European Union

FTAA …….. Free Trade Areas of the Americas

FTA …….. Free Trade Area

GATT ……General Agreement on Trade and Tariffs

HIV …….. Human-immuno Deficiency Virus

IPC …….. Intellectual Property Committee

LDC …… Least Developed Countries

MNC ….. Multinational Corporations

NAMA … Non Agricultural Market Access

NGO ….. Non-governmental Organisation

PPY …… Person Per Year

R § D ….. Research and Development

TRIPS … Trade Related Aspects of Intellectual Property

US ……. . United States

USTR….. United States Trade Representative

WTO …… World Trade Organisation

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CHAPTER ONE: INTRODUCTION AND BACKGROUND

1.1 Objective of the study

This study evaluates the benefits and the problems of implementing the World Trade Organisation's (WTO) decision on the implementation of Paragraph 6 of the Doha Declaration by Developing country members. A lot has been said about the implementation of the said WTO decision by Third World countries. While some writers contend that the deal on the implementation of Paragraph 6 of the Doha Declaration has been beneficial to Developing Country members, others postulate that it has not brought any meaningful change to the health plight of citizens of these countries and has worsened instead of ameliorating their condition.[1] Therefore, the purpose of this study shall be thus:

a. Discuss the reasons for the incorporation of a multilateral agreement on intellectual property within the World Trade Organization (WTO) framework
b. Analyse Paragraph 6 of the Doha Declaration stating the flexibilities it brought to certain provisions of TRIPS.
c. Evaluate the problems encountered, and the benefits accruing to African countries as a result of the WTO 30 August decision on the implementation of Paragraph 6 of the Doha Declaration and investigate whether the costs have been more than the benefits or vice versa.

[1] See joint NGO statement released on September 10, 2003, by 14 NGO: ACT Up Paris, Consumer Project on Technology, Consumer International, Essential Action, European AIDS Treatment Group, Health Action International, Health GAP, International People's Health Council, Medicine sans Frontières, OXFAM International, People's Health Movement, SEATINI, Third World Network and Women in Development. Available at <www.lists.essential.org/pipermail/ip-health/2003-september/005245.html>, accessed on October 12, 2004

d. Examining how certain countries of the developed world especially the USA are circumventing this decision through several initiatives while others such as Canada was at the forefront of implementing the said decision.
e. Making recommendations, which shall aim at striking a balance between the interests of Developing countries (who are for the most part intellectual property users) and the interests of patent owners of pharmaceutical products.

1.2 Background

On the 30 of August 2003, the WTO announced that it had resolved the issue of giving poor countries access to essential medicines without breaching its own laws on intellectual property.[2] The decision settled the one remaining piece of unfinished business on intellectual property and health that was left over from the WTO ministerial conference in Doha, November 2001.[3] It set out conditions under which patents could be waived to allow developing country members to issue compulsory licenses to import cheap generic drugs to fight critical diseases such as aids, tuberculosis and malaria. At the end of the negotiations leading to the agreement, WTO's Director General, Supachai Panitchpakdi said:

> … this is a historic agreement for the WTO, …[t]he final piece of the jigsaw has fallen into place, allowing poorer countries to make full use of the flexibilities of the WTO's intellectual property rules in order to deal with the disease that ravage their people…[4]

However, this agreement has come under a barrage of criticism in recent times. In a joint NGO statement on this WTO deal on medicines, it was described as "a gift bound in a red tape".[5] Critics say the conditions and the

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[2] *See* "New deal from the World Trade Organization may not provide essential medicines for poor countries". Available at <www.bmj.com>, accessed on October 12, 2004
[3] *Decision removes final patent obstacle to cheap drug imports*, available at <www.wto.org>, accessed on October 12, 2004
[4] *Ibid*
[5] A gift bound in a red tape is the term, which has been used to describe the August 2003 WTO deal on medicines. This phrase was used in a joint NGO statement released on September 10, 2003, by 14 NGO: ACT Up Paris, Consumer Project on Technology, Consumer International, Essential Action, European AIDS Treatment Group, Health Action International, Health GAP, International People's Health Council, Medicine sans Frontières, OXFAM International, People's Health Movement, SEATINI, Third World Network and Women in Development. Available at <www.lists.essential.org/pipermail/ip-health/2003-september/005245.html>, accessed on October 12, 2004

requirements attached to it make it very difficult for developing countries to use it.[6] They also hold that as a means of trade policy, it contradicts the basic principles of the WTO and free trade.[7]

The current debate on access to medicine on the one hand and the stringent protection of intellectual property rights on the other could be traced from the entry into force of the agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). This agreement was one of the most astonishing outcomes of the Uruguay round of multilateral trade talks, which saw the establishment of the WTO.[8]

Before and during the Uruguay round, Developed Countries pressed and lobbied hard for the incorporation of an agreement on intellectual property within the multilateral trading system. They were concerned that the products protected by intellectual property rights in the North could not be protected in the south where there was often no equivalent intellectual property system. In the area of drugs and medicines, pharmaceutical companies were concerned that they would lose their competitive advantage as the knowledge behind the invention was utilised without a profit to them. Thus, the North responded by introducing TRIPS as a means of ensuring that the countries of the south provide an Intellectual property system to complement their own.[9]

Within a few years of its existence, concerns were raised[10] that it was inequitable to the South especially as it made it difficult for countries in chronic health crisis to grant compulsory licenses for the production of generic versions of certain drugs. The need to address this issue arose from concerns related to Article 31(f) of the TRIPS Agreement, which requires that production under compulsory licensing must be primarily for the supply of the domestic market. The ensuing protests and criticisms caused WTO members to revisit the TRIPS agreement and make certain inroads aimed at relaxing

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[6] *See* joint NGO statement on TRIPS and Public Health, released on the September 10, 2003, available at <www.cptech.org>, accessed on October 12, 2004.

[7] *Ibid*

[8] Capling, A., (1999) "Intellectual Property". Hocking B., and McGuire S., (Eds) *Trade Politics*: *International, Domestic and Regional Perspectives*. London, Routledge Press at 79

[9] Katherine Weston, "The Impact of TRIPS on Agricultural Economies in the Developing World", *Murdoch University Electronic Journal of Law,* Vol. 10, No 3, September 2003 at 2, available at <www.murdoch.edu.au>, accessed on October 12, 2004.

[10] Shiva, V., (2001) *Protect or plunder? Understanding Intellectual property rights,* Zed Books, London, at 95

the rigidity of some of its articles. Thus, in Qatar, (2001) member states came up with the Doha Declaration. Paragraph 6 of this declaration on public health noted the particular problems faced by countries with insufficient manufacturing capacities and economies of scale to make effective use of one of the key flexibilities afforded by TRIPS Agreement, the right to undertake compulsory licensing, for some or all drugs.[11]

After almost two years of waiting and political positioning, WTO member countries finally came to an agreement on the 30 of August 2003 on how to implement paragraph 6 of the Doha Declaration.[12] This agreement recognises that compulsory licensing is necessary to serve the public health in developing countries. A compulsory license with respect to a patent is defined as granting the use of a patent to a third party without the authorisation of the patent holder.[13]

The implementation decision establishes a global trade framework for a remedy to developing countries. Actual implementation, however, will require legal and regulatory implementation in importing and exporting countries, as well, as, ultimately, actual decisions to issue compulsory licenses in importing and exporting countries.

1.3 Problem Statement

Access to drugs promotes and protects the right to health. However, in most African countries, this right is not guaranteed due to the inaccessibility of drugs. Although the reasons for this are many and varied, empirical evidence suggests that strong intellectual property rules are to blame.[14] Striking a balance between the interests of the public to gain access to cheap versions

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[11] Robert Weissman, "Paragraph 6 implementation recommendations". Available at <www.cptech.org >, accessed on October 12, 2004

[12] World Trade Organization – Council for Trade-Related Aspects of Intellectual Property Rights. 'Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health". IP/C/W/405 (Aug. 30, 2003) (discussing the availability of compulsory licensing under Article 31 of the TRIPS agreement), available at <www.wto.org>, accessed on October 12, 2004.

[13] BLACK'S LAW DICTIONARY 931 (7th ed. 1999) (defining compulsory license as "a statutorily created license that allows certain parties to use copyrighted material without the explicit permission of the copyright owner in exchange for a specified royalty").

[14] Shiva, V., (2001) *Protect or plunder? Understanding Intellectual property rights,* Zed Books, London, at 95

of generic drugs on the one hand and the interests of pharmaceutical companies to make as much profit as possible from their products have been an arduous task. Luckily, WTO members agreed on a decision to implement Paragraph 6 of the Doha Declaration, which allows the granting of compulsory licenses. But, has this decision to implement Paragraph 6 of the Doha Declaration been beneficial to Africa or is it a "gift bound in a red tape"? This question will be investigated and addressed in the mini thesis.

1.4 Scope

The study shall be limited to the implications for developing country members the WTO 2003 decision on the implementation of Paragraph 6 of the Doha Declaration on public health. The geopolitical region under consideration would be WTO developing country members, especially Sub-Saharan African countries such as Cameroon and South Africa. However, reference will also be made to the activities of some developed countries' governments especially the United States of America that hinder the smooth operation of the 2003 WTO deal on Paragraph Six of the Doha Declaration, and others such as Canada, which has made salutary attempts to implement the said decision.

1.5 Significance of Research

This paper will examine the flaws inherent in the TRIPS provisions on health and the WTO August 2003 deal on compulsory licenses. This will intend help policy makers and negotiators from developing country members to understand the platform from which to negotiate current and future intellectual property rules.

Profit maximisation is for the most part the principal and sole objective of pharmaceutical companies. This makes it very difficult for any compromise to be struck between their pecuniary interests and the desperate interests of the disease stricken poor citizens of the developing world. In this light, the mini thesis will demonstrate the considerable influence and pressure exerted by these companies on their governments to resist any attempts to relax international intellectual property rights, which will benefit developing countries and distort their profit margins.

Finally, taking into cognizance the recent debate on whether or not the 2003 WTO deal on medicine is beneficial to third world countries, this research paper will attempt to locate the true position of Developing Country Members.

1.6 Research Methodology

The work of researchers and Country health reports from intergovernmental and non-governmental organisations will be used.

Textbooks; journal articles and the Internet shall be the main sources of information. This is because these contain the most up-to-date available data on the subject matter under examination.

Furthermore, the actual negotiations of Paragraph 6 and the proposals and reactions to it from both the developed and developing world will also be used.

1.7 Review of Chapters

This study is divided into four chapters. Chapter one deals with the general introduction, which lays the background for the discussion. It examines, *inter alia,* the reasons, which led to the incorporation of an intellectual property regime within the WTO framework.

Chapter two discusses Article 31(f) of the TRIPS agreement and the stringent conditions that it attached to patents. It also highlights the criticisms from developing countries that triggered Paragraph 6 of the Doha Declaration, which made certain inroads to the said Article 31(f) for example allowing developing countries to undertake compulsory licensing for the production of generic versions of patented drugs.

Chapter three evaluates whether the WTO August 30 2003 deal on medicine has been beneficial to Sub-Saharan African countries or whether it is merely "a gift bound in a red tape" to them.

In Chapter four, the activities of certain developed countries' government in hindering/ promoting the smooth implementation of the WTO decision on Paragraph 6 is analysed.

Finally, a conclusion shall be drawn from the discussion and recommendations will be proffered accordingly.

1.8 Reasons for the incorporation of a multilateral agreement on IP within the WTO framework: background to TRIPS

The Uruguay Round introduced for the first time in the history of the General Agreement on Tariffs and Trade (GATT) multilateral negotiations on TRIPS.[15] Under strong pressure by the industrialised countries, a specific agreement on the availability and enforcement of such rights became part of the final Act of the round: Agreement on the Trade-Related Aspects of Intellectual Property Rights (hereinafter referred to as the TRIPS agreement)

This agreement was one of the most astonishing outcomes of the Uruguay Round of multilateral trade talks, which saw the establishment of the WTO.[16] This agreement establishes minimum standards on Copyrights, Trademarks, Geographical Indications, Industrial Designs, Patents, Integrated Circuits and Trade Secrets. These relate both to the availability of rights as well as to their enforcement. This means that member countries cannot, in the specific areas and issues covered by the agreement, confer a lower level of protection than provided under the agreement. At the same time, members cannot be obliged to provide "more extensive" protection.[17] All members have to comply with these standards by modifying their national laws to accord with the rules of the agreement.[18]

1.9 The Drafting Process.

Before and during the Uruguay Round, Developed Countries pressed and lobbied hard for the incorporation of a multilateral agreement on intellectual property rights. Many reasons have been advanced as to why Developed Countries urgently needed an agreement on intellectual property.

Firstly, technology became a factor of growing importance in international competition, particularly for the production of technology-segments of

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[15] Correa, C. M., (2000) *Intellectual Property, the WTO and Developing Countries the TRIPS Agreement and Policy Options*, Zed Books London. P 1

[16] Capling A., (1999) "Intellectual Property", Hocking B., and Mc Guire S., (Eds) *Trade Politics: International, Domestic and Regional Perspectives*. London, Routledge Press at P 79

[17] See Article 1.1 of the TRIPS Agreement.

[18] *See* <www.southcentre.org>, accessed on November 23, 2004

international trade.[19] This trend was reflected in the steady increase of research and development (R & D) expenditures in industrialized countries since the 1970s, with growing participation of the private sector in total R & D. In many of these countries, half or more R & D expenditures are funded by the private sector, particularly by big companies in science-intensive sectors.[20]

Furthermore, the elimination or reduction of trade barriers in Developing Countries increased the opportunities for direct exports to those countries. It also led to increased pressure by multinational enterprises to get unrestricted access to those markets and to be freed from the obligation to exploit patented inventions locally or to transfer technology to local firms.[21]

Moreover the 1980s saw the rise of newly industrialised countries which competed favourably with Western European countries and the US in the production of certain goods - consumer electronics and high-tech goods- which historically has been under the exclusive control of the US and the Western European countries. The erosion of the technological leadership of US firms coupled with high US trade deficit was partially attributed to a too-open technological and scientific system, which allowed foreign countries to imitate and profit from US innovations. Thus a major source of declining. American competitiveness was conceived to be the losses from overseas piracy and counterfeiting activities.[22]

In general, the process of drafting TRIPS can hardly be considered as having been a real negotiating process. *Shiva Vandana* holds that GATT members did not negotiate TRIPS; it was only imposed by MNCs who used the US Government to force it on the other members.[23] He contends that the basic framework for TRIPS was conceived and shaped in a joint statement presented to the GATT Secretariat in June 1988 by the Intellectual Property Committee (IPC) of USA and the industry associations of Japan and Europe.

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[19] Correa, C. M., (2000) *Intellectual Property, the WTO and Developing Countries the TRIPS Agreement and Policy Options*, Zed Books London. P 3

[20] *Ibid*

[21] Correa, C. M., (2000) *Intellectual Property, the WTO and Developing Countries the TRIPS Agreement and Policy Options*, Zed Books London. P 3

[22] Correa, C. M., (2000) *Intellectual Property, the WTO and Developing Countries the TRIPS Agreement and Policy Options*, Zed Books London. P 3

[23] Shiva, V., (2001) *Protect or plunder? Understanding Intellectual property rights,* Zed Books, London, at 95

IPC is a coalition of thirteen major US corporations dedicated to the finalisation of TRIPS in their favour.[24] The members of IPC are corporations like Bristol Myers, Dupont, General Electric, General Motors, Hewlett Packard, Johnson and Johnson, Merck, Monsanto, Pfizer, Rockwell and Warner.[25] Developing Countries reluctantly negotiated increased standards of protection for intellectual property rights in the Uruguay Round, and finally acquiesced in making important concessions in terms of reforms of their intellectual property legislation, without obtaining any real compensating concession from industrialised countries.[26] The main concession gained by the Developing World, if at all it was a concession, was the provision in the agreement for transition periods of four years for Developing Countries and eleven years for the least developed to bring their legislation in line with the TRIPS agreement.[27]

[24] Shiva, V., (2001) *Protect or plunder? Understanding Intellectual property rights,* Zed Books, London, at 95
[25] *Ibid*
[26] Correa, C. M., (2000) *Intellectual Property, the WTO and Developing Countries the TRIPS Agreement and Policy Options*, Zed Books London, at 3.
[27] *See* <www.southcentre.org>, accessed on November 24, 2004

CHAPTER TWO: PATENTS, COMPULSORY LICENSING, ACCESS TO ESSENTIAL MEDICINES AND THE TRIPS AGREEMENT.

Through the adoption of the TRIPS Agreement in 1994, the WTO Members sought to implement uniform international protection of intellectual property rights[28]. The TRIPS Agreement allows Members to "adopt measures necessary to protect public health and nutrition" so long as they coincide with the provisional foundations set forth in the Agreement.[29]

Patents and compulsory licensing are the two major concepts that come into play when one looks at the TRIPS Agreement and access to essential medicines. A patent can be defined as a legal title granted by the state in a specific country that gives exclusive rights over the manufacture and use of an invention to the owner of this invention in that country in exchange for the full disclosure of the invention to the public[30] while a compulsory license with respect to a patent is defined as granting the use of a patent to a third party without the authorisation of the patent holder.[31] On the face of it, the TRIPS Agreement deals adequately with the issue of patents access to essential medicines and public health crises in Developing Countries through Articles 7, 8 and 31. Article 7 provides that the protection and enforcement of intellectual property rights should contribute not only to the promotion of technological innovation, but also to the transfer and dissemination of technology to the mutual advantage of producers and users of technological knowledge in a manner conducive to social and economic welfare and which balances rights and obligations.[32] Article 8.1, on its side is to the effect that Members may

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[28] *See* Agreement on Trade Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, LEGAL INSTRUMENTS-RESULTS OF THE URUGUAY ROUND vol. 31, 33 ILM 81 (1994) (setting minimal standards of protection of intellectual property rights to be recognized by all Members countries of the WTO)

[29] *See* Article 8 of the TRIPS Agreement.

[30] "Patent situation of HIV/AIDS-related drugs in 80 countries", Joint UNAIDS/WHO publication, (January 2000), Geneva.

[31] BLACK'S LAW DICTIONARY 931 (7th ed. 1999) (defining compulsory license as a "statutorily created license that allows certain parties to use copyrighted materials without the explicit permission of the copyright owner in exchange of a specified royalty")

[32] Duncan Matthews, "WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public health: a solution to the access to essential

adopt measures necessary to protect public health and nutrition and promote public interest in sectors of vital importance and technological development, provided such measures are consistent with the provisions of the Agreement. Though a "consistency test" is to be applied, this principle stresses that no Member country can be prevented from taking into account its own public interest in its IPRs legislation in the post-TRIPS Agreement environment.[33]

Article 31[34] refers to 'other use', that is to say use other than that permitted under Article 30. So, although not expressly referred to as compulsory licensing provisions, Article 31 allows for 'use without authorisation', in effect a compulsory licence granted by the competent national authority or a third party to manufacture a patented product without the authorisation of the right holder. In this respect, the public interest goal of achieving broader access to the patented invention is considered more important than the private interest of the right holder in fully exploiting his exclusive rights[35]. What this means in the context of public health imperatives is that compulsory licensing is intended to permit countries to produce generic drugs that are more affordable than patented proprietary medicines[36]. Since this amounts to an exception to the exclusive rights of the patent holder, Article 31 also sets out restrictive conditions that must be satisfied before a compulsory licence can be awarded. These conditions include the following: that a reasonable period of time is set to negotiate a license with the right holder on the basis of reasonable commercial terms. However, this requirement may be waived by a Member in the case of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use[37] and that authorisation of such a use shall be liable, subject to adequate protection of the legitimate

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medicines problem?", (2004) *Journal of International Economic Law* 7(1) Oxford University Press, at 77

[33] Correa, C. M., (2000) *Intellectual Property, the WTO and Developing Countries the TRIPS Agreement and Policy Options*, Zed Books London. at 7.

[34] The provisions of this Article are found in the *addendum* to the mini thesis

[35] Richard et al., "Broad-Based Compulsory Licensing of Pharmaceutical Technologies: Unsound Public Policy", (2001) 4 *Journal of World Intellectual Property* 463 at 471

[36] Correa, C. M., (2000) *Intellectual Property, the WTO and Developing Countries the TRIPS Agreement and Policy Options*, Zed Books London. P 3

[37] Article 31(b)

interest of persons so authorised to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur.[38]

2.1 Problems Created by Article 31(f)

The most controversial of all the exceptions to patents contained in the TRIPS Agreement is Article 31(f). It provides that "any such use [of a compulsory licence] shall be authorised predominantly for the supply of the domestic market of the Member authorising such use". This has the practical effect of preventing exports of generic drugs to countries that do not have significant pharmaceutical industries themselves.[39]

The limitation imposed by Article 31(f) creates two inter-linked problems:

1. By restricting the availability of export drugs made under compulsory license, it limits countries that are not in a position to support manufacturing under compulsory license (or where patent protection is not in force) in the availability of supply of generic import drugs, and;

2. By requiring compulsory licensees to supply a predominant part of their production to the domestic market, it limits the flexibility of countries to authorize the export of compulsory-licensed drugs and thereby to exploit economies of scale.[40]

Article 31(f) creates difficulties on the demand and supply side of the generic drug pipeline.

The demand side problem is self-evident. If a developing Member lacks manufacturing capacity for a particular drug, and there are no Members that are able to supply it by export under compulsory license (or exception), there may be no affordable supply of the drug.[41]

The supply side problem is identified because there are WTO Members, including developing Members, with the capacity to address the drug import needs of a wide range of developing Members under compulsory license, but

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[38] Article 31(g)

[39] Frederick M Abbott, "The TRIPS Agreement, Access to Medicines and the WTO Doha Ministerial Conference", (2001), *Quaker United Nations Office- Geneva, Occasional Paper* 7, at 13

[40] Frederick M Abbott, "Compulsory licensing for Public Health Needs: the TRIPS Agreement at the WTO after the Doha Declaration on Public Health", (2002), *Quaker United Nations Office- Geneva, Occasional Paper* 9, at 27

[41] *Ibid*

that may be inhibited from undertaking this role because of the Article 31(f) limitation.[42]

2.2 The Pharmaceutical Companies' Lawsuit against the Government of South Africa.[43]

The potential impact of the TRIPS Agreement on access to essential medicines was brought into focus in February 1998 in South Africa, when forty-two pharmaceutical companies (applicants) brought an action before the High Court of South Africa (Transvaal Provincial Division) against the Government of South Africa (composed of ten respondents) to challenge the constitutionality of some of the provisions embodied in the Medicines Amendment Act 90 of 1997[44] and that the act was inconsistent with TRIPS. The legal action brought, but subsequently abandoned by the Pharmaceutical Manufacturers Association of South Africa concerned, in particular, Article 10 of the South African Medicines and Related Substance control Amendment Act of 1997, which added Section 15C to the 1965 Medicines and Related Substance Control Act,[45] in doing so allowing the Minister of Health to abrogate patents, issue compulsory licences and allow parallel imports of pharmaceutical products in order to increase availability and lower the cost of medicines.[46]

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[42] Frederick M Abbott, "Compulsory licensing for Public Health Needs: the TRIPS Agreement at the WTO after the Doha Declaration on Public Health", (2002), *Quaker United Nations Office- Geneva, Occasional Paper* 9, at 27

[43] The legal suit was *Pharmaceutical Manufacturers Association and others v. President of the Republic of South Africa and others* (Transvaal Provincial Division case no: 4183/98)

[44] Tshimanga Kongolo, "Public interest versus the pharmaceutical industry's monopoly in South Africa" (2001) *The Journal of World Intellectual Property* vol. 4 No.5 at 616. *See* also *Notice of motion in the High Court of South Africa* (Transvaal Provincial Division) Case No. 4183/98, available at <www.cptech.org/ip/health/sa/pharmasuit> accessed on November 25, 2004

[45] Section 15C states that "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 Patent Act 1978 (Act No. 57 of 1978), determine that the rights with regards to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine…" (D Matthews, above n 26, at 79, fn 22 quoting Amendment Act reprinted in Tshimanga Kongolo, "Public interest versus the pharmaceutical industry's monopoly in South Africa" *The Journal Of World Intellectual Property* vol. 4 No.5 2001 at 605)

[46] Duncan Matthews "WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public health: a solution to the access to essential medicines problem?" (2004) *Journal of International Economic Law* Oxford University Press, at 79.

In terms of the TRIPS Agreement, what the South African legislation lacked were the detailed provisions required by Article 31 of the TRIPS Agreement, particularly the requirement that compulsory licence be granted only on a non-exclusive and non-assignable basis, with the possibility of the judicial review and with adequate remuneration for the patent holder.[47] But the compatibility of the South African compulsory licensing provisions with Article 31 of the TRIPS Agreement was difficult to ascertain conclusively since the exceptions in the South African Amendment Act are considered ambiguous. The case proved particularly emotive and because access to anti-retroviral drugs for the treatment of HIV/AIDS, such as AZT (Zidovudine), was constrained in South Africa by the prohibitively high price of those medicines. On April 2001, the pharmaceutical companies that, since 1998, had challenged the constitutionality of the 1997 Amendment Act via a lawsuit announced the withdrawal of their action.

2.3 The Case of Article 68 of the Brazilian Industrial Property Act.

The problematic nature of the compulsory licensing provisions contained in the TRIPS Agreement was again highlighted in June 2001 when the U.S government brought an action against Brazil in the WTO. [48] Brazil had taken legislative action to cure her deplorable health - AIDS crisis by enacting a law that permitted the granting of compulsory licences to generic producers of anti-retroviral drugs to combat HIV/AIDS. The U.S complained that Article 68 of Brazil's 1996 Industrial Property Law[49] which required that a patented product be produced in Brazil, otherwise it can be the subject of a compulsory licence, was violative of Article 27(1) of the TRIPS Agreement which is to the effect that patents shall be available for any inventions, whether product or processes, in all fields of technology, provided that they are new, contain an inventive step, and are capable of industrial application. Furthermore, such patents shall be available and patents rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are

[47] Frank Wooldridge, "Affordable Medicines – TRIPS and United States Policies", (2000), 4(1) Intellectual Property Quarterly 103, at 108

[48] *Request for the Establishment of a Panel by the United States, Brazil – Measures Affecting Patent Protection*, WT/DS199/1, 8 June 201

[49] Law No. 9,279 of 14 May 1996; effective from May 1997

imported or locally produced. However, the U.S ultimately dropped its action against Brazil due to widespread criticism from various groups advocating the increase of access to drugs in developing countries.[50]

2.4 The Doha Declaration and Public Health

As a result of the problems encountered in the interpretation of some of the TRIPS provision (in particular Article 31), and in response to concerns about high prices for patented drugs and the use of compulsory licences, WTO Members met in the Qatari capital of Doha, from the 9 – 14 of November and adopted the Declaration on the TRIPS Agreement on Public Health. This Declaration marked a turning point in political and legal relations at the WTO.[51]

Originally an initiative of the African Group, joined thereafter by a number of developing countries,[52] the Doha Declaration acknowledges the gravity of the public health problems afflicting many developing least-developed countries, especially, those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.[53] In the same line of reasoning, the Declaration sets out that intellectual property protection is important for the development of new medicines, and recognises its effects on prices.[54] Furthermore, the Doha Declaration reaffirmed the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for public health purpose and that the TRIPS Agreement should be interpreted and implemented in a manner supportive of the WTO Members' right to protect public health and, in particular, to promote access to medicines for all.[55] In addition, the Declaration recognised the flexibilities contained in the TRIPS Agreement with respect to the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted; the

[50] Mark Lang "What a long, strange 'TRIPS' it's been: Compulsory licensing from the adoption of TRIPS to the Agreement on Implementation of the Doha Declaration, (2004) 3 *John Marshall Review of Intellectual Property Law* 331 at 337

[51] Frederick M. Abbott, "The Doha Declaration on the TRIPS Agreement and Public Health: lighting a dark corner at the WTO", (2002) *Journal of International Economic Law*, 5(2) Oxford University Press at 469

[52] Tshimanga Kongolo, "WTO Doha Declaration and intellectual property: African perspectives" (2002) *African Yearbook of International Law*, 185 at 201

[53] Paragraph 1 of the Doha Declaration on the TRIPS Agreement and Public Health

[54] Tshimanga Kongolo, *loc cit*

[55] Paragraph 4 of the Doha Declaration on the TRIPS Agreement and Public Health.

right of each Member to determine what constitutes a 'national emergency' or other circumstances of extreme emergency it being understood that public health crises can represent a national emergency or other circumstances of extreme emergency; and the effect of provisions of TRIPS Agreement that allow each Member freedom to establish its own regime for exhaustion of intellectual property rights.[56]

However, as stated above, the main problem was that the compulsory licensing provisions of the TRIPS Agreement were of little practical use to countries with little or no pharmaceutical manufacturing capabilities, since Developing Countries could not import from other Members with manufacturing capacity until the second Member had also invoked a compulsory licence and that even then the second Member would fall foul of Article 31(f) because the compulsory licence would have to be 'predominantly for the supply of the domestic market' of the Member granting the licence.[57] In recognition of this problem, Paragraph 6 of the Doha Declaration explicitly recognised that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. Paragraph 6 set a deadline of the end of 2002 by which the council for TRIPS (hereafter the TRIPS Council) was instructed to find an expeditious solution to this problem and report to the General council of the WTO.[58] Overall, then, the text of the Doha Declaration was interpretive in nature and designed to reaffirm the flexibilities already contained in the provisions of Article 31 if the TRIPS Agreement.[59]

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[56]Duncan Matthews "WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public health: a solution to the access to essential medicines problem?" (2004), 7(1) *Journal of International Economic Law* Oxford University Press, at 82

[57] Sandra Bartelt: "Compulsory licenses pursuant to TRIPS Article 31 in the light of the Doha Declaration on the TRIPS Agreement and Public Health", (2003), 6(2) *Journal of World Intellectual Property* 283, at 286

[58] *See* World Trade Organization, *Declaration on the TRIPS Agreement and Public Health,* WT/MIN (01)/DEC/2 (Nov. 20, 2001) (recognizing the gravity of public health problems afflicting developing countries and the need for internal action to help combat these problems).

[59] Duncan Matthews "WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public health: a solution to the access to essential medicines problem?" (2004), 7(1) *Journal of International Economic Law* Oxford University Press, at 82

It should be noted that concerns as to the legal status of the Doha Declaration have been raised in recent times. This is one area in which legal opinions differ. *Vandoren* claims that when disputes arise over measures taken by Members on public health grounds, the Declaration can be used to argue that the panel should interpret the TRIPS Agreement in a manner supportive of a Member's right to protect public health.[60] *Bartelt* also suggests that, by virtue of Article 31(3) of the Vienna Convention, the Doha Declaration should be regarded as 'subsequent practice in application of the treaty' because paragraph 5(a) of the Declaration gives clear guidelines for interpretation, stating that the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular its objectives and principles.[61] However, *Reichman* offers a word of caution, acknowledging that Article 31(3) of the Vienna Convention may apply, but also stressing that the precise legal status of the Doha Declaration does remain uncertain, the practical implications being uncertainty as to the extent to which future WTO panels and the Appellate Body will draw guidance from the Declaration when deciding upon complaints.[62]

2.5 Failed attempts to implement Paragraph 6 of the Doha Declaration

The euphoria created by the Doha Declaration especially it's Paragraph 6 which urged Members to find expeditious solutions to TRIPS was soon to die as Members persistently failed to arrive at a compromise in finding "an expeditious solution". In fact, the December 2002 deadline was missed. To adequately understand why this happened, it would be necessary to give a chronological analysis of the failed negotiations aimed at implementing Paragraph 6 of the said Declaration.

Negotiations on the implementation of Paragraph began in June 2002 with the meeting of the TRIPS Council. The African Group proposed a moratorium on bringing complaints against low-income Developing Countries before the

[60] Paul Vandoren: *"Médicaments sans Frontières*? Clarification of the Relationship between TRIPS and Public Health Resulting from the WTO Doha Ministerial Declaration", (2002) 5(1) *Journal of World Intellectual Property* 5 at 8

[61] Sandra Bartelt: "Compulsory licences pursuant to TRIPS Article 31 in the light of the Doha Declaration on the TRIPS Agreement and Public Health", (2003), 6(2) *Journal of World Intellectual Property* 283, at 286

[62] *Ibid*

Dispute Settlement Body of the WTO in relation to Article 31(f) of the TRIPS Agreement.[63] One of the advantages of a moratorium was that it would set aside any WTO dispute settlement proceedings that might otherwise arise for breach of Article 31(f) of the TRIPS Agreement through the production and export of pharmaceutical products to a third country in order to address a public health crisis in the latter. However, this idea was dropped for two reasons: firstly since there was arguably no sound legal basis for not applying the dispute settlement procedure in instances of a moratorium there was a risk that, even as a temporary arrangement, a moratorium on dispute against Members that take action to address public health crises in countries with insufficient or no manufacturing capacities was likely to have the inherent problem of lacking legal certainty as to the behaviour of potential complainants, particularly Developed Country WTO Members;[64] and secondly, there was the problem that implicit in the moratorium is the proviso that it would apply only if developing countries compensate patent holders for compulsory licences, and only until expected end date of the Doha Development Round of multilateral trade negotiations in January 2005, when the transitional arrangements for developing countries under Article 65(4) of the TRIPS Agreement will also come to an end. With the prospect of a temporary solution of the kind offered by a moratorium lasting only until the end of the Doha Round, the likelihood was that trade-offs and package deals would emerge, as they did during the original TRIPS negotiations, with Developing Countries offering trade advantages and market access in key areas, such as agriculture, in return for agreeing to the more restrictive interpretation of Article 31(f) proposed by developed countries.[65]

[63] *Proposal on Paragraph 6 of the Ministerial Declaration on TRIPS Agreement and Public Health*, Joint Communication from the African Group in the WTO, IP/C/W/351, 24 June 2002, para 6 (g)

[64] Bourgeois and Burns: "Implementing Paragraph 6 of the Doha Declaration on TRIPS and Public Health: The Waiver Solution" (2002) 5(6) *Journal of World Intellectual Property* 835 at 839

[65] Bourgeois and Burns: "Implementing Paragraph 6 of the Doha Declaration on TRIPS and Public Health: The Waiver Solution" (2002) 5(6) *Journal of World Intellectual Property* 835 at 839

Another attempt was made[66] to see if it was possible for a waiver of Article 31(f) of the TRIPS Agreement could be granted to WTO Members facing public health crises, but lacking domestic manufacturing capacity. This could be achieved under Article IX: 3-4 of the WTO Agreement.

Other attempts made included examining the possibilities of amending Article 31(f) of the TRIPS Agreement to allow exports of products produced under compulsory licences and broadly interpreting the limited exceptions clause of Article 30.[67]

The first attempt aimed at amending Article 31(f) of TRIPS failed due to the divergent views of WTO Members especially the EU and US. The EU proposed that any solution allowing an exemption to the Article 31(f) requirement that generic drugs produced under compulsory licence to be 'predominantly' for domestic use should be limited to the production of medicines where the gravity of public health problems afflict developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.[68] However, the US adopted a somewhat restrictive position. The US view was that broadening the exception to cover any 'other epidemics', in keeping with the wording of the Doha Declaration, would risk the inclusion of 'lifestyle' illnesses such as obesity or the common cold that should not be excluded from the compulsory licensing provisions of the TRIPS Agreement.[69]

Differences in opinions led to the failure of the second attempt i.e. broadly interpreting the limited exception clause. The US for the most part consistently argued for a strict interpretation of Article 30,[70] whereas the EC and its Member States questioned its legal merits due to doubts about whether the

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[66] Bourgeois and Burns: "Implementing Paragraph 6 of the Doha Declaration on TRIPS and Public Health: The Waiver Solution" (2002) 5(6) *Journal of World Intellectual Property* 835 at 839

[67] *Ibid*

[68] *Concept Paper Relating to Paragraph 6 of the Ministerial Declaration on the TRIPS Agreement and Public Health,* Communication from the EC and their Member States to the TRIPS Council, IP/C/W/339, 4 March 2002

[69] See "Drugs for the Poor", available at <www.washingtonpost.com.>, accessed on December 2nd , 2004

[70] *Paragraph 6 of the Ministerial Declaration on the TRIPS Agreement and Public Health*, Second Communication from the United States, IP/C/W/358, 9 July 2002.

criteria of Article 30 offer sufficient scope for an authoritative interpretation.[71] The problems created by this differences in opinion was exacerbated by the WTO Dispute Panel Decision in the case of *Canada – Patent Protection of Pharmaceutical Products,* where it indicated that a compulsory licence issued under Article 30 must meet three cumulative conditions which must all be satisfied for the exception to fall within the scope of Article 30: first, the exception must be of limited nature; second, it may not unreasonably conflict with a normal exploitation of the patent; and, third, it may not unreasonably prejudice the legitimate interests of the patent holder, taking into account the legitimate interests of third parties.[72]

Following the Panel decision in *Canada – Patent Protection, Bartelt* maintains that there are doubts as to whether a compulsory licence to manufacture and supply generic drugs to another WTO Member could be justified under Article 30 since it would be unlikely to meet the requirement of not conflicting with the normal exploitation of the patent, since compulsory licensing could be described as being 'diametrically opposed to the subject-matter of the patent, which is to reward the inventor for his creative efforts'.[73]

2.6 The *Motta* Text

The solution that was nearly adopted under tight time pressures is the so-called "December 16" or "Motta text". The text attempted to strike a compromise under which the TRIPS Agreement would be amended so that any country with manufacturing capacities could export, while developing countries without manufacturing capacities in the pharmaceutical sector would be allowed to benefit from the system in the face of public health problems.[74]

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[71] Thomas A Hagg, "TRIPS Since Doha: How Far Will the WTO Go Toward Modifying the Terms of Compulsory Licensing?", (2002) 84(12) *Journal of the Patent and Trademark Office Society* , 945 at 969.

[72] WTO Panel Report, *Canada – Patent Protection of Pharmaceutical Products*, WT/DS114/R, adopted on March 17, 2000.

[73] Sandra Bartelt, "Compulsory Licenses Pursuant to TRIPS Article 31 in the Light of the Doha Declaration on the TRIPS Agreement and Public Health", (2003) 6(2) Journal of World Intellectual Property 283 at 300

[74] "Main elements of the Chair's 16 December 2002 Draft Compromise Decision (Perez Motta Text)", European Commission (Trade and Development) Press Release, 9 January 2003, available at www.europa.eu.int/comm/trade/csc/memo090103_en.htm, accessed on the December 3rd 2004.

Under this text, countries importing generic pharmaceutical products and using the Paragraph 6 mechanism would be expected to take measures to prevent re-exportation, provided such measures were 'reasonable', 'within their means' and 'proportionate' to their administrative capacities and the risk of trade diversion.[75] Exporting countries would be obliged to require the beneficiary company of the compulsory licence (1) to export their entire production to the countries needed and (2) to clearly identify the products through labelling or marking and through special colouring or shaping of the products themselves. However, when the TRIPS Council met on December 20th 2002, the deadline for reaching an agreement on the conclusion of Paragraph 6, there was a deadlock. The US blocked an agreement on grounds that the text was too broad and went beyond the focus of HIV/AIDS, tuberculosis and malaria. This made the negotiations to be halted and the Chairman had to convene another meeting which was held in February 2003.[76] The February 2003 meeting was a dismal failure as no party was willing to relinquish her key demand. The next TRIPS Council meeting held on the 4-5 of June 2003, ended without any substantial progress to a solution.[77] Meanwhile, earlier on, specifically on 9 January 2003, the EC had come up with a proposal aimed at removing WTO constraints requiring compulsory licences to be 'predominantly' for domestic supply in the case of medicines to combat a limited list of 22 infectious diseases (including HIV/AIDS, tuberculosis and malaria) that are generally recognised by health experts to have the most damaging impact on developing countries.[78]

Due to these intransigencies on the part of the various governments, there was an implicit call to the Council on TRIPS to find an expeditious solution to the Paragraph 6 problem. This breakthrough did happen on the 30 of August

[75] "Main elements of the Chair's 16 December 2002 Draft Compromise Decision (Perez Motta Text)", European Commission (Trade and Development) Press Release, 9 January 2003, available at www.europa.eu.int/comm/trade/csc/memo090103_en.htm, accessed on the December 3rd 2004.

[76] Duncan Matthews "WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public health: a solution to the access to essential medicines problem?" (2004), 7(1) *Journal of International Economic Law* Oxford University Press, at 94

[77] *Ibid*

[78] "EU seeks to Break the Current deadlock on WTO Access to Medicines: a multinational solution is needed", European Commission (Trade and Development) Press Release, January 9th , 2003, available at <www.europa.eu.int/comm/trade/csc/pr090103_en.htm>, accessed on December 3rd, 2004

2003. In the next chapter, the WTO August 2003 implementation decision will be analysed. However, it is worthy to analysed some of the solutions that were proposed by scholars before the WTO came up with its August 2003 deal.

2.7 Proposed solutions to the Paragraph 6 Problems

Commentators have offered several solutions in response to the Paragraph 6 Problem.[79] These solutions fit into four main types: an amendment to Article 31(f) of the TRIPS Agreement, a waiver of a Member's responsibilities under 31(f), a dispute settlement-based solution, and an authoritative interpretation of Article 30 of TRIPS.[80]

1. Solution #1: Amendment to Article 31(f) of the TRIPS Agreement

One solution to the Paragraph 6 Problem is to amend or delete Article 31(f) of the TRIPS Agreement. Because such an amendment is "of a nature that would alter the rights and obligations of the Members,"[81] it would only "take effect for the Members that have accepted them upon acceptance by two-thirds of the Members and thereafter for each other Member upon acceptance by it."[82] In order to accept an amendment, a Member delivers an instrument of acceptance to the WTO Secretariat, but only after fulfilling the necessary requirements under its domestic legal system.[83] The practical effect is that before a Member country accepts an amendment, it must ratify it at the national level.[84] While *Sun* does not suggest how Article 31 should be amended, he seems to suggest deleting the article's "predominately" requirement.[85] *Attaran* and *Divya Murthy*,[86] on the other hand, propose

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[79] Jennifer Mary Rogers, "The TRIPS Council Solution to the Paragraph 6 problem: Toward compulsory licences viability to Developing Countries" (2004) 13 *Minnesota Journal of Global Trade* at 5

[80] *Ibid*

[81] See Marrakech Agreement Establishing the World Trade Organization (Apr. 15, 1994), Annex 1C, 1867 U.N.T.S. 154, 33 I.L.M. 1144 (1994), available at http://www.wto.org/english/docs_e/legal_e/04-wto.pdf (last visited Jan. 5, 2004) [hereinafter WTO Agreement].

[82] In the case of an amendment that would not alter the rights and obligations of the Members, all Members can be bound by the vote of two-thirds of the Members. Id. para. 4

[83] Haochen Sun, "A Wider Access to Patented Drugs Under the TRIPS Agreement" 21 B.U. Int'l L.J. 101, 107 (2003). Available at www.international.westlaw.com.innopac.up.ac.za/find/default.wl, accessed on November 20, 2004

[84] Ibid

[85] Ibid

amending TRIPS to create an exception to Article 31(f) for Members to issue compulsory licenses to export to another Member that lacks the ability to manufacture its own pharmaceuticals.[87] *Murthy* also suggests amending the definition of "third party" to include foreign entities when a Member does not have sufficient manufacturing ability.[88]

Although an Article 31 amendment has the benefit of permanence, *Attaran* and Sun do not consider this the best option.[89] Sun describes the national ratification requirements as "legally insecure and time consuming."[90] Bureaucratic problems also arise when a product is patented in the importing country, because Article 31 requires two compulsory licenses: one for the exporting country and one for the importing country.[91] In addition, Article 31(h) calls for the patentee to be adequately remunerated when a compulsory license is issued.[92] With two compulsory licenses, this would result in the patent holder being paid twice for the same product.[93] Due to these problems, none of the commentators have recommended the Article 31(f) amendment as the best option.[94]

2. Solution #2: Waiver of Responsibilities Under Article 31(f) of the TRIPS Agreement

Sun and *Attaran* both address the potential solution of a waiver of a Member's

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[86] Amir Attaran, "The Doha Declaration on the TRIPS Agreement and Public Health, Access to Pharmaceuticals, and Options Under WTO Law", (2002)12 *Fordham Intellectual Property, Media and Entertainment Law Journal,* 859, 870 & n.21

[87] Ibid

[88] Divya Murthy, "The Future of Compulsory Licensing: Deciphering the Doha Declaration on the TRIPS Agreement and Public Health", (2002) 17 *American University International Law Review.* 1299, 1319-20.

[89] Amir Attaran, "The Doha Declaration on the TRIPS Agreement and Public Health, Access to Pharmaceuticals, and Options Under WTO Law", (2002)12 *Fordham Intellectual Property, Media and Entertainment Law Journal,* 859, 870 & n.21

[90] Haochen Sun, "A Wider Access to Patented Drugs Under the TRIPS Agreement", 21 B.U. Int'l L.J. 101, 107 (2003).

[91] Amir Attaran, "The Doha Declaration on the TRIPS Agreement and Public Health, Access to Pharmaceuticals, and Options Under WTO Law", (2002)12 *Fordham Intellectual Property, Media and Entertainment Law Journal,* 859, 870 & n.21

[92] TRIPS Agreement, art. 31(h).

[93] Amir Attaran, "The Doha Declaration on the TRIPS Agreement and Public Health, Access to Pharmaceuticals, and Options Under WTO Law", (2002)12 *Fordham Intellectual Property, Media and Entertainment Law Journal,* 859, 873 & n.21

[94] Divya Murthy, Comment, "The Future of Compulsory Licensing: Deciphering the Doha Declaration on the TRIPS Agreement and Public Health", 17 Am. U. Int'l L. Rev. 1299, 1319-20 (2002).

obligations under Article 31(f) of the TRIPS Agreement.[95] The Ministerial Conference has the authority to waive obligations imposed on a Member by the TRIPS Agreement.[96] *Attaran* frames his discussion in terms of Member countries requesting waivers on an individual basis, dismissing this option as "slow and cumbersome," because the Ministerial meets only every two years and because a waiver must be reviewed yearly after being granted.[97] On the other hand, Sun points to cases where the relevant Council recognised the need for a waiver to apply to several Members, resulting in a "collective waiver."[98] Thus, under the collective waiver situation, individual countries would not each have to request a waiver.[99] The requirement of yearly Ministerial review would still apply, however, and Sun cites this as a negative aspect of the waiver, along with its temporary nature.[100] Because of the annual review, Members might challenge the waiver yearly, perhaps arguing that the exceptional circumstances justifying the waiver are no longer present.[101] Due to its temporary and potentially legally unstable nature, the waiver is similarly not considered one of the best options.[102]

3. Solution #3: Dispute Settlement Solutions

A third category of potential solutions relates to an agreement not to bring dispute settlement proceedings against Members who produce and export generic pharmaceuticals intended for poor countries without the manufacturing capacity in violation of Article 31(f). The first form this could take is a moratorium on dispute settlement, as discussed by *Sun*.[103] In this

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[95] Amir Attaran, "The Doha Declaration on the TRIPS Agreement and Public Health, Access to Pharmaceuticals, and Options Under WTO Law", (2002)12 *Fordham Intellectual Property, Media and Entertainment Law Journal,* 859, 870 & n.21

[96] See WTO Agreement, art. ix, para. 3. The waiver process would begin with a request for a waiver submitted to the TRIPS Council. The Council would create a draft of the waiver, and send it to the Ministerial Conference, which could then grant the waiver upon approval by three-fourths of its Members.

[97] Amir Attaran, "The Doha Declaration on the TRIPS Agreement and Public Health, Access to Pharmaceuticals, and Options Under WTO Law", (2002)12 *Fordham Intellectual Property, Media and Entertainment Law Journal,* 859, 870 & n.21

[98] Haochen Sun, "A Wider Access to Patented Drugs Under the TRIPS Agreement", 21 B.U. Int'l L.J. 108 (2003).

[99] *Ibid*

[100] *Ibid*

[101] Haochen Sun, "A Wider Access to Patented Drugs Under the TRIPS Agreement", 21 B.U. Int'l L.J. 101, 107 (2003).

[102] Ibid

[103] Ibid

situation, WTO Members would agree not to bring a WTO complaint against countries that produce patented pharmaceuticals in the situation described above.[104] Although the WTO Agreement does not specifically address moratoria, the Ministerial Conference has the authority to decide on a moratorium on disputes arising under Article 31(f) of the TRIPS Agreement.[105] A related version of this solution is a rule of non-justiciability, as discussed by *Attaran*.[106] This would involve the Ministerial Conference amending Appendix Two of the Dispute Settlement Understanding (DSU), the codification of special WTO dispute settlement rules.[107]

The difference between a moratorium and a rule of non-justiciability is that a moratorium is an agreement decided on by the Ministerial Conference,[108] while a rule of non-justiciability actually becomes a part of the DSU by amendment.[109] The United States argued in favor of a moratorium in March 2002, because it would not require an amendment to TRIPS and could be overseen by the TRIPS Council.[110] *Sun* dismisses the moratorium option because, like a waiver, it would be a temporary solution.[111] In contrast, *Attaran* presents the rule of non-justiciability as the best solution, arguing that it is more consistent with the legal design of TRIPS and there are precedents in WTO law for using a rule of non-justiciability.[112]

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[104] Haochen Sun, "A Wider Access to Patented Drugs Under the TRIPS Agreement", 21 B.U. Int'l L.J. 101, 107 (2003).
[105] Ibid
[106] Amir Attaran, "The Doha Declaration on the TRIPS Agreement and Public Health, Access to Pharmaceuticals, and Options Under WTO Law", (2002)12 *Fordham Intellectual Property, Media and Entertainment Law Journal,* 859, 870 & n.21
[107] Ibid
[108] Haochen Sun, "A Wider Access to Patented Drugs Under the TRIPS Agreement", 21 B.U. Int'l L.J. 101, 107 (2003).
[109] Amir Attaran, "The Doha Declaration on the TRIPS Agreement and Public Health, Access to Pharmaceuticals, and Options Under WTO Law", (2002)12 *Fordham Intellectual Property, Media and Entertainment Law Journal,* 859, 870 & n.21
[110] See Richard Elliot, *'U.S. Offers Moratorium on Compulsory Licensing Disputes, Rejects Amending TRIPS*" Available at http://lists.essential.org/pipermail/ip-health/2002-March/002760.html, accessed on November 20, 2004. At that time the United States also opposed an amendment of Article 31 and an authoritative interpretation of Article 30, two potential solutions the European Union had presented.
[111] Haochen Sun, "A Wider Access to Patented Drugs Under the TRIPS Agreement", 21 B.U. Int'l L.J. 121-23 (2003).
[112] Amir Attaran, "The Doha Declaration on the TRIPS Agreement and Public Health, Access to Pharmaceuticals, and Options Under WTO Law", (2002)12 *Fordham Intellectual Property, Media and Entertainment Law Journal,* 859, 870 & n.21

4. Solution #4: Article 30-based Solutions

Another solution that has been suggested is an authoritative interpretation of Article 30 under Article IX, Paragraph 2 of the WTO Agreement.[113] This solution has the benefit of permanence.[114] An interpretation can be adopted if three-fourths of Members vote for it.[115] Unlike the Article 31 solution, here only one compulsory license would be required.[116] This solution also avoids the double compensation problem found in the Article 31 solution.[117] In spite of this, *Attaran* argues that "an interpretation cannot achieve by the back door what would otherwise require an amendment."[118] Although *Attaran* prefers the rule of non-justiciability to this solution, both *Sun* and *Murthy* argue that the Article 30 interpretation is the best solution.

In the end, these four potential methods of solving the Paragraph 6 Problem each have their benefits and drawbacks. As noted by *Sun*, although these features would be considered in crafting the solution, the TRIPS Council's exact solution would be the result of political negotiations.[119]

[113] Ibid. See also Divya Murthy, Comment, "The Future of Compulsory Licensing: Deciphering the Doha Declaration on the TRIPS Agreement and Public Health", 17 Am. U. Int'l L. Rev. 1299, 1319-20 (2002).
[114] Haochen Sun, "A Wider Access to Patented Drugs Under the TRIPS Agreement", 21 B.U. Int'l L.J. 125 (2003).
[115] See WTO Agreement, art. ix, para. 2.
[116] Amir Attaran, "The Doha Declaration on the TRIPS Agreement and Public Health, Access to Pharmaceuticals, and Options Under WTO Law", (2002)12 *Fordham Intellectual Property, Media and Entertainment Law Journal,* 869 & n.21
[117] Ibid at 873
[118] Ibid 874
[119] Haochen Sun, "A Wider Access to Patented Drugs Under the TRIPS Agreement", 21 B.U. Int'l L.J. 116 (2003).

CHAPTER THREE: THE AUGUST 2003 DECISION ON THE IMPLEMENTATION OF PARAGRAPH 6 OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH.

Almost two years after the Doha Declaration had urged the Council to find an "expeditious solution" to the problem of implementation of TRIPS, WTO Members, however, finally adopted an agreement on the interpretation of the ambiguous TRIPS Articles ("Implementation Decision") on the 30 of August 2003.[120]

The final breakthrough was achieved when Ambassador *Motta*'s successor as Chairman of the TRIPS Council, *Vanu Gopala Menom* of Singapore, met with a small group of WTO Members to negotiate a solution to paragraph 6. This group, comprising the United States, Kenya, Brazil, South Africa and India succeeded in producing a draft Decision on 21 August 2003, followed by a revised draft, almost identical to the original version, on 26 August. Following approval by the TRIPS Council on 28 August, the General Council of the WTO was then presented with a final draft of the Decision on implementation of paragraph 6 of the Doha Declaration, which it adopted on 30 August 2003.[121]

Developing[122] and Developed Countries[123] alike reacted positively to the Implementation Agreement; however, some countries permanently opted out

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[120] World Trade Organization – Council for Trade-Related aspects of Intellectual Property Rights, *Implementation of Paragraph 6 of Doha Declaration on the TRIPS Agreement and Public Health*, IP/C/W/405 (Aug. 30, 2003) (discussing the availability of compulsory licensing under Article 31 of the TRIPS Agreement)

[121] Duncan Matthews "WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public health: a solution to the access to essential medicines problem?" (2004), 7(1) *Journal of International Economic Law* Oxford University Press, at 95

[122] *See* statement made by Kenyan Ambassador to the WTO, Amina Chawahir Mohamed, after the deal was concluded: "All people of good will and good conscience will be very happy today with the decision that the WTO Members made… it's especially good news for the people of Africa who desperately need access to affordable medicine", available at <www.washingtonpost.com>, accessed on December 5, 2004.

[123] *See* European Trade Commission, *Access to Essential Medicines: EU Strongly Welcomes WTO Deal on Generic Medicines*. Available at <www.europa.eu.int>, accessed on December 5, 2004.

of utilising the provisions of the agreement,[124] while others maintained that they would only use the system only in urgent emergency situation.[125]

The implementation Agreement defines numerous terms, including "pharmaceutical product," "eligible importing Member," and "exporting Member."[126]

Furthermore, the implementation Agreement makes compulsory licensing easily accessible to least developed countries by defining an eligible importing Member as "any least developed country Member", without any further requirements.

In addition, it waives the requirement of Article 31(f) of the TRIPS Agreement that when a compulsory licence is used, it must predominantly for supply of the domestic market. For this waiver to occur, both the eligible importing Member and the exporting Member must meet a number of conditions. On the one hand, the importing Member must: specify the names and expected quantities of the product needed; establish that she has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Annex of the Implementation Decision and lastly must have granted or intend to grant a compulsory licence in accordance with Article 31 of the TRIPS Agreement and the provisions of

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[124] World Trade Organization – Council for Trade-Related aspects of Intellectual Property Rights, *Implementation of Paragraph 6 of Doha Declaration on the TRIPS Agreement and Public Health*, IP/C/W/405 (Aug. 30, 2003) (discussing the availability of compulsory licensing under Article 31 of the TRIPS Agreement). Within the meaning of "exporting members," the agreement notes that certain countries will not use the system in this Decision. These countries are: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxemburg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, the United Kingdom and the United States.

[125] These countries consist of Chinese Hong Kong, Israel, Korea, Kuwait, Chinese Macao, Mexico, Qatar, Singapore, Taiwan, Turkey, and United Arab Emirates. Others such as the Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, the Slovak Republic and Slovenia stated that they would only use the benefit of the decision in the event of a national emergency; and after their accession to the EU, they will opt out of using the system as the twenty-three countries mentioned above.

[126] Implementation Agreement, *ibid*. For the purposes of this Decision, "pharmaceutical product" means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration. It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included; "eligible importing Member means any least developed country Member, and any other Member that has made a notification to the Council for TRIPS of its intention to use the system as an importer, it being understood that a Member may notify at any time in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use and lastly, "exporting Member" means a Member using the system set out in this Decision to produce pharmaceutical products for, and export them to, an eligible importing Member.

the Implementation Decision, where a pharmaceutical product is patented in her territory. On the other hand, the exporting Member shall notify the Council for TRIPS of the grant of the licence, including the conditions attached to it. The information provided shall include the name and address of licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of licence. In addition, the notification shall also indicate the address of the website referred to.

Moreover, the Implementation Agreement sets out numerous conditions that the compulsory licence itself must incorporate.[127] The Implementation Agreement also clears up some prior concerns of double compensation to the patent holder that a Member would encounter under the requirement of adequate remuneration in Article 31(h). In addition, the implementation Agreement states that importing Members are to take reasonable measures to prevent re-exportation of the products that they have imported under a compulsory licence. It also provides that Members shall assist one another in preventing re-exportation from occurring, and, if a Member has a problem with another Members' compliance with this requirement, that Member may bring the issue before the Council for TRIPS for review.

A separate statement from the WTO General Council Chairperson *Carlos Perez del Castillo* clarifies that Members are to implement the Decision in good faith to protect public health problems and not for industrial or commercial policy objectives and that issues such as preventing the

[127] World Trade Organization – Council for Trade-Related aspects of Intellectual Property Rights, *Implementation of Paragraph 6 of Doha Declaration on the TRIPS Agreement and Public Health*, IP/C/W/405 (Aug. 30, 2003) (discussing the availability of compulsory licensing under Article 31 of the TRIPS Agreement): "[T]he compulsory license issued by the exporting Member under this Decision shall contain the following conditions: (i) only the amount necessary to meet the needs of eligible importing Member(s) may be manufactured under the license and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council of TRIPS; (ii) products produced under the license shall clearly identified as being produced under the system set out in this Decision through specific labeling or marking. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the product themselves, provided that such distinction is feasible and does not have a significant impact on price; and (iii) before shipment begins, the licensee shall post on a website the following information: -the quantities being supplied to each destination as referred to in indent (i) above; and the distinguishing features of the product(s) referred to in indent (ii) above.

medicines from getting into wrong hands are important.[128] Furthermore, it suggests that any disputes arising between Members be resolved "expeditiously and amicably".[129]

3.I The Legal Status of the August 2003 Decision.

Having analysed the provisions of the Decision on the implementation of Paragraph 6 of the Doha Declaration, it is necessary to consider its legal status and effects. As stated above the WTO August 2003 Decision provides temporary waivers to the obligations contained in Article 31(f) of the TRIPS Agreement.

As per Article 57 of the Vienna Convention on the Law of Treaties, a waiver does not imply any change in substantive treaty obligations it only temporarily suspend their operations. In the context of the WTO, a waiver means that a member shall not initiate a complain against another member if the latter acted under the terms of the adopted waiver. However, to the extend that a Member's national law is not revised to implement the terms of the waiver, patent owners may invoke provisions of the national law to block the export of a patented drug by other companies.[130] Therefore it is submitted that the extent to which generic drug makers could actually be able to export under the August 2003 Decision will depend on how far national laws allow for it.

3.2 WTO August 2003 Deal on Medicines: Is it a Gift bound in a Red Tape to Developing Countries?

Many criticisms have been levied against the WTO August 2003 decision on the implementation of Paragraph 6 of the Doha Declaration. While some critics[131] hold that the deal did nothing in changing the *status quo*, others hold

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[128] World Trade Organization, *The General Council Chairperson's Statement on implementation of paragraph 6of the Doha Declaration on the TRIPS Agreement and Public* Health, (August 30, 2003), available at <www.wto.org/english/news_e/news03_e/trips_stat_28aug03_e.htm>, accessed on October 12, 2004.

[129] *Ibid*

[130] Carlos M. Corea, "Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health", Buenos Aires, April 24, 2004. Available at www.who.int/medecines/organisation/mgt/wto_Doha Decision Para 6 f I, accessed on the April 20, 2005

[131] Raghavan C., "Medicine won't be cheaper under TRIPS and the public health decision", Geneva: Third World Network, August 31, 2003. Available at

that the deal is nothing more than a "gift bound tightly in a red tape".[132] The following reasons can, however, be advanced to support the above views.

The first thing, which makes the August 2003 deal a complicated one, is the fact that there is the requirement of the issuance of two compulsory licences (one by the exporting state and the other by the importing state) for the implementation decision to be used. This may be the more problematic in many Developing Countries especially Sub-Saharan African countries where there may be a lot of administrative and other bottlenecks for an importing country to persuade the exporting country to grant a compulsory license for a drug in dire need in the latter country.

Secondly, many constraints have been added on the business practices of the generic companies. Concerns remain that the added costs associated with altering packaging, pill size and colour will have a detrimental effect on the availability of essential medicines in Developing Countries, reducing the incentives for generic drug companies, which will find it less cost-efficient to produce identifiable pills. [133]

Furthermore, the WTO deal introduced an extra layer of uncertainty by stating that the system should not be an instrument to pursue industrial or commercial policy objectives, creating uncertainty over the role that will be played by the businesses that manufacture and sell the generic drugs. As such, critics worry that this statement is ambiguous and may make developing countries reluctant to use compulsory licensing under the system.[134] One

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<www.twnside.org.sg/title/5409b.htm>, accessed on December 6, 2004. See also the statement of Oxfam's head of Advocacy, Celine Charveriat:"the proposed deal is largely cosmetic and will not make a significant difference to the millions of sick people who die unnecessarily in the Third World every year." Available at <www.cptech.org>, accessed on October 12, 2004.

[132] A gift bound in a red tape is the term, which has been used to describe the August 2003 WTO deal on medicines. This phrase was used in a joint NGO statement released on September 10, 2003, by 14 NGO: ACT Up Paris, Consumer Project on Technology, Consumer International, Essential Action, European AIDS Treatment Group, Health Action International, Health GAP, International People's Health Council, Medicine sans Frontieres, OXFAM International, People's Health Movement, SEATINI, Third World Network and Women in Development. Available at <www.lists.essential.org/pipermail/ip-health/2003-september/005245.html>, accessed on October 12, 2004

[133] Duncan Matthews "WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public health: a solution to the access to essential medicines problem?" (2004), 7(1) *Journal of International Economic Law* Oxford University Press, at 95

[134] *See* Press Release, MSF, Flawed WTO Drugs Deal Will Do Little to Secure Future Access to Medicines in Developing Countries (Aug. 30, 2003). Available at

editorial expressed the concern shared by developing countries that if the statement "means no for-profit manufacturer or distributor can be involved at any level, the provision is a poison pill. It is not reasonable to believe that any charitable operation can gear up to make and supply what the global AIDS fight needs."[135]

In addition, the decision leaves unclear whether or not economic efficiency is a ground for determining a lack of manufacturing capacity in the importing country. The lack of clarity on this issue has been defended as a matter of "creative ambiguity", but already the U.S is telling the Philippines and other countries that they will oppose "economic efficiency" as grounds for allowing a country to import generics.[136]

Besides, the deal gives the WTO itself new authority to second guess and interfere in the granting of individual compulsory licenses to generic companies. Also, it is submitted here that the administrative burden associated with the procedural arrangements for notifying the WTO of its decision to use the mechanism and undergo TRIPS Council scrutiny will result in lengthy delays and prove costly for developing country governments.[137]

Moreover, as a measure of trade policy, the August 2003 implementation decision contradicts the basic principles of the WTO and free trade.[138] First, it explicitly accepts a protectionist framework, where rich countries can export to poor countries, but 23 rich countries were allowed to bar imports from Developing Countries. Second, the long list of new regulatory requirements does not apply to compulsory licenses in countries with capacity for manufacturing. Thus, one may conclude here that the entire framework of

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http://www.msf.org/content/page.cfm?articleid=C1540425-7F56-4D60-A6CB9D7ABA6D627F, accessed on September 20, 2004

[135] Put Fighting Disease First, Star Ledger, Sept. 10, 2003, at 14, available at 2003 West Law 18727632.

[136] Duncan Matthews "WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public health: a solution to the access to essential medicines problem?" (2004), 7(1) *Journal of International Economic Law* Oxford University Press, at 95

[137] Duncan Matthews "WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public health: a solution to the access to essential medicines problem?" (2004), 7(1) *Journal of International Economic Law* Oxford University Press, at 95

[138] *Ibid*

export restrictions is designed to limit rather than promote economic efficiency, the putative rational for free trade agreements.[139]

Another criticism levied against the August 2003 deal is the requirement for the payment of adequate remuneration. The requirement is somewhat vague as no clear definition has been provided for adequate remuneration. This has led to different interpretations from Developed and Developing Countries. Developed countries posit that if Developing and Least Developed Countries are to grant compulsory licences, full compensation to the patent holder is required.[140] At the other end of the spectrum, developing and least developed countries proposed that the patent holder receive no, or at most minimal, remuneration for use of the patent.[141] Granting adequate remuneration in the form of full market value as Developing countries urge, would not only be contradictory to the TRIPS Agreement and the Doha Declaration, but would also give the patent holders a windfall by enabling them to reap profits in a market where there were none previously.[142]

In addition, the Implementation Agreement confuses the issue of adequate remuneration even more by first noting in the Preamble that "exceptional circumstances exist justifying waivers from the obligations set out in "(TRIPS Article 31(h)]" and then later stating in Paragraph 3 that "[w]here a compulsory licence is granted by an exporting Member under the system set out in this Decision, adequate remuneration pursuant to Article 31(h) of the TRIPS Agreement shall be paid."[143]

In all likelihood, the Preamble of the Implementation Agreement is simply confirming that the existing right to issue a compulsory license without negotiation with the patent holder in situations of national emergency is

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[139] See NGO statement released on September 10, 2003, by 14 NGO: ACT Up Paris, Consumer Project on Technology, Consumer International, Essential Action, European AIDS Treatment Group, Health Action International, Health GAP, International People's Health Council, Medicine sans Frontieres, OXFAM International, People's Health Movement, SEATINI, Third World Network and Women in Development. Available at <www.lists.essential.org/pipermail/ip-health/2003-september/005245.html>, accessed on October 12, 2004

[140] Nabila Ansari, "International Patent Rights in a Post-Doha World" 11 (2002) *International Trade Law Journal*

[141] Mark Lang "What a long, strange 'TRIPS' it's been: Compulsory licensing from the adoption of TRIPS to the Agreement on Implementation of the Doha Declaration, (2004) 3 *John Marshall Review of Intellectual Property Law* 331 at 337

[142] *Ibid*

[143] See WTO August 2003 Implementation Agreement

preserved in the Agreement, but if that is the case, why does the Preamble use such indirect language? And why does the Preamble use the words "exceptional circumstances" instead of the often-used words "national emergency ?"[144]

Another controversial issue that emerged during the Paragraph 6 negotiations was which nations would qualify as "eligible importing Member(s)"; in other words, which countries would be able to make use of the exceptions to patent protection and import generic drugs to combat public health crises?[145]

The reason for the contentiousness of the issue is that, while Paragraph 6 of the Doha Declaration conferred a mandate on WTO Members to resolve the textual difficulty of countries with the concurrent problems of: (1) "insufficient or no manufacturing capacities in the pharmaceutical sector," and (2) "difficulties in making effective use of compulsory licensing," it did not include a requirement that a country face a genuine public health problem, nor did it include a requirement that the country lack the resources to purchase needed medicines from the manufacturer.[146] The lack of such requirements could lead to the perverse result of small, wealthy nations, such as Liechtenstein, Luxembourg, or Singapore, qualifying under the exception, as those nations have "insufficient or no manufacturing capacities" for pharmaceuticals. Thus, Paragraph 6 could be read to "solve" the fictitious problems of rich and healthy countries.[147]

Clearly, it is not appropriate to extend the solution to developed countries or to wealthy developing countries that choose not to manufacture certain drugs.[148] And while most parties could agree that the exception to patent protection should assist only poor countries that are truly incapable of manufacturing sufficient quantities of pharmaceuticals, any attempts to limit the use of the proposed exceptions to poor economic countries that lack sufficient

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[144] Bryan Mercurio, "TRIPS Patents, and access to life-saving drugs in the Developing World" (2004) 211 *Marquette Intellectual Property Law Review* at 15

[145] *Ibid*

[146] See Doha Declaration

[147] Amir Attaran, "The Doha Declaration on the TRIPS Agreement and Public Health, Access to Pharmaceuticals, and Options Under WTO Law", (2002)12 *Fordham Intellectual Property, Media and Entertainment Law Journal,* 859, 870 & n.21

[148] Bryan Mercurio, "TRIPS Patents, and access to life-saving drugs in the Developing World" (2004) 211 *Marquette Intellectual Property Law Review* at 15

manufacturing capabilities met fierce resistance.[149] For instance, Hong Kong stated that even though it did not envisage using the exception, it would not agree to its exclusion as an eligible country.[150] Hong Kong relied on the fact that "the only criterion for eligibility under the [Doha Declaration] was . . . insufficient manufacturing capacities."[151] South Africa and other rich developing nations concurred with the above stance, believing that Members should be allowed to elect not to benefit from the importation of products in the pharmaceutical sector to address public health needs under Paragraph 6, but that Members should not be excluded from the regime.[152]

The position advocated by Hong Kong, South Africa, and others counters the spirit of the Doha Declaration. Paragraph 1 of the Doha Declaration, which states that the WTO Ministerial "recognise[s] the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics," quite clearly implies that Paragraph 6 applies only to developing and LDCs.[153] Paragraph 1 reflects that the proposals initiated by developing countries as a solution to their problems, and the solution to the Paragraph 6 Mandate should have recognised the history and reasoning behind the Declaration and been predicated on a country's poor economic and poor health status.[154] In this regard, Paragraph 1(b) of the Implementation Agreement fails to take full account of the purpose of the Doha Declaration and leaves the system open to widespread and potentially debilitating abuse.[155] In order to reach consensus, developed countries abandoned the notion that an "eligible importing Member" must be a poor nation suffering from a public health crisis. Therefore, as drafted and adopted, the Implementation Agreement allows for

[149] Bryan Mercurio, "TRIPS Patents, and access to life-saving drugs in the Developing World" (2004) 211 *Marquette Intellectual Property Law Review* at 15

[150] WTO Council for TRIPS, Minutes of Meeting Held in the Centre William Rappard on 25-27 and 29 November, and 20 December 2002, IP/C/M/38 (Feb. 5, 2003), PP 38, 45

[151] See WTO Ministerial Conference, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (Nov. 20, 2001)

[152] Bryan Mercurio, "TRIPS Patents, and access to life-saving drugs in the Developing World" (2004) 211 *Marquette Intellectual Property Law Review* at 13

[153] See WTO Ministerial Conference, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (Nov. 20, 2001)

[154] Bryan Mercurio, "TRIPS Patents, and access to life-saving drugs in the Developing World" (2004) 211 *Marquette Intellectual Property Law Review* at 15

[155] Bryan Mercurio, "TRIPS Patents, and access to life-saving drugs in the Developing World" (2004) 211 *Marquette Intellectual Property Law Review* at 13

any Member of the WTO to make use of the patent exceptions, so long as that nation is suffering from a public health crisis and has insufficient manufacturing capabilities to meet demand.[156] While the Implementation Agreement notes that some Members have stated that they will not make use of the system and others have pledged to make use of the system only in situations of national emergency or other extreme circumstances, these statements are unlikely to be binding if, in fact, those nations later decide to make use of the patent exceptions.[157]

In this respect, poor developing countries especially from Sub-Saharan Africa could face competition from small wealthy developed countries in the procurement of drugs since the latter countries would argue that they are facing national emergency and that they do not have the capacity to manufacture certain drugs. If such competition arises, pharmaceutical companies would be more incline to sell to Developed Countries which as a result of their wealth, have a greater purchasing power and available market than their poverty stricken counterparts from the developing world. Hence, the implementation decision notwithstanding, access to drugs in the developing world still remains a serious problem.

3.3 Forging Ahead with Doha: the case of Cameroon, Malawi, and the Andean Community.[158]

Despite the multiple attempts to weaken the Doha Declaration, the past two years have also seen certain countries moving forward to take advantage of the flexibilities it has afforded.[159] Cameroon has been able to access the best international prices for antiretrovirals (ARVs) because its Ministry of Health authorised the importation of generic versions of patented drugs when they were available at lower prices than the originator. As a result, the national procurement agency pays about US$277 per person/year (ppy) for its first-line

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[156] Bryan Mercurio, "TRIPS Patents, and access to life-saving drugs in the Developing World" (2004) 211 *Marquette Intellectual Property Law Review* at 13

[157] *Ibid*

[158] The Andean community is made up of Bolivia, Colombia, Ecuador, Peru and Venezuela

[159] Doha Derailed: A progress report on TRIPS and access to medicines. Available at <www.accessmed-msf.org/prod/publications.asp?scntid=3D2782003111 >, accessed on October 12, 2004

treatment combination-one of the lowest available internationally.[160] Similarly, it is possible to buy a generic first-line ARV combination in Malawi for about US$ 288 ppy; as an LDC, Malawi does not have to enforce or grant pharmaceutical patents until 2016.[161]

In addition, by including generic companies in the price negotiations, the Andean Community and five other Latin American countries (Argentina, Chile, Paraguay, Mexico and Uruguay) were able to establish price ceilings for ARVs that are significantly lower than the existing prices in any of the countries.

By finding ways to overcome patent barriers, Cameroon, Malawi and the Latin American countries are acting in accordance with the core principle of Doha, that TRIPS should be "interpreted and implemented in a manner supportive of WTO Members right to protect health."[162]

[160]Doha Derailed: A progress report on TRIPS and access to medicines. Available at <www.accessmed-msf.org/prod/publications.asp?scntid=3D2782003111 >, accessed on October 12, 2004

[161] *Ibid*

[162] Doha Derailed: A progress report on TRIPS and access to medicines. Available at <www.accessmed-msf.org/prod/publications.asp?scntid=3D2782003111 >, accessed on October 12, 2004

CHAPTER FOUR: OUTSIDE THE GATES OF THE WTO: DANGEROUS BILATERAL AND REGIONAL TRADE DEALS; THE CASE OF THE UNITED STATES OF AMERICA

It has been said that the principle of bilateralism has with respect to intellectual property rights, enabled the U.S government to bypass multilateral commitments made in respect of intellectual property.[163] The U.S has been pursuing a number of regional or bilateral trade agreements that would, in effect, weaken or even completely annul the Doha Declaration.[164] Negotiations to tighten patent protection are underway in regions heavily burdened by disease, with perhaps the most severe example being the Free Trade Area of the Americas (FTAA) Agreement, which includes 34 countries of the Western hemisphere and covers 800 million people.[165]

In addition to FTAA, the U.S is currently negotiating free trade agreements with five Central American countries (Costa Rica, El Salvador, Guatemala, Honduras and Nicaragua in CAFTA), the Dominican Republic, the Southern African Customs Union (Botswana, Lesotho, Namibia, South Africa and Swaziland), Morocco, Bahrain and Australia. By exerting pressure on countries to adopt TRIPS-plus provisions,[166] the U.S is going back on its word and breaching the commitments it made when it agreed to the Doha Declaration four years ago.[167]

4.1 Background to US bilateralism

US bilateralism on intellectual property was largely a response to its failure to obtain an agreement on trade in counterfeit goods at the end of the Tokyo Round (1979) and the resistance of developing countries in the first half of the

[163] Jean Frederick Morin, " Le droit international de brévets: entre le multilaterisme et le bilatérisme américain" *Etudes internationales*, Vol 34, No 3, December 2003, 537

[164] Doha Derailed: A progress report on TRIPS and access to medicines. Available at <www.accessmed-msf.org/prod/publications.asp?scntid=3D2782003111 >, accessed on October 12, 2004

[165] *Ibid*

[166] TRIPS plus provision is the name that has been given to those provisions found in bilateral and regional agreements (e.g. FTAA), which are not found in the TRIPS agreements and which are for the most part stringent to comply with than the original TRIPS provisions.

[167] Doha Derailed: A progress report on TRIPS and access to medicines. Available at <www.accessmed-msf.org/prod/publications.asp?scntid=3D2782003111 >, accessed on October 12, 2004

1980s to including intellectual property as a negotiating item in a new GATT round.[168] Led by India and Brazil, ten developing countries at first opposed the US proposal to make a code on intellectual property a negotiating item (the remaining countries were Argentina, Cuba, Egypt, Nicaragua, Nigeria, Peru, Tanzania and Yugoslavia).[169] Breaking the resistance of these 'hard liners' was fundamental to achieving the outcome the US wanted. During the 1980s the US reformed its Trade Act of 1974 to create a linkage with intellectual property.[170] The principal enforcement tool of US trade policy, section 301 was amended to make it clear that it could be used to obtain protection for US intellectual property; a mechanism known as 'Special 301' was created requiring the United States Trade Representative (USTR) to identify countries denying adequate and effective protection for intellectual property rights and the administration of the Generalised System of Preferences program (giving developing countries duty free trading privileges in the US market) was linked to the adequate protection of US IPRs.[171] At the same time as it reformed its trade law in the 1980s to accommodate intellectual property the US linked its Bilateral Investment Treaty (BIT) program to the goal of adequate and effective protection for intellectual property.[172]

It should be noted that in bilateral trade negotiations between states involving a strong and weak state, generally speaking the strong state comes along with a prepared draft text which acts as a starting point for the negotiations.[173] Bilateral negotiations are complex and lengthy affairs, features which make

[168] Peter Drahos, " Bilateralism in Intellectual Property". A paper prepared for OXFAM GB as part of its cut the cost of medicine campaign, London, 2002

[169] A. Jane Bradley, 'Intellectual Property Rights, Investment, and Trade in Services in the Uruguay Round: Laying the Foundations', 23 (1987) *Stanford Journal of International Law*, 57, 81, fn. 72.

[170] Peter Drahos, " Bilateralism in Intellectual Property". A paper prepared for OXFAM GB as part of its cut the cost of medicine campaign, London, 2002

[171] *Ibid*

[172] The model BIT program that the US developed in the 1980s protected intellectual property as an investment activity. By 1987 the US had signed a BIT with eleven developing countries and was negotiating with seven others. See F. Abbott, 'Protecting First World Assets in the Third World: Intellectual Property Negotiations in the GATT Multilateral Framework', Symposium: Trade-Related Aspects Of Intellectual Property, 22 (1989), *Vanderbilt Journal of Transnational Law*, 689, 712, fn12.

[173] Peter Drahos, " Bilateralism in Intellectual Property". A paper prepared for OXFAM GB as part of its cut the cost of medicine campaign, London, 2002

them costly even for strong states.[174] In order to lower the transaction costs of bilateralism the US has developed models or prototypes of the kind of bilateral treaties it wishes to have with other countries.[175] Once a model treaty is ratified by the Senate, US trade negotiators know that if they stick to its terms in other negotiations there is a good chance the treaties flowing from these negotiations will also be approved.[176] For the US there are very strong incentives for a standardization of bilateral treaty standards.[177] So, for example, the BIT which the US signed with Nicaragua in 1995 was based on the prototype that the US had developed for such treaties in 1994.[178] Similarly the Free Trade Agreement that the US has negotiated with Jordan is serving as a model for other FTAs being negotiated with Chile and Singapore. At this juncture, it is necessary to examine one of such bilateral investment treaty that contain TRIPS-plus provisions entered into by the US.

4.2 The US - Jordan FTA[179]

The US-Jordan FTA is a good example of a wide-ranging agreement containing provisions on trade in goods, in services, intellectual property rights, environment and labour, electronic commerce and government procurement. In contrast to the somewhat soft provisions on environment and labour (e.g. each Party "shall strive to ensure" that its labour standards are consistent with international norms)[180] the provisions on intellectual property are long and detailed.[181] The TRIPS plus features of the Jordan FTA include the following:

- the requirement that each Party give effect to UPOV and that in the case of Jordan it ratify UPOV within 12 months;

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[174] Peter Drahos, " Bilateralism in Intellectual Property". A paper prepared for OXFAM GB as part of its cut the cost of medicine campaign, London, 2002
[175] *Ibid*
[176] *Ibid*
[177] *Ibid*
[178] Peter Drahos, " Bilateralism in Intellectual Property". A paper prepared for OXFAM GB as part of its cut the cost of medicine campaign, London, 2002
[179] Agreement between the USA and the Hashemite Kingdom of Jordan on the Establishment of a Free Trade Area, signed by both parties in October, 2000.
[180] Article 6.3 of the Agreement.
[181] Peter Drahos, " Bilateralism in Intellectual Property". A paper prepared for OXFAM GB as part of its cut the cost of medicine campaign, London, 2002

- the grant to authors, performers and phonogram producers of an exclusive importation right;

- the regulation of the government use of computer software;

- narrowing the grounds of exclusion from patentability (basically, the grounds of exclusion in Article 27.3(b) of TRIPS are omitted);

- a redrafted compulsory licensing provision which confines the use of compulsory licences to specified cases rather than as in the case of TRIPS, placing conditions on the use of compulsory licences. (The specified cases are for remedying an anti-competitive practice, use in public non-commercial contexts, national emergencies and other cases of extreme urgency, and the failure to meet working requirements.); and

- an obligation to provide for an extension of patent term to compensate patent owners for regulatory delays in being able to exploit the patent.[182]

There are other important aspects to this agreement that make it TRIPS plus or that take the evolution of intellectual property rights beyond TRIPS.[183] As a general point it is abundantly clear that the US has constructed a model agreement that meets the problems it perceives with TRIPS or that resolves some of the ambiguities of TRIPS.[184] So, for example, Article 39.3 of TRIPS, which obliges a Member to protect data submitted as part of the process of getting regulatory approval for the marketing of pharmaceutical or agricultural products involving "new chemical entities", leaves open the question of what is meant by a new chemical entity, whereas the Jordan FTA stipulates that

[182] Peter Drahos, " Bilateralism in Intellectual Property". A paper prepared for OXFAM GB as part of its cut the cost of medicine campaign, London, 2002
[183] *Ibid*
[184] *Ibid*

new chemical entity includes "protection for new uses for old chemical entities for a period of three years".

The Jordan FTA also contains a Memorandum of Understanding on issues related to the protection of Intellectual Property Rights (MOU). This MOU contains further prescriptions and standards on intellectual property which Jordan has to meet. For example, Jordan's exclusion of mathematical methods from patentability has to be clarified by it to avoid the exclusion of business methods and computer-related inventions. [185] Normally this kind of task would fall to the judiciary of a country. [186] Similarly the MOU stipulates the level of criminal penalties for certain kinds of infringement. Generally the level of criminal penalties in a state is a matter of domestic policy and culture.[187]

Another key feature of the Jordan FTA is the creation of a Joint Committee "to supervise the proper implementation" of the Agreement.[188]. The Joint Committee would appear to come close to exercising a law-creating function.[189] Its functions include considering and adopting amendments to the Agreement and developing guidelines and rules for its proper implementation.[190] Heading the Joint Committee is the United States Trade Representative (USTR) and Jordan's Minister for Trade. Obviously there are some hard questions to ask about the role of such a committee, not least of all how it squares with the promotion of the ideal of democratic law-making.[191]

[185] Peter Drahos, " Bilateralism in Intellectual Property". A paper prepared for OXFAM GB as part of its cut the cost of medicine campaign, London, 2002
[186] *Ibid*
[187] *Ibid*
[188] Article 15(1) of US-Jordan FTA
[189] Peter Drahos, " Bilateralism in Intellectual Property". A paper prepared for OXFAM GB as part of its cut the cost of medicine campaign, London, 2002
[190] Article 15 of the US-Jordan FTA
[191] Peter Drahos, " Bilateralism in Intellectual Property". A paper prepared for OXFAM GB as part of its cut the cost of medicine campaign, London, 2002

4.3 Possible implications of bilateral and regional negotiations on the implementation of the 30 August Decision to African countries.

As discussed above, one sees that many bilateral and regional agreements have been concluded containing TRIPS - plus provisions. Some of the more damaging TRIPS - plus provisions negotiated in bilateral and regional agreements that may have a negative impact on the implementation of the 30 August Decision on African countries include:[192]

1) Limits on the circumstances in which compulsory licences on pharmaceutical products including essential medicines may be issued by some African states;
2) An extension on the minimum period of patent protection beyond the 20 year minimum prescription contained in TRIPS which would delay the introduction of generic pharmaceuticals;
3) A new responsibility given to drug regulatory authorities to consider the patent status of drugs before granting marketing authorisation to manufacturers of generics. This may be harmful to generic drug producers as drug regulatory authorities in some African countries have no or very little experience of patents. It is unlikely that the patent authorities would have the necessary immediate expertise to make decisions concerning patents and the process, which would further delay the availability of essential generics;
4) Imposing on African government, the principle of limiting of data on pharmaceutical tests to drug regulating authorities, which is potentially harmful because generic companies traditionally rely on test data of resource based companies to prove the efficacy and safety of their products; and
5) The potential restriction of parallel importation to limited geographical configurations, which would prevent African countries from sourcing generics from the cheapest global supplier.[193]

[192] Tenu Avafia, "Summary documents of South Africa's implementation of the WTO's 30 August Decision" (2004), (unpublished).

[193] Tenu Avafia, "Summary documents of South Africa's implementation of the WTO's 30 August Decision" (2004), (unpublished). *See* also the recently concluded US FTA with

The above shows some of the dangerous consequences that may flow from bilateral intellectual property agreements. According to an UNCTAD study, TRIPS could have certain negative impacts on developing countries including higher prices for drugs and technologies under IPR protection and restrictions on the diffusion of technologies.[194] The current crop of bilateral agreements does nothing to reduce the possibility of these negative impacts and may well increase them.[195]

4.4 Putting pen to paper: Actions of some Developed Countries aimed at promoting the August 2003 Agreement; the case of Canada and the European Union.

Irrespective of the bilateral and regional agreements being concluded by the U.S, which would have a significant negative impact on the implementation of the August 2003 agreement, some Developed countries have been carrying out a series of actions, aimed at promoting the implementation of the said agreement. Canada is a quintessential example. In May 2004, she passed Bill C-9 which amends the *Patent Act* and the *Food and Drugs Act* to provide the legislative framework to enable Canada to respond to the August 30, 2003 decision of WTO on the Agreement on Trade-Related Aspects of Intellectual Property Rights and Public Health.[196] In October 2004, she released for public comments regulations that would enable the implementation of the said Bill. The Bill, C-9 which finally came into force in autumn 2004, enables Canada to provide cheap pharmaceutical products to developing and least developed countries. The Canadian example is the first attempt internationally to implement the WTO General Council Decision of 30 August to waive patent rights to permit developing countries to import less expensive versions of high-priority medicines from other countries.

Morocco which contains provisions that effectively prohibit the parallel importation of pharmaceuticals including essential medicines.

[194] UNCTAD, The TRIPS Agreement and Developing Countries, UN, New York and Geneva, 1997, 18.

[195] Peter Drahos, " Bilateralism in Intellectual Property". A paper prepared for OXFAM GB as part of its cut the cost of medicine campaign, London, 2002

[196] *See* "The Jean Chrétien Pledge to Africa Act Approved by Parliament". Available at <www.ic.gc.ca/cmb/welcomeic.nsf>, accessed on December 19, 2004.

Furthermore, the European Commission in October 2004, proposed a regulation to allow manufacturers of generic pharmaceuticals to produce patented medicines for export to "countries in need" without sufficient capacity to produce them.[197] This in line with the WTO decision of 30 August 2003. The proposed Regulation puts no further restriction on the medicines and diseases to be covered. To help ensure that medicines get to the patients who need them and to protect patent holders, customs authorities will be able to prevent the re-importation into the EU of medicines produced under the system.

Internal Market Commissioner *Frits Bolkestein* said: "The WTO decision and our proposed Regulation can help save lives by helping countries in need to acquire affordable medicines, without undermining the patent system, which is one of the main incentives for the research and development of new medicines."[198]

Trade Commissioner *Pascal Lamy* said: "By adopting this proposal the EU leads the way in ensuring access to affordable medicines for poor countries. It shows that we are delivering on our promises in the Doha Development Agenda. I now hope that it can be taken forward quickly by the EU Member States and the European Parliament."[199]

The proposed Regulation would set up a system for companies who wish to manufacture medicines for export to apply to national authorities for the grant of a "compulsory licence" from a patent holder who has exclusive rights over the manufacture and sale of the products concerned. Most national laws at present do not allow compulsory licences for export because until recently the WTO TRIPS Agreement provided for compulsory licences only "predominantly for the supply of the domestic market".

Provided countries in need notify to the WTO the medicines they need, it would be up to generic companies to decide to apply for licences to manufacture them.

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[197] *See* EC proposal for a regulation of the European Parliament and of the Council on compulsory licensing of patent to the manufacturers of pharmaceutical products for export to countries with pubic health problems. Brussels, October 29, 2004.

[198] *See* EC proposal for a regulation of the European Parliament and of the Council on compulsory licensing of patent to the manufacturers of pharmaceutical products for export to countries with pubic health problems. Brussels, October 29, 2004.

[199] *Ibid*

Once export takes place, all parties have an interest in seeing that medicines are not diverted from those who need them. The Commission's proposal would prohibit re-importation into the EU and provide for customs authorities to take action against goods being re-imported. The patent holder could use existing national procedures to enforce its rights against re-imported goods if they do enter the EU, and the licence could be terminated.

While the EU does not require a medicinal marketing authorization for exported products, importing countries may want to ensure that medicines are safe and effective. In the proposal provision is made for use of the EU's scientific opinion procedure for evaluating medicines under Regulation (EC) no 726/2004.[200]

4.5 Panorama of the ongoing negotiations within the WTO from August 30, 2003 to present date in relation to the implementation decision of Paragraph 6 of Doha and Public Health.

4.5.1 The TRIPS Council Meeting of March 2004.

So many things have happened since the conclusion of an agreement to implement paragraph 6 of the Doha Declaration was arrived at in August 30, 2003. While some countries have tried to stymie the agreement by entering into dangerous bilateral agreements containing TRIPS plus provisions, others have done their best by enacting legislation aimed at facilitating the implementation of the said agreement.

However, in the TRIPS Council Meeting of March 8, 2004, a divergence of opinions was seen between the U.S on the one hand and some Developing Countries on the other. These countries were split on whether a written statement, which was read by the chairman of the WTO Council on TRIPS and ultimately allowed the U.S to agree to this modification to TRIPS, should be reflected in a final amendment to the TRIPS Agreement. Reflecting that statement in an amendment is seen as critical by the U.S, as it contains pledges that Developing Countries will only take advantage of the new rules

[200] *See* EC proposal for a regulation of the European Parliament and of the Council on compulsory licensing of patent to the manufacturers of pharmaceutical products for export to countries with pubic health problems. Brussels, October 29, 2004.

to deal with health crises, and that several of the more advanced Developing Countries would not use the agreement except in the most dire emergencies to import generic drugs manufactured under a compulsory license.[201] But Developing countries resisted this U.S demand by arguing that the statement was not part of a formal agreement.

At issue was a written statement from the former TRIPS council chairman *Vanu Gopala Menom*, which was read in an August 31 TRIPS Council meeting. That same meeting accepted a December 2002 agreement to give Developing Countries that lack the capacity to manufacture generic drugs a waiver from the WTO rules that would allow them to import generic copies of patented drugs manufactured in third countries under a compulsory license. According to the U.S, she only accepted that agreement after countries agreed to the Menom's statement.[202]

Developing Countries argued that they believe the Chairman Statement was never intended to be legally binding, and was instead intended to allay the fears of brand-name pharmaceutical companies that the TRIPS would be misused, such as through the diversion of drugs to rich countries. The eleven developing countries identified as opting out of using the compulsory licensing rules in the *Menom* statement argued they wanted to avoid turning what they see as a voluntary statement into something more legally binding.[203]

The U.S strongly disputed this suggestion, as they argue the December 2002 agreement prepared by then TRIPS Council Chair *Eduardo Perez Motta* was only agreed to by the U.S in connection with the *Menom* statement.

The U.S and Developing Countries also disagree over what legal form an amendment to the TRIPS should take, with the U.S suggesting a footnote to the TRIPS. However, Developing Countries want the decision reflected in a new paragraph that would be included in TRIPS Article 31. Developing Countries were uncomfortable with a footnote because they do not believe it would be as strong as the text within the TRIPS.[204] Thus, it became clear from

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[201] *See* "WTO Members re-open fight over substance of TRIPS-Health Agreement", Inside US Trade – March 12, 2004. Available at <www.cptech.org>, accessed on October 12, 2004.
[202] *See* "WTO Members re-open fight over substance of TRIPS-Health Agreement", Inside US Trade – March 12, 2004. Available at <www.cptech.org>, accessed on October 12, 2004.
[203] *Ibid*
[204] *See* "WTO Members re-open fight over substance of TRIPS-Health Agreement", Inside US Trade – March 12, 2004. Available at <www.cptech.org>, accessed on October 12, 2004. *See*

the differences at this meeting that the June 2004 deadline for agreeing to an amendment incorporating the decision into TRIPS was far fetched. Small wonder, the new chairman, *Joshua Law* suggested the deadline could be extended by another nine months.[205]

4.5.2 The WTO General Council Meeting of July 2004

The next great event was the WTO meeting of July 2004. However, at the meeting WTO Members concentrated most of their time in negotiating issues relating to Agriculture and Non- Agriculture Market Access (NAMA). In his final report, the Director General, *Supachai Panitchpakdi*, reaffirmed Members commitments to progress with the TRIPS negotiations.[206]

4.5.3 The TRIPS Council Meeting of December 2004

Public health and biodiversity-related concerns emerged as major issues at the year's final meeting of the WTO Council for Trade-related Aspects of Intellectual Property Rights (TRIPS) on 1-2 December. At the meeting, Nigeria submitted a proposal (IP/C/W/437) on behalf of the African Group - which includes all African WTO Members - for converting the waiver provided for in the 30 August 2003 Decision on pharmaceutical patents into a formal amendment of the TRIPS agreement. Many developed countries criticized the Nigeria-led proposal, arguing that it sought to re-open the debate on the substance of the Decision and would only complicate current discussions.[207] The supporters of the proposal countered that the suggested text was only an attempt to simplify the complex nature of the waiver.

The African Group submission proposed a text for amending TRIPS Article 31, and marked the first substantial contribution to the debate since the Decision itself. Prior discussions had been limited to technical questions about how to include the waiver in the Agreement. Some Developed Country

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also statement by one Developing country delegate: "A footnote is something that adds clarity to the main body of a text, but if there is a conflict between the text and a footnote, the main text wins the day". Available at <www.cptech.org>, accessed on October 12, 2004.

[205] *Ibid*

[206] " Key Developing Countries seek to move debate forward on disclosures". Available at www.ictsd.org/weekly/TripsCouncil.04-09-22/story1.htm, access on May 16, 2005.

[207] "TRIPS Council considers Public Health, Biodiversity". Available at <www.ictsd.org/weekly/04-12-08/story1.htm>, accessed on December 21, 2004.

Members disagreed with the proposed text. The US in particular criticized it for not including several provisions of the 30 August Decision. Countries including the US, the EU, Japan, Canada, and Switzerland argued that the omissions amounted to an attempt by the African Group to re-open the agreement struck in 2003. They see the amendment as a strictly technical exercise involving the incorporation of the waiver into the TRIPS Agreement. They said that the negotiations leading up to the 30 August Decision were very difficult and that the current text represents a fragile balance that should not be renegotiated; new debates on the amendment would be counterproductive.[208]

The proposal's co-signatories, with the support of the Philippines, countered that though their proposed amendment goes beyond the mere introduction of the waiver's text into Article 31, it does not make any substantive changes to it. They argue that at most, it only simplifies the text of the waiver by leaving out the parts that are redundant in view of other provisions in the TRIPS Agreement, including its preamble. In addition, the US demanded that the General Council Chair's Statement of 30 August be included in any amendment to the TRIPS Agreement. Most Developing Countries generally resist this, due to the limiting language of the statement and its direct reference to specific pharmaceutical corporations.[209]

In the end, due to the late presentation of the African proposal, most countries decided not to comment. The issues were carried forward to the TRIPS Council meeting of March 2005, with Members having high expectations to agree on an amendment of the TRIPS Agreement.[210] As we shall see below these expectations were all dashed as Members could not arrive at a consensus.

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[208] "TRIPS Council considers Public Health, Biodiversity". Available at <www.ictsd.org/weekly/04-12-08/story1.htm>, accessed on December 21, 2004.

[209] *Ibid*

[210] TRIPS Council considers Public Health, Biodiversity". Available at <www.ictsd.org/weekly/04-12-08/story1.htm>, accessed on December 21, 2004.

4.5.4 TRIPS Council Meeting of 8-9 March 2005

Public health and biodiversity issues were again the items sparking the most discussion at the meeting of the WTO Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS) on 8-9 March 2005. Members were unable to reach consensus on how to formally amend Article 31 of the TRIPS Agreement in order to facilitate the export of drugs produced under compulsory licence.

Public health-related discussions focused on a submission from Rwanda on behalf of the African Group (composed of African WTO Members) containing legal arguments supporting the group's December 2004 proposal[211] for the amendment of Article 31 of the TRIPS Agreement. The submission addresses the legal form of the amendment, justifications for the modification of the 30 August Decision, and the status of the Chair's statement. The communication contends that a footnote would not suffice for the amendment of TRIPS Article 31, because a footnote would not provide sufficient certainty and legal security with respect to the implementation of the amendment. Thus, the African Group argues, the amending text should be inserted into the body of the Agreement.[212]

Discussion and comments on the submission reaffirmed the positions taken by Members at the December TRIPS Council meeting. The EU concurred with the US, stating that the African Group's proposal did not reflect all the elements of the 30 August Decision and was, therefore, unacceptable.[213] However, the EU did agree with the African Group's argument that the footnote approach was not the best solution to amend the TRIPS Agreement. It also supported the proposed option of reading the Chair's statement at the

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[211] For the African Group Proposal, *See* "TRIPS Council considers Public Health, Biodiversity". Available at <www.ictsd.org/weekly/04-12-08/story1.htm>, accessed on December 21, 2004. Also see paragraph 4.4.3 above (The TRIPS Council Meeting of December 2004) for an analysis of the proposal of the African Group.
[212] "TRIPS Council Meeting suspended in effort to meet public health deadline". Available at www.ictsd.org/weekly/05-03-16/story1.htm, accessed on April 20, 2005.
[213] *Ibid*

time of the adoption of the amendment. Other developed countries such as Switzerland, Japan, and Canada said that the Chair's summary was, in their opinion, an essential part of the Decision and a key element in their willingness to agree on the Decision. They stated their preference for the footnote approach, but showed some willingness to consider alternative solutions. On the other hand, several developing countries, including Argentina, Brazil, Hong Kong-China, India, Jamaica, Kenya, Malaysia, and the Philippines supported the African Group's proposal by stressing that the Decision and the Chair's summary had different legal status and that including the latter in the amendment would unjustifiably upgrade its legal status.[214]. Some developing countries recalled that the main purpose of the 30 August Decision was to provide an answer to a humanitarian problem, and that its implementation should be carried out in that spirit. All developed and developing countries expressed their commitment to meet the agreed deadline of 31 March 2005 to amend the TRIPS Agreement.

Members accepted the proposal by TRIPS Council Chair *Miller* of Hong Kong, China to continue the consultations aimed at finding a solution within the agreed deadline. However, his proposal to discuss the text of the Decision paragraph-by-paragraph was rejected by the Unites States and Switzerland, which argued that this approach would *de facto* reopen negotiations on the Decision.[215] Thus, countries agreed to suspend the session while the Chair continued consultations aimed at meeting the 30 March 2005 deadline.

4.5.5 TRIPS Council Meeting of 30-31 March 2005.

The World Trade Organisation for the second time missed the deadline for concluding a "permanent solution" to the problem facing countries that have no or inadequate drug manufacturing capacity so that they can have access to affordable medicines in their meeting of 30-31 March 2005.

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[214] "TRIPS Council Meeting suspended in effort to meet public health deadline". Available at www.ictsd.org/weekly/05-03-16/story1.htm, accessed on April 20, 2005.
[215] Shashikant Sangeeta, "Heated discussions as TRIPS and Health deadline is missed", South Development Monitor, SUNS No 5772, Geneva, Monday April 4, 2005. Available at www.cptech.org/weblog/suns04042005.html, accessed on May 5, 2005

The deadline of 31 March passed without agreement. It was marked instead by a formal meeting of the TRIPS Council which highlighted sharp differences and at times acrimony between developing countries and major developed countries.[216]

At the end of the meeting, the TRIPS Council chairperson, Ambassador *Tony Miller* of Hong Kong China said that his successor, Ambassador *Choi Hyuck* of Korea would conduct consultations, with the aim of finding a solution before the WTO General Council meeting of 26-27 May, which has thus become the new target date.[217]

At the 31 March meeting of the TRIPS Council, there were heated discussions over the content and legal form of the amendment, and especially on the circumstances in which the 30 August 2003 decision and statement were made.[218]

"The African Group which makes up a large portion of the WTO's membership cannot and will not accept an interpretation of paragraph 11 that says the August decision and the Chairman's statement in its entirety should form the amendment" said Ambassador *Valentine Rugwabiza* of Rwanda, coordinator of the African Group.[219]

The Group stated that its proposals incorporated the Decision wherever it was appropriate, but it was also necessary to leave out certain parts of the Decision that were redundant, nor should the Chairman's statement be adopted in the permanent solution.[220] This contrasted with the view of the United States and the EU who repeated their position that the amendment

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[216] Shashikant Sangeeta, "Heated discussions as TRIPS and Health deadline is missed", South Development Monitor, SUNS No 5772, Geneva, Monday April 4, 2005. Available at www.cptech.org/weblog/suns04042005.html, accessed on May 5, 2005

[217] *Ibid*

[218] Shashikant Sangeeta, "Heated discussions as TRIPS and Health deadline is missed", South Development Monitor, SUNS No 5772, Geneva, Monday April 4, 2005. Available at www.cptech.org/weblog/suns04042005.html, accessed on May 5, 2005.

[219] Shashikant Sangeeta, "Heated discussions as TRIPS and Health deadline is missed", South Development Monitor, SUNS No 5772, Geneva, Monday April 4, 2005. Available at www.cptech.org/weblog/suns04042005.html, accessed on May 5, 2005

[220] *Ibid*

had to be based on the Decision and the Chairman's statement as otherwise a consensus would be difficult.[221]

The African Group's interpretation of paragraph 11 of the Decision received overwhelming support from developing countries. Zambia (on behalf of LDCs), Benin (on behalf of the ACP countries), Argentina, Brazil, India, Philippines, Sri Lanka and Peru, were in agreement with the African Group's position that the amendment does not need to be a direct transposition of the Decision and the Chairman's statement.[222]

They concurred that the ordinary meaning of the sentence "the amendment will be based, where appropriate, on this Decision" indicates that only the parts of the Decision that are appropriate are to be used in the amendment.[223]

The Decision is in the form of a waiver of Article 31(f) of TRIPS (which mandates that production under compulsory licensing is to be predominantly for the domestic market) to enable countries with manufacturing capacity to export essential medicines to countries with no or insufficient manufacturing capacity.[224]

This Decision and the Chairman's statement contain several conditions and measures which exporting and importing countries have to comply with, raising concerns amongst analysts that they are too cumbersome and thus rendering the "temporary solution" difficult to operate.[225] Paragraph 11 of the Decision directed the TRIPS Council to prepare an amendment to the TRIPS agreement which "will be based, where appropriate, on this Decision."[226]

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[221] Shashikant Sangeeta, "Heated discussions as TRIPS and Health deadline is missed", South Development Monitor, SUNS No 5772, Geneva, Monday April 4, 2005. Available at www.cptech.org/weblog/suns04042005.html, accessed on May 5, 2005.

[222] Shashikant Sangeeta, "Heated discussions as TRIPS and Health deadline is missed", South Development Monitor, SUNS No 5772, Geneva, Monday April 4, 2005. Available at www.cptech.org/weblog/suns04042005.html, accessed on May 5, 2005.

[223] *Ibid*

[224] *Ibid*

[225] Shashikant Sangeeta, "Heated discussions as TRIPS and Health deadline is missed", South Development Monitor, SUNS No 5772, Geneva, Monday April 4, 2005. Available at www.cptech.org/weblog/suns04042005.html, accessed on May 5, 2005.

[226] *Ibid*

In a statement to the TRIPS Council, Rwanda, on behalf of the African Group, referring to the *Terri Shiavo case*[227] in the United States, quoted the US President as saying that "where there are serious questions and substantial doubts, our society, our laws, and our courts should have a presumption in favour of life. It should be our goal as a nation to build a culture of life".[228]

The Rwanda Ambassador declared that dedication "to build a culture of life" should be stronger, more urgent and immediate in the TRIPS Council which has been mandated to find a permanent solution on how to ensure sustainable supply of essential generic medicines to the millions of people dying everyday, particularly in Africa.[229] Unfortunately, Rwanda felt that this dedication and determination seemed to be lacking, as four years had passed since this issue had been raised but Members were not moving closer to finding a permanent solution to this problem .[230]

The Rwandan Ambassador further referred to a proposal submitted by the African Group on how to incorporate the temporary waiver into TRIPS, with detailed explanations including why certain parts of the Decision were redundant and should not form any part in the permanent solution.[231] However, it appeared that some members are not engaging constructively in the discussion; for instance, they acknowledge that some parts of the waiver are redundant but to date no concrete proposal had been tabled by any of them.[232]

The Rwandan Ambassador reminded Members of the circumstances prevailing prior to and at the time the Decision was agreed to. Many options had been proposed by the African Group, which allowed countries to export

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[227] This case was a highly politicised case in the United States in which the courts on the request of Terri Shiavo's (a brain-damaged woman) husband, ordered that her Terri Shiavo feeding tube be removed, leading to her dead.

[228] Shashikant Sangeeta, "Heated discussions as TRIPS and Health deadline is missed", South Development Monitor, SUNS No 5772, Geneva, Monday April 4, 2005. Available at www.cptech.org/weblog/suns04042005.html, accessed on May 5, 2005

[229] *Ibid*

[230] *Ibid*

[231] *Ibid*

[232] Shashikant Sangeeta, "Heated discussions as TRIPS and Health deadline is missed", South Development Monitor, SUNS No 5772, Geneva, Monday April 4, 2005. Available at www.cptech.org/weblog/suns04042005.html, accessed on May 5, 2005.

and import affordable generic medicines to satisfy the public health needs of people worldwide.[233] However, "we faced a lot of pressure from some Members which imposed many conditions that were difficult to meet", she added.[234]

The African Group and many other developing and least developed countries were never entirely happy with the interim solution and this was made very clear during the TRIPS Council meetings, said the Ambassador.[235] Recalling the understanding that was reached by Members on the Decision, she said: "We agreed to this "interim solution" on the understanding precisely that it was only an interim solution, while discussions to find a permanent solution would continue.[236] This understanding is reflected in paragraph 11 of the Decision".

Rwanda contented that the Chairman's statement, had been read when the Decision was adopted more as an attempt to provide comfort language to assuage the concerns of the pharmaceutical industries that generic manufacturers would gain a strong foothold in the pharmaceutical market and that the Statement therefore had to be put in its proper context.[237] She also added that during the informal TRIPS Council meetings, some developing and least developed countries' delegates had expressed their reservations over the content of the Statement and this clearly indicated that the Statement was never intended to form any part of the permanent solution.[238]

The African Group submitted that the main reason the Statement was allowed to be read by countries with reservations is because they felt an urgent need to make a contribution to the success of the Cancun Ministerial

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[233] Shashikant Sangeeta, "Heated discussions as TRIPS and Health deadline is missed", South Development Monitor, SUNS No 5772, Geneva, Monday April 4, 2005. Available at www.cptech.org/weblog/suns04042005.html, accessed on May 5, 2005.

[234] *Ibid*

[235] Shashikant Sangeeta, "Heated discussions as TRIPS and Health deadline is missed", South Development Monitor, SUNS No 5772, Geneva, Monday April 4, 2005. Available at www.cptech.org/weblog/suns04042005.html, accessed on May 5, 2005.

[236] Shashikant Sangeeta, "Heated discussions as TRIPS and Health deadline is missed", South Development Monitor, SUNS No 5772, Geneva, Monday April 4, 2005. Available at www.cptech.org/weblog/suns04042005.html, accessed on May 5, 2005.

[237] *Ibid*

[238] Shashikant Sangeeta, "Heated discussions as TRIPS and Health deadline is missed", South Development Monitor, SUNS No 5772, Geneva, Monday April 4, 2005. Available at www.cptech.org/weblog/suns04042005.html, accessed on May 5, 2005

Conference.[239] There was a strong feeling then that a solution, even if it was an interim one, had to be concluded before Cancun so that the meeting could focus on other issues and thus have a better chance of success.[240]

It was felt at that time that a Chairman's statement would help facilitate the quick conclusion to the interim solution, but with the understanding that a permanent solution would require more careful consideration, taking into account all the aspects, including how the mechanism chosen could be operationalised in practice.[241]

Thus, the Chairman's statement no longer exist should be seen as a facility that served a particular purpose at that time, mainly to meet the deadline of having a temporary settlement before the Cancun meeting. These circumstances however no longer exist.[242]

The African Group sought clarification about a footnote referring to the Chairman's statement that it said had been added to the Decision without the express consent of the Members.[243] According to the African Group, when the Decision in document IP/C/W/405 was agreed to, there was no reference to the Chairman's statement.[244]

A senior official of the intellectual property division at the WTO, clarified that Members had not agreed to include that footnote in the Decision, and that was why the footnote uses an asterisk (unlike the decision, which uses numbers), and it is in the introduction, not the decision itself.[245] Therefore, including or excluding the footnote does not affect the decision or the legal status of the chairperson's statement, he said. It was included because

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[239] *Ibid*
[240] Shashikant Sangeeta, "Heated discussions as TRIPS and Health deadline is missed", South Development Monitor, SUNS No 5772, Geneva, Monday April 4, 2005. Available at www.cptech.org/weblog/suns04042005.html, accessed on May 5, 2005
[241] *Ibid*
[242] Shashikant Sangeeta, "Heated discussions as TRIPS and Health deadline is missed", South Development Monitor, SUNS No 5772, Geneva, Monday April 4, 2005. Available at www.cptech.org/weblog/suns04042005.html, accessed on May 5, 2005.
[243] *Ibid*
[244] *Ibid*
[245] Shashikant Sangeeta, "Heated discussions as TRIPS and Health deadline is missed", South Development Monitor, SUNS No 5772, Geneva, Monday April 4, 2005. Available at www.cptech.org/weblog/suns04042005.html, accessed on May 5, 2005.

readers might find the information helpful.[246] According to trade diplomats, the Decision could be reissued without the footnote, if Members wished.[247]

The workability of the Decision in practice was also questioned by the African Group.[248] It referred to a recent African Union Workshop on Patents and Access to Medicines attended by policy makers from 35 African countries, which had expressed concern that the Decision imposes several conditions on importers and exporters who wish to make use of the waiver and which thus may affect the countries' ability to supply generic medicines to countries with insufficient or no manufacturing capacity. [249]

The Rwanda Ambassador elaborated that the African policy makers had thus expressed concerns about the workability of the "interim solution" and called for "a more appropriate 'permanent solution' that revises TRIPS and that removes the Article 31(f) constraint without placing new constraints so that the export and import of generic medicines can be smoothly facilitated."[250] They had also expressed support for the position of the African Group in the WTO in seeking a permanent solution.[251]

According to the Rwandan Ambassador it was evident that policy makers at the national level consider the interim solution as containing shortcomings that may affect the operational effectiveness to meet the goal of supplying affordable medicines and so that an appropriate permanent solution is urgently required.[252]

Recalling the commitment of Member States in the Doha Declaration "to interpret and implement the TRIPS Agreement in a manner supportive of

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[246] *Ibid*
[247] Shashikant Sangeeta, “Heated discussions as TRIPS and Health deadline is missed”, South Development Monitor, SUNS No 5772, Geneva, Monday April 4, 2005. Available at www.cptech.org/weblog/suns04042005.html, accessed on May 5, 2005
[248] *Ibid*
[249] Shashikant Sangeeta, “Heated discussions as TRIPS and Health deadline is missed”, South Development Monitor, SUNS No 5772, Geneva, Monday April 4, 2005. Available at www.cptech.org/weblog/suns04042005.html, accessed on May 5, 2005.
[250] *Ibid*
[251] *Ibid*
[252] Shashikant Sangeeta, “Heated discussions as TRIPS and Health deadline is missed”, South Development Monitor, SUNS No 5772, Geneva, Monday April 4, 2005. Available at www.cptech.org/weblog/suns04042005.html, accessed on May 5, 2005.

WTO Member's right to protect public health and, in particular, to promote access to medicines for all", the African Group stated that they were not convinced that the 30 August 2003 decision together with the Chairman's statement as it stands today will fulfil the commitment to protect public health and promote access to medicines for all".[253]

The Group also expressed the wish to seek a solution that is "permanent, sustainable, secure and predictable".[254] The Rwandan Ambassador said the Group had put forward a proposal based on the appropriate elements of the decision, complete with detailed explanation about the proposal.[255] The Group urged all Members to share their interpretation of paragraph 11 of the Decision and to engage constructively with the intention of resolving expeditiously the Doha Declaration's paragraph 6 problem, in favour of supplying affordable medicines to those who are most in need.[256]

The African Group was of the view that a permanent solution is within reach if members act in accordance with the letter and spirit of paragraph 11 of the Decision.[257] It hoped that further consultations will finalise the amendment so that a Decision can be adopted at the General Council meeting in May 2005.[258]

Many other developing countries, including India, Brazil, Philippines, Sri Lanka, Argentina, and Peru expressed agreement with and support for the position adopted by the African Group.[259]

On behalf of the Least Developed Countries (LDC), the Ambassador of Zambia also fully supported the statement made by Rwanda.[260] He said that it

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[253] Shashikant Sangeeta, “Heated discussions as TRIPS and Health deadline is missed”, South Development Monitor, SUNS No 5772, Geneva, Monday April 4, 2005. Available at www.cptech.org/weblog/suns04042005.html, accessed on May 5, 2005

[254] *Ibid*

[255] Shashikant Sangeeta, “Heated discussions as TRIPS and Health deadline is missed”, South Development Monitor, SUNS No 5772, Geneva, Monday April 4, 2005. Available at www.cptech.org/weblog/suns04042005.html, accessed on May 5, 2005.

[256] *Ibid*

[257] Shashikant Sangeeta, “Heated discussions as TRIPS and Health deadline is missed”, South Development Monitor, SUNS No 5772, Geneva, Monday April 4, 2005. Available at www.cptech.org/weblog/suns04042005.html, accessed on May 5, 2005

[258] *Ibid*

[259] *Ibid*

was the understanding of the LDC Group that the intention never was that the August decision would be regarded as the "consensus solution".[261] It was, and is, only an interim solution" and paragraph 11 is indicative of the intention of Member States, he continued.[262]

The group of LDCs also stressed that they always had reservations over the content and the status of the Chairman's statement and expressed the view that there was never an agreement or any kind of understanding amongst Member States that all elements of the Statement will form part of the amendment.[263]

At the height of discussions over how to resolve the paragraph 6 problem, many promises were made by major developed countries to other Member states, to obtain their support for the Decision and the reading of a Chairman's statement, said Zambia, supporting the African Group's version of the circumstances prevailing at that time.[264] He added that "we were informed that the 30 August decision was only an interim solution and that discussions to finding a permanent solution by amending TRIPS would continue," quoting paragraph 11 of the decision as to how the discussions would proceed.[265]

The LDCs stressed that the view held by some members, that certain Groups of countries wish to reopen the debate that was conclusively ended in August of 2003, simply has no basis and is not supported by paragraph 11 of the Decision.[266] The Zambian Ambassador called on Members to refrain from

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[260] *Ibid*
[261] Shashikant Sangeeta, "Heated discussions as TRIPS and Health deadline is missed", South Development Monitor, SUNS No 5772, Geneva, Monday April 4, 2005. Available at www.cptech.org/weblog/suns04042005.html, accessed on May 5, 2005.
[262] *Ibid*
[263] Shashikant Sangeeta, "Heated discussions as TRIPS and Health deadline is missed", South Development Monitor, SUNS No 5772, Geneva, Monday April 4, 2005. Available at www.cptech.org/weblog/suns04042005.html, accessed on May 5, 2005.
[264] *Ibid*
[265] Shashikant Sangeeta, "Heated discussions as TRIPS and Health deadline is missed", South Development Monitor, SUNS No 5772, Geneva, Monday April 4, 2005. Available at www.cptech.org/weblog/suns04042005.html, accessed on May 5, 2005
[266] *Ibid*

making statements that misinterpret the circumstances prevailing and the understanding reached at the time the Decision was adopted.[267]

He added that the African Group proposal is consistent with paragraph 11 of the Decision and that the Group had selected the most appropriate elements of the decision to form the amendment, and the LDC Group would like to have the proposal discussed positively and built upon.[268] "We underline the urgency of the issue, and this is not a matter of procedural debate for us but rather an emergency, on which depends the lives of millions of our people. We urge Members to work for a permanent solution by the General Council meeting of May 2005."[269]

Kenya said there were certain things in common between Britain and Africa, in that Britain treats its written and unwritten laws with equal weight, and Africa similarly treats the written and unwritten promises equally.[270] The Kenyan delegate asserted that oral promises made behind the scenes have to be honoured and had to be brought back to the table for discussion.[271]

Kenya declared that they had been promised that any problems they had with the Decision would be sorted out at the amendment stage."[272] They requested Members to learn a lesson from the words of an African elder, "Since we can't go back in time and reverse the damage that has been done, you can take action now, to make it better for the future."[273]

In contrast to the positions taken by developing countries, the US, EU and Switzerland repeated their argument that the Decision struck a balance between a range of concerns felt by different groups of members, and was the

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[267] *Ibid*
[268] Shashikant Sangeeta, "Heated discussions as TRIPS and Health deadline is missed", South Development Monitor, SUNS No 5772, Geneva, Monday April 4, 2005. Available at www.cptech.org/weblog/suns04042005.html, accessed on May 5, 2005
[269] *Ibid*
[270] *Ibid*
[271] *Ibid*
[272] Shashikant Sangeeta, "Heated discussions as TRIPS and Health deadline is missed", South Development Monitor, SUNS No 5772, Geneva, Monday April 4, 2005. Available at www.cptech.org/weblog/suns04042005.html, accessed on May 5, 2005.
[273] *Ibid*

result of difficult negotiations, according to trade officials.[274] They said a consensus on an amendment will be difficult to achieve if the substance of the waiver is renegotiated and they also repeated their position that the General Council Chairperson's statement was part of the consensus.[275]

Switzerland said it is currently revising its laws so that its companies can export generics under the Decision and this revision will be endangered if the substance of the waiver is going to be renegotiated.

The US representative called the issue of "unwritten promises" raised by the African Group as "perceived promises". According to trade officials, the US said it was concerned to hear unsubstantiated accusations, and as far as it was concerned there were no behind the scenes promises made, and its negotiators at that time had been transparent.

In response to this, the Kenyan representative stood his ground, saying that he had prepared a statement that was to be read at the General Council on 30 August 2003 but he was prevailed upon by delegations of the developed countries not to do so.[276] He added that they had made promises to his delegation and high officials in his capital to reassure them, so that he would not have to make the statement he had prepared, at the General Council meeting when the Chairman's statement was read out and the Decision adopted.[277]

Kenya also made reference to some parts of a statement made by Canada on the eve of the adoption of the Decision in August 2003.[278] Kenya said that the

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[274] *Ibid*
[275] Shashikant Sangeeta, "Heated discussions as TRIPS and Health deadline is missed", South Development Monitor, SUNS No 5772, Geneva, Monday April 4, 2005. Available at www.cptech.org/weblog/suns04042005.html, accessed on May 5, 2005.
[276] *Ibid*.
[277] Shashikant Sangeeta, "Heated discussions as TRIPS and Health deadline is missed", South Development Monitor, SUNS No 5772, Geneva, Monday April 4, 2005. Available at www.cptech.org/weblog/suns04042005.html, accessed on May 5, 2005
[278] *Ibid*.

Canadian statement might remind Members of the pressures facing the developing countries, particularly the African Group at that time.[279]

At an informal meeting of the Heads of Delegations on 29 August 2003, Canada said, "The final thank you goes to all my African colleagues because it was their countries and their citizens who were always recognised as the primary beneficiaries of the Declaration on TRIPS and Public Health.[280] It was their people who had the most need. And yet, they have demonstrated remarkable patience with us, on such a "life and death" issue. I am not sure many of us, in similar circumstances, would have acted as honourably."[281]

This statement made by Canada that it is indeed an issue of "life and death" is echoed in the African Group's present statement.

The meeting ended with no agreement on the amendment to the TRIPS Agreement.[282] The chairperson *Tony Miller* said that consultations would be carried on by his successor Ambassador *Choi Hyuck* with the aim of reaching agreement by the General Council meeting of 26-27 May 2005, as proposed by the African Group and the Trade Negotiations Committee, which is guiding the current WTO trade liberalisation negotiations.[283] A document on the issue could emerge in July, and the issue could be part of the outcome of the WTO ministerial conference in Hong Kong in December as well as part of the final Doha Development Agenda results, possibly completed by the end of 2006.[284]

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[279] Shashikant Sangeeta, "Heated discussions as TRIPS and Health deadline is missed", South Development Monitor, SUNS No 5772, Geneva, Monday April 4, 2005. Available at www.cptech.org/weblog/suns04042005.html, accessed on May 5, 2005

[280] *Ibid*

[281] *Ibid*.

[282] *Ibid*

[283] Shashikant Sangeeta, "Heated discussions as TRIPS and Health deadline is missed", South Development Monitor, SUNS No 5772, Geneva, Monday April 4, 2005. Available at www.cptech.org/weblog/suns04042005.html, accessed on May 5, 2005

[284] William New, "TRIPS public health Amendment Deadline missed". Available at www.Ip-watch.org/weblog/index.phpp=37&res=ff&print=0, accessed on May 5, 2005.

4.5.6 India's Patent Bill, 2005

India is one of the leading developing countries in the production of generic versions of patented drugs and has traditionally been the primary provider of drugs to African countries.[285] In March 2005, she passed a Patent Bill (Bill No.32-C of 2005) to replace her Patent Ordinance of 2004. By passing this Bill, India was merely fulfilling its TRIPS obligations as it had to conform with the WTO's intellectual property agreement by 2005.[286] However, it should be noted that this Bill created a national uproar in India especially among companies specialised in producing generic versions of patented drugs[287] and has been criticised for being non compliant with some provisions of the TRIPS Agreement.[288] Since this Bill will have a direct impact on developing countries (especially Sub-Saharan African countries) who greatly rely on India for cheap versions of generic drugs, it is imperative for it to be examined. However, this analysis will be limited to pharmaceutical patents and compulsory licences.

India's Patents Ordinance of 2004 defined inventive step to mean a "feature that makes the invention not obvious to a person skilled in the art". This definition was in compliance with the explanatory note to Article 27(1) of the TRIPS Agreement which states that inventive step is synonymous with non obviousness. However, the 2005 Bill redefines inventive step. It defines inventive step to mean *"a feature of an invention that involves technical advances as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art".*[289]

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[285] *See* Tenu Avafia, "Comments on the latest amendments to the Indian patent legislation and the impact on African countries". Available at www.tralac.org, accessed on March 29, 2005

[286] *Ibid*

[287] "India's Patents Bill, 2005 – Is it TRIPS Compliant" Available at www.lexorbis.com, accessed on April 7, 2005

[288] "India's Patents Bill, 2005 – Is it TRIPS Compliant" Available at www.lexorbis.com, accessed on April 7, 2005

[289] Section 2(1)(ja) of India's Patents Bill, 2005

From the above, one sees that for an invention to be non-obvious under the new Indian Patent Bill, it has to have economic significance or technical advances as compared to existing knowledge. The wording *'technical advances as compared to existing knowledge'* rather dilutes the very basis of obviousness/novelty requirements for if an invention is not distinctive over prior act, it is not patentable.[290] It is submitted that such wording could have the impact on making the whole definition of patent vague and arbitrary.[291]

The second phrase is *'economic significance'.* By bringing the above under non-obviousness, the Bill directly interferes with the time-tested principles of patent law, and in that process, creates a new definition that can lead to loose interpretations.[292]

In addition to the above, the Bill expanded the scope of issuance of compulsory licenses for manufacture and export of patented pharmaceutical products to countries having insufficient manufacturing capacity in the pharmaceutical sector, if that country has by notification allowed such importation.[293]

Furthermore, Indian law makers have included double usage patents in the Bill even though the WTO obligation does not require India to grant patents on new uses of known drugs or combinations of known drugs. In this respect, *Anand Grover*, project director of Lawyers Collective HIV/AIDS Unit said:"…a drug like QWT which was used against cancer in the mid 70s and now used for HIV can be patented simply on the grounds of new usage".[294]

From the above analysis, one sees that India's new patent law will have a rippling effect on developing countries and may well spell doom for the access to medicine in Sub-Saharan African countries by skyrocketing the drug prices making them unaffordable. Before this Bill was passed, India's pharmaceutical

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[290] "India's Patents Bill, 2005 – Is it TRIPS Compliant" Available at www.lexorbis.com, accessed on April 7, 2005
[291] *Ibid*
[292] "India's Patents Bill, 2005 – Is it TRIPS Compliant" Available at www.lexorbis.com, accessed on April 7, 2005
[293] *See* Section 92A(1) of India's Patents Bill, 2005
[294] Harbaksh Singh Nanda," Health groups slam India's new patent law", Available at www.washingtontimes.com/upi-breaking /20050324-105633-9090r.htm

majors like Cipla and Ranbaky were spearheading making AIDS drugs and exporting them to African nations at a very low cost as compared to multinational pharmaceutical majors.[295] For example, in Africa, exports by Indian companies helped nose-dive the annual price of Anti retroviral treatment from $14,000 a decade ago to $200.[296] They also simplified the therapy by making pills containing 3 AIDS drugs. However, today, all this seem to be changing. An increment in drug prices in Developing Countries is forecasted in the foreseeable future since most of the Indian generic companies will now be forced to change their production policies i.e. from making versions of generic drugs to the discovery of new drugs.

[295] Harbaksh Singh Nanda," Health groups slam India's new patent law", Available at www.washingtontimes.com/upi-breaking /20050324-105633-9090r.htm
[296] *Ibid*

CHAPTER FIVE: CONCLUSION AND RECOMMENDATIONS

5.1: Conclusion

After two years of political rigmarole, WTO Members finally agreed on a decision to implement Paragraph 6 of the Doha Declaration. This Decision presents a step in the right direction to increasing the availability of cheap drugs to developing countries suffering from health crises. At the time of its entry into force, it was contemplated that that the Decision would be a great mile stone in alleviating the adversities often faced by citizens of Developing Countries in their quest for acquiring medicines. However, the status quo still remains unchanged. Even though, some developing countries like Cameroon have profited from the system since they have made use of the Decision's compulsory license provisions to import versions of generic drugs, many developed countries are still to benefit from the deal. Its procedural difficulties, to say the least has been a major stumbling block to Developing Countries wanting to use the Decision. Dangerous bilateral and regional treaties and pieces of national legislation that contain TRIPS-plus provisions for the most part have not helped the situation.

It is submitted that, for most Developing Countries to fully enjoy the benefits of this Decision, much still has to be done at the level of the WTO. Until countries fully match their commitments with concrete actions (as with the case of Canada who recently passed a legislation enabling the provision of cheaper versions of generic drugs to developing countries) and stop paying lip service to the current WTO deal on medicine, and until a permanent solution is found on the Paragraph 6 problem, one can not help but remain cynical and look at the entire TRIPS negotiations with lurking suspicion – that it is always to preserve the interests of Western Pharmaceutical companies especially as so many deadlines aimed at reaching a final decision on the August 2003 deal has been missed. Accordingly, the following recommendations are thus proffered.

5.2: Recommendations

Firstly, exporting country members should grant all applications for a compulsory license by a potential exporting manufacturer, contingent on the exporter showing that they plan to export in response to a request by an eligible importer.[297]

Licenses should authorise production of a quantity needed by the eligible importer. The license should be open-ended, so that exporters are authorised to export over time, whatever amounts an importing country indicates it needs, subject to a system whereby the importing country provide notification of the required amounts, and those amounts are disclosed on a timely basis in a manner consistent with the WTO system of transparency. The term of the license should be for the life of the patent in the exporting country; unless the imported country indicates that it is no longer eligible.[298]

In addition, there should be no requirement in the exporting country for a prior negotiation with the patent holder, and certainly not if one took place in the importing country. The TRIPS obligation for negotiation for a reasonable period of time shall be deemed met by negotiations if required, that occurred in the importing country.[299]

Besides, the implementing legislation should ideally apply to all healthcare inventions, and at least to all pharmaceutical products, defined in the Paragraph 6 Agreement as inclusive of all products of the pharmaceutical sector, including active ingredients needed for manufacture of pharmaceutical and diagnostic kits. Implementing legislation should specify that it applies to vaccine.[300]

Furthermore, countries should desist from passing pieces of legislation or entering into bilateral trade treaties which contain TRIPS plus provisions. By entering into such bilateral trade treaties, most Developing Countries are dangerously voyaging into uncharted seas since for the most part, the

[297] 'Paragraph 6 Implementation Recommendations', Available at <www.cptech.org>, accessed on October 12, 2004.
[298] 'Paragraph 6 Implementation Recommendations', Available at <www.cptech.org>, accessed on October 12, 2004.
[299] *Ibid*
[300] *Ibid*

negative impacts of such treaties are often felt shortly after their implementation or when there is a health emergency, a situation which is hardly anticipated when such treaties are being negotiated and signed. It is worthy to note that the benefits of multilateralism in trade and the dangers of bilateralism have long been recognised.[301] In this connection, *Robert Weissman* notes that as countries craft legislation implementing such bilateral trade treaties, the overriding principle should be to make the system as smooth and efficient as possible.[302] In the case of bilateralism on intellectual property developing countries should consider forming a veto coalition against further ratcheting up of intellectual property standards.[303] The alliance between NGOs and developing countries on the access to medicines issue and the fact that this alliance has managed to obtain Special Sessions of the TRIPS Council on this issue suggests that this coalition is a realistic possibility.[304] The position of such a veto coalition should be converting the Council on TRIPS from a body that secures a platform to one that polices a ceiling.[305] This bold new agenda for the Council on TRIPS would be standstill and rollback of intellectual property standards in the interests of reducing distortions and increasing competition in the world economy.[306] If developing countries cannot forge a unified veto coalition against further ratcheting up of intellectual property standards, they can be assured that they will be picked off one by one by the growing wave of US bilaterals on both intellectual property and investment more broadly.[307]

Clearly the formation of such a veto coalition presents a huge challenge to current networks of transnational activism.[308] It would require the leadership of visionary NGOs.[309] Developing countries would have to begin to co-

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[301] J. Jackson, The World Trading System, The MIT Press, Cambridge, Mass., London, 1997, 158.

[302] 'Paragraph 6 Implementation Recommendations', Available at <www.cptech.org>, accessed on October 12, 2004.

[303] Peter Drahos, " Bilateralism in Intellectual Property". A paper prepared for OXFAM GB as part of its cut the cost of medicine campaign, London, 2002

[304] Peter Drahos, " Bilateralism in Intellectual Property". A paper prepared for OXFAM GB as part of its cut the cost of medicine campaign, London, 2002

[305] *Ibid*

[306] *Ibid*

[307] Peter Drahos, " Bilateralism in Intellectual Property". A paper prepared for OXFAM GB as part of its cut the cost of medicine campaign, London, 2002

[308] *Ibid*

[309] *Ibid*

ordinate their bilateral and multilateral strategies much more closely than they have to date.

Thus far, the WTO August 2003 Decision has been examined. It is submitted that the Decision is to a very large extent “a gift in a red tape”. The procedural difficulties encountered in its implementation far outweigh the positive impacts of the deal. To alleviate the health crises in developing countries, the WTO Members should go a step further by amending Article 31(f) of the TRIPS Agreement so that the Paragraph 6 issue of the Doha Declaration shall be laid to rest once and for all, bringing an end to the lengthy negotiations and antagonistic positions that have characterised the TRIPS Council in particular and the entire WTO this far.

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Addendum

In order to facilitate clarity and understanding of the ongoing WTO – TRIPS debate on public health and access to drugs, articles of the TRIPS provisions, the Doha Declaration as well as the WTO implementation decision of August 30 2003, which have formed the basis of the discussion in this research paper are reprinted below in the form of an addendum.

Article 31of the TRIPS Agreement[310]

Other Use without Authorization of the Right Holder

Where the law of a Member allows for other use[311] 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 provisions shall be respected:

(a) authorization of such use shall be considered on its individual merits;

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified

[310] These provisions were downloaded from the WTO website, <www.wto.org>, accessed on the December 22, 2004.
[311] "Other use" refers to use other than that allowed under Article 30.

as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;

(d) such use shall be non-exclusive;

(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

(l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:

(i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

(ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and

(iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

WORLD TRADE ORGANIZATION

WT/MIN(01)/DEC/2
20 November 2001

(01-5860)

MINISTERIAL CONFERENCE
Fourth Session
Doha, 9 – 14 November 2001

DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

Adopted on 14 November 2001

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.

3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.

4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

6. We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an

expeditious solution to this problem and to report to the General Council before the end of 2002.

7. We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2. We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

GENERAL COUNCIL

WT/L/540

1 September 2003

Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health

Decision of the General Council of 30 August 2003

The General Council,

Having regard to paragraphs 1, 3 and 4 of Article IX of the Marrakesh Agreement Establishing the World Trade Organization ("the WTO Agreement");

Conducting the functions of the Ministerial Conference in the interval between meetings pursuant to paragraph 2 of Article IV of the WTO Agreement;

Noting the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) (the "Declaration") and, in particular, the instruction of the Ministerial Conference to the Council for TRIPS contained in paragraph 6 of the Declaration to find an expeditious solution to the problem of the difficulties that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face in making effective use of compulsory licensing under the TRIPS Agreement and to report to the General Council before the end of 2002;

Recognizing, where eligible importing Members seek to obtain supplies under the system set out in this Decision, the importance of a rapid response to those needs consistent with the provisions of this Decision;

Noting that, in the light of the foregoing, exceptional circumstances exist

justifying waivers from the obligations set out in paragraphs (f) and (h) of Article 31 of the TRIPS Agreement with respect to pharmaceutical products;
Decides as follows:

1. For the purposes of this Decision:

(a) "pharmaceutical product" means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration. It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included;[312]

(b) "eligible importing Member" means any least-developed country Member, and any other Member that has made a notification [313] to the Council for TRIPS of its intention to use the system as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. It is noted that some Members will not use the system set out in this Decision as importing Members [314] and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency;

(c) "exporting Member" means a Member using the system set out in this Decision to produce pharmaceutical products for, and export them to, an eligible importing Member.

[312] This subparagraph is without prejudice to subparagraph 1(b).
[313] It is understood that this notification does not need to be approved by a WTO body in order to use the system set out in this Decision.
[314] Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom and United States of America.

2. The obligations of an exporting Member under Article 31(f) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out below in this paragraph:

(a) the eligible importing Member(s) [315] has made a notification[316] to the Council for TRIPS, that:

(i) specifies the names and expected quantities of the product(s) needed ;[317]

(ii) confirms that the eligible importing Member in question, other than a least developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Annex to this Decision; and

(iii) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Article 31 of the TRIPS Agreement and the provisions of this Decision;[318]

(b) the compulsory licence issued by the exporting Member under this Decision shall contain the following conditions:

(i) only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS;

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[315] Joint notifications providing the information required under this subparagraph may be made by the regional organizations referred to in paragraph 6 of this Decision on behalf of eligible importing Members using the system that are parties to them, with the agreement of those parties.

[316] See fn 112 above

[317] The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to this Decision

[318] This subparagraph is without prejudice to Article 66.1 of the TRIPS Agreement.

(ii) products produced under the licence shall be clearly identified as being produced under the system set out in this Decision through specific labeling or marking. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price; and

(iii) before shipment begins, the licensee shall post on a website [319] the following information:

- the quantities being supplied to each destination as referred to in indent (i) above; and
- the distinguishing features of the product(s) referred to in indent (ii) above;

(c) the exporting Member shall notify [320] the Council for TRIPS of the grant of the licence, including the conditions attached to it.[321] The information provided shall include the name and address of the licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the licence. The notification shall also indicate the address of the website referred to in subparagraph (b)(iii) above.

3. Where a compulsory licence is granted by an exporting Member under the system set out in this Decision, adequate remuneration pursuant to Article 31(h) of the TRIPS Agreement shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. Where a compulsory licence is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) shall be waived in respect of those products for

[319] The licensee may use for this purpose its own website or, with the assistance of the WTO Secretariat, the page on the WTO website dedicated to this Decision.
[320] It is understood that this notification does not need to be approved by a WTO body in order to use the system set out in this Decision.
[321] The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to this Decision.

which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.

4. In order to ensure that the products imported under the system set out in this Decision are used for the public health purposes underlying their importation, eligible importing Members shall take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system. In the event that an eligible importing Member that is a developing country Member or a least-developed country Member experiences difficulty in implementing this provision, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in order to facilitate its implementation.

5. Members shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system set out in this Decision and diverted to their markets inconsistently with its provisions, using the means already required to be available under the TRIPS Agreement. If any Member considers that such measures are proving insufficient for this purpose, the matter may be reviewed in the Council for TRIPS at the request of that Member.

6. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products:

> (i) where a developing or least-developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least developed countries, the obligation of that

Member under Article 31(f) of the TRIPS Agreement shall be waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question;

(ii) it is recognized that the development of systems providing for the grant of regional patents to be applicable in the above Members should be promoted. To this end, developed country Members undertake to provide technical cooperation in accordance with Article 67 of the TRIPS Agreement, including in conjunction with other relevant intergovernmental organizations.

7. Members recognize the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem identified in paragraph 6 of the Declaration. To this end, eligible importing Members and exporting Members are encouraged to use the system set out in this Decision in a way which would promote this objective. Members undertake to cooperate in paying special attention to the transfer of technology and capacity building in the pharmaceutical sector in the work to be undertaken pursuant to Article 66.2 of the TRIPS Agreement, paragraph 7 of the Declaration and any other relevant work of the Council for TRIPS.

8. The Council for TRIPS shall review annually the functioning of the system set out in this Decision with a view to ensuring its effective operation and shall annually report on its operation to the General Council. This review shall be deemed to fulfill the review requirements of Article IX:4 of the WTO Agreement.

9. This Decision is without prejudice to the rights, obligations and flexibilities that Members have under the provisions of the TRIPS Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the

Declaration, and to their interpretation. It is also without prejudice to the extent to which pharmaceutical products produced under a compulsory licence can be exported under the present provisions of Article 31(f) of the TRIPS Agreement.

10. Members shall not challenge any measures taken in conformity with the provisions of the waivers contained in this Decision under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994.

11. This Decision, including the waivers granted in it, shall terminate for each Member on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that Member. The TRIPS Council shall initiate by the end of 2003 work on the preparation of such an amendment with a view to its adoption within six months, on the understanding that the amendment will be based, where appropriate, on this Decision and on the further understanding that it will not be part of the negotiations referred to in paragraph 45 of the Doha Ministerial Declaration (WT/MIN(01)/DEC/1).

ANNEX

Assessment of Manufacturing Capacities in the Pharmaceutical Sector

Least-developed country Members are deemed to have insufficient or no manufacturing capacities in the pharmaceutical sector.

For other eligible importing Members insufficient or no manufacturing capacities for the product(s) in question may be established in either of the following ways:

(i) the Member in question has established that it has no manufacturing capacity in the pharmaceutical sector;

OR

(ii) where the Member has some manufacturing capacity in this sector, it has examined this capacity and found that, excluding any capacity owned or controlled by the patent owner, it is currently insufficient for the purposes of meeting its needs. When it is established that such capacity has become sufficient to meet the Member's needs, the system shall no longer apply.