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Access to Essential Medicine Issues and The Doha Declaration: Contents, the Legal Status and the Problems with Implementation

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Ide pencetusan Deklarasi Doha dilatarbelakangi oleh protes dari negara-negara berkembang yang menilai bahwa pasal-pasal pelindung TRIPS (*the TRIPS Safeguards*) tidak jelas dan bersifat multi interpretasi. Negara-negara berkembang berusaha mencari sebuah alat tafsir terhadap *the TRIPS Safeguards* tersebut yang memenuhi persyaratan hukum internasional, khususnya Konvensi Wina yang mengatur tentang Hukum Perjanjian Internasional dan proses legislatif negosiasi berdasarkan kerangka kerja pembuatan keputusan WTO (*WTO decision making framework*). Melalui Deklarasi Doha, negara-negara berkembang mencapai tujuan utama mereka untuk mencari penjelasan terhadap penafsiran *the TRIPS Safeguards* tersebut. Meskipun demikian, di masa yang akan datang, perbedaan tingkat ekonomi, teknologi dan kepentingan di antara negara-negara anggota WTO akan menjadi salah satu pemicu perdebatan mengenai manfaat perlindungan paten obat berdasarkan ketentuan WTO dan pengaruhnya terhadap akses obat esensial. Hasil yang optimal dari perdebatan tersebut akan sangat tergantung pada kehendak para pihak yang terlibat untuk mencari solusi yang tidak memihak kepentingan salah satu negara anggota WTO.

A. Introduction

The Doha Declaration also has a pivotal role in managing the problems in access to essential medicines resulting from the

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pharmaceutical patent protection. The Doha Declaration was developed after protests from developing and least developed countries asserting the TRIPS safeguards were unclear and ambiguous. Developing countries and least developed countries sought an interpretive tool for the TRIPS safeguards which fulfills the requirements of international law, in particular the Vienna Convention on the Law of Treaties and the legislative process of negotiation under the WTO decision making framework. Through the Doha Declaration, developing and least developed countries achieved their goal to clarify the TRIPS safeguards.

This chapter will discuss in detail the access to essential medicine related issues from the perspective of the Doha Declaration. The key question is to what extent the Doha Declaration manages the impact of pharmaceutical patent protection on access to essential medicines. A second question is the legal status of the Doha Declaration and how to resolve a conflict of interpreting provisions.

B. The Doha Declaration and access to essential medicines

This section analyzes the historical background of the Doha Declaration, including its contents and legal status from the perspective of international law. Some issues, such as the implementation of the Doha Declaration are also discussed.

1. History and background of the Doha Declaration: Is it a means of rejecting pharmaceutical patent protection in developing countries?

The motivation behind the Doha Declaration is to seek a clear interpretation of the TRIPS safeguard articles and not to abolish patent system under the TRIPS Agreement. What developing countries and involved NGOs seek is a balance between patent holder interests and the public interests of developing and least developed countries.

In the post TRIPS era, developing countries believe that the TRIPS Agreement gives more benefits to pharmaceutical companies of developed countries and prevents access to cheaper and affordable drugs.[1] A reduction of drug prices has occurred when developing countries applied safeguards, such as parallel imports and compulsory license. The effort to enact safeguard legislation has resulted in US legal action, such as the dispute between the US government and the Brazilian government when Brazil considered the adoption of compulsory license.[2] Another example was a dispute between big pharmaceutical companies and the South African government in its plans for adoption of parallel imports and compulsory license.[3]

These disputes demonstrate that the TRIPS safeguard articles are weak and meaningless because the interpretation of those articles has favored the developed countries' perspectives. Since access to cheaper drugs in the post TRIPS era was obstructed by the unclear interpretation of the TRIPS safeguard articles, developing countries and NGOs urged the WTO council to include public health issues in the agenda of WTO Ministerial meeting in Seattle 1999. Unfortunately, little real attention to that issue happened until the Fourth Ministerial meeting in Doha in 2001.[4]

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[1] *See* Bryan C. Mercurio, *TRIPS, Patents, and Access to Life Saving Drugs in the Developing World*, 8 MARQ. INTELL. PROP. L. REV. 211, 1 (2004); Mariama Williams, *The TRIPS and Public Health Debate: An Overview*, International Gender and Trade Network, available at http://www.genderandtrade.net/wto/TRIPS_PublicHealth.Pdf (August 2001); *see* Peter Drahos and John Braithwaite, *Intellectual Property, Corporate Strategy, Globalization: TRIPS in Context*, 20 WIS. INT'L L. J. 451, (1-15) 2002.

[2] Srividhya Ragavan, *Can't We All Get Along? The Case For A Workable Patent Model*, 35 Arizona State Law Journal 117, 21-22 (2003).

[3] Divya Murthy, *The Future of Compulsory Licensing: Deciphering the Doha Declaration on the TRIPS Agreement and Public Health*, 17 American University International Law Review 1299, 5 (2002); Srividhya Ragavan (2), *Id. at 21*; Richard Gerster, *People Before Patents-The Success Story of the Indian Pharmaceutical Industry*, available at http://www.gersterconsulting.ch/docs/India%20_Pharma_Success _Story.pdf.

[4] Bryan C. Mercurio, *supra* note 1, at 1.

At the WTO Ministerial Conference at Doha, Qatar (9 – 14 November, 2001), WTO members adopted a resolution about the relationship between TRIPS and public health called the Doha Declaration. This success was affected by a proposal from the African Group in early 2001 which requested the Council for TRIPS to agree about the relationship between the TRIPS Agreement and public health.[5] At the Doha meeting, all members of the WTO declared seven important points about the relation between the TRIPS Agreement and public health issues. The Doha Declaration is a milestone where developing countries emphasized public health issues[6], of little concern for the powerful

[5] Carlos M. Correa (2), *The Implications of the Doha Declaration on the TRIPS Agreement and Public Health*, Health Economics and Drugs EDM Series No.12, June 2002, at 2 (in DGDFC and WHO, *Informal Technical Discussion on the TRIPS Agreement and Public Health*, Jakarta, May 31 – June 1, 2004).
At that time, Zimbabwe representing the African Group stated about the need to access to medicine during the preparation of declaration. In June 2001, the Council for TRIPS discussed intellectual property issues from the perspectives of public health for the first time (Ellen t' Hoen, *Public Health and International Law: TRIPS, Pharmaceutical Patents, And Access to Essential Medicines: A Long Way From Seattle To Doha*, 3 CHI. J. INT'L L. 27, 6 (2002); Carlos M. Correa (2), *Id.*, at 2-3).
Apart from the draft proposed by the African Group and other developing countries, at that meeting some countries, such as the US, Japan, Switzerland, Australia and Canada prepared another alternative draft which focuses on the role of intellectual property for encouraging R&D. They also argued that "intellectual property contributes to public health objectives globally" (Ellen t'Hoen, *Id.*, at 7). Another group, the EU prepared the draft focusing on the solution to the problem of compulsory license in country which has insufficient production capacity or no capacity by allowing the country to implement compulsory license as far it is consistent with article 30 of the TRIPS Agreement. Majority of the members choose the draft proposed by African Group. They also stated their commitment to comply with the TRIPS Agreement (Ellen t'Hoen, *Id.*, at 7).

[6] The Doha Declaration is a reflection of victory of developing countries (*see* Ruth Mayne, *The Global Campaign on Patents and Access to Medicines: An Oxfam Perspective*, in GLOBAL INTELLECTUAL PROPERTY RIGHTS KNOWLEDGE, ACCESS AND DEVELOPMENT 245 (Peter Drahos and Ruth Mayne, 2002); Stephanie A. Barbosa, *Implementation of the Doha Declaration: Its Impact on American Pharmaceuticals*, 36 RUTGERS L. J. 205, 4 (2004).

pharmaceutical companies that generally argued that the TRIPS Agreement has nothing to do with public health.[7] Prior to the Doha Declaration, pharmaceutical companies stated that public health problems in developing countries are chiefly caused by lack of political will and inappropriate public health policies.[8] These are important factors but there is a correlation between pharmaceutical patent protection and the problems in the public health sector. Access to essential drugs is not solely caused by political will and public health policies. Pharmaceutical patent protection is a critical barrier.[9] These factors work together in creating inadequate drug access, a major public health issue in poor countries, outweighs the patent-based protection appropriate to markets located in wealthy nations (see chapter VI).

2. The Doha Declaration: contents, the legal status and the problems with implementation

What are the contents of the Doha Declaration? Why is the Declaration very important to solve the problems of access to essential medicines in developing countries? Both of these

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[7] *See* Harvey E. Bale, Jr., *Patents and Public Health: a Good and Bad Mix?* available at http://www.cnehealth.org/pubs/bale_patents_and_public_health.htm; Owen Lippert, *Poverty, Not Patents, is the Problem in Africa*, available at http://www.cnehealth.org/pubs/lippert_poverty_not_ patents.htm.

[8] Amir Attaran, *How Do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries?* Health Affairs, Volume 23, number 3, at 155, available at http://content.health affairs.org/cgi/reprint/23/3/155 (last visited 03/21/06); Harvey E. Bale, Jr., *Id.*; Owen Lippert, *Id.*.

[9] Several researchers conducted studies on the impact of pharmaceutical patent on price of drugs. For examples: Nogues (1990, 1993), Challu (1991), Chambouleyron (1995), Watal (1996, unpublished) (*see* United Nations Conference On Trade And Development, *supra* note 10, at 62) and K.Bala and Kiran Sagoo (1999) (in K, Bala and Kiran Sagoo, *supra* note 20); *see* Carlos M. Correa (2), *supra* note 5, at 12 : *see* also Carlos Correa (1), INTEGRATING PUBLIC HEALTH CONCERNS INTO PATENT LEGISLATION IN DEVELOPING COUNTRIES 2 (2000).

questions are the focus of this section. Several problems of the implementation of the Doha Declaration in developing and least developed countries which have no or insufficient domestic capacity to produce pharmaceutical products are also discussed in this section.

a) The contents of the Doha Declaration and comments

The Doha Declaration consists of seven paragraphs which provide an interpretation to Articles 7 and 8 of the TRIPS Agreement.[10] Paragraphs 1-3 are preambles of the Declaration and paragraphs 4-7 are operative ones of the Declaration.[11]

- Paragraph 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."

This paragraph refers to communicable diseases faced by many developing and least developed countries. It notes that several diseases, describe elsewhere as neglected diseases, exist in those countries and implies the need to be solved. While the TRIPS Agreement includes public health related articles they are open to different interpretations by the WTO members. In fact, interpretation of these articles, particularly compulsory licensing, is a source of conflict between developed and developing countries.

During the negotiation of the Doha declaration the US government tried to limit the group of epidemic diseases covered in

[10] Carlos M. Correa (2), *Id.*, at 12.

[11] Frederick Abbott, *The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO*, 5 J. INT'L ECON. L. 469, 12 (2002).

the declaration to HIV/AIDS alone, excluding other diseases such as malaria, tuberculosis.[12] The motivation behind this selectivity appears to be protecting the interests of pharmaceutical industries in developed countries. The inclusion of additional diseases in paragraph 1 has important consequences. Relevant drugs for those diseases that are produced by big pharmaceutical companies will potentially be the target of compulsory license under the Doha Declaration. From their economic perspective, this safeguard could reduce potential profits of those companies.[13]

- Paragraph 2:

Paragraph 2 states the important role of the WTO in solving the public health problems of developing and least developed countries:

> "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."

During the Doha negotiations most developed countries attempted to deny the relationship between pharmaceutical patent protection and public health under the TRIPS Agreement. By proclaiming a comprehensive role of the WTO, the declaration implicitly asserts that the TRIPS Agreement and its consequences for the public health problems in those countries cannot be separated. The TRIPS Agreement provides both pharmaceutical patent protection and safeguards intended to help manage problems in the public health sector arising from the protection of pharmaceutical patent.

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[12] Carlos M. Correa (2), *supra* note 10., at 12.

[13] The benefits of the TRIPS Agreement to companies in developed countries are discussed in detail in Peter Drahos and John Braithwaite, *supra* note 1, at 1-15.

- Paragraph 3:

The members of the WTO agree that the protection of intellectual property is important but also are concerned about the impact of the protection on price of drugs. Under the Doha Declaration, they declare that:

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

This paragraph stresses that a balance between the interests of pharmaceutical companies and the interests of consumers should be a priority in implementing the TRIPS Agreement. This paragraph also reaffirms patent rights but includes the need to address related public health issues, such as affordable prices.

- Paragraph 4:

Paragraph 4 is the core and the most important part of the Doha Declaration because this states clearly the objective of the declaration. It says:

> "We agree that the TRIPS Agreement does not and should not prevent members form 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."

The inclusion of "access to medicines for all" and "provisions in the TRIPS Agreement, which provide flexibility for this purpose" is aimed at attempts to ignore TRIPS critical safeguards, such as

parallel imports and compulsory license. The Doha Declaration was necessary because developed countries argued that TRIPS safeguards were conflicted with the main purpose for TRIPS.

- Paragraph 5 :

Paragraph 5 declares that members have the right to interpret pro public health articles provided by the TRIPS Agreement, including compulsory license or national emergency that justify the "exhaustion of intellectual property."

> "Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:
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> a. 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.
> b. Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.
> c. Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crisis, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.
> d. 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."

The most important part of Doha Declaration is its interpretation of the TRIPS provisions. Disputes brought by developed countries against developing countries about patent protection and public health issues are in part due to unclear provisions of the TRIPS Agreement about public health related policies and their use by the members. The restricted interpretation of the TRIPS Agreement

caused an imbalance between protection and pro public health issues. Paragraph 5 supports the interpretation of the TRIPS Agreement from an international law perspective rather than individual members' perspectives or interests.

- Paragraph 6:

Paragraph 6 addresses problems faced by countries which have no or insufficient capacity to produce pharmaceutical products:

> "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."

The different level of development among members in producing pharmaceuticals is the core problem in implementing compulsory license. In addition, Article 31 of the TRIPS Agreement only allows the adoption of compulsory licenses for domestic market which precludes developing and least-developed countries with little or no abilities in pharmaceutical manufacturing. An option to import products produced under compulsory license in other developing countries cannot be used since the TRIPS Agreement bans the importation or exportation of products.

- Paragraph 7:

This paragraph emphasizes a pivotal role for developed countries to transfer their technologies to least developed countries. It says:

> "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 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."

Developed countries are reluctant to transfer their technologies to countries which do not provide sufficient protection for intellectual property, such as least developed countries that have not complied yet with the TRIPS Agreement. Introducing the process of technology in such countries will be slow or absent. Developing countries hope that the Doha declaration will facilitate the transfer of technology as mandated by Article 66.2 of the TRIPS Agreement.

b). The legal status of the Doha Declaration

The existence of the Doha Declaration provides developing and least developed countries with potential strategies (safeguards) to reduce the impact of pharmaceutical protection on public health. This declaration offers several policies that are derived from the TRIPS Agreement, such as bolar provision, parallel imports, compulsory license and government use with a clear interpretation made by the declaration.[14] The legal status of the Doha Declaration is questioned by many countries. Since it is not categorized as an authoritative interpretation according to Article IX.2 of the Marrakesh Agreement Establishing the WTO[15] the US and other developed countries believe that the Doha declaration cannot be used to interpret the TRIPS Agreement because it has no legal authority.[16] The Declaration, therefore, is not legally binding in the

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[14] Carlos Correa (2), *supra* note 12, at 49.

[15] Carlos Correa, *Id.*

[16] James Thuo Gathii, *The Legal Status of the Doha Declaration on TRIPS and Public Health Under the Vienna Convention on the Law of Treaties*, 15 HARV. J. L. & TECH. 291, 11 (2002); *see* also Lissett Ferreira, *Access to Affordable HIV/AIDS Drugs: the Human Rights Obligations of Multinational Pharmaceutical Corporations*, 71 FORDHAM L. REV. 1133, 6 (2002).

dispute resolution process of the WTO.[17] This makes the status of the Doha declaration is uncertain and unclear whether this can be used as legal binding interpretation or amendment to Articles 7 and 8 of the TRIPS Agreement?[18]

Because the TRIPS Agreement is an international treaty, the legality of its interpretation has to be referred to the Vienna Convention on the Law of Treaties (hereinafter the Vienna Convention), particularly Articles 31.[19] Based on this article, the Doha Declaration can be interpreted as a subsequent agreement and subsequent practice among the members of WTO.[20]

The first interpretation of its legal status derives from Article 31§ 3(a) of the Vienna Convention on the Law of Treaties. According to this article, the Doha Declaration falls into category a subsequent agreement which interprets the provisions of a treaty according to its context.[21] From this perspective, the Doha Declaration fulfils this requirement because it interprets the substantive contents of Article 7 and 8 of the TRIPS Agreement. In addition, there is a precedent, where the Appellate Body used such a

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[17] Alan O. Sykes, *TRIPS, Pharmaceuticals, Developing Countries, and the Doha "Solution"*, 3 CHI. J. INT'L L. 47, 5 (2002).

[18] M. Gregg Bloche and Elizabeth R. Jungman, *Health Policy and the WTO*, 31 J. L. MED. & ETHICS 529, 9 (2003); M Gregg Bloche, *WTO Deference to National Health Policy: Toward an Interpretive Principle*, 5 J. INT'L ECON. L. 825, 8 (2002).

[19] James Thuo Gathii, *supra* note 16, at 11; M Gregg Bloche and Elizabeth R. Jungman, *Id.*, at 9-10; Haochen Sun, *A Wider Access to Patented Drugs Under the TRIPS Agreement*, 21 B. U. INT'L L. J. 101, 15 (2003); Divya Murthy, *supra* note 3, at 6; Patrick L. Wojahn, *A Conflict of Rights: Intellectual Property Under TRIPS, the Right to Health, and AIDS Drugs*, 6 UCLA J. INT'L L. & FOREIGN AFF. 463, 12 (2001-2002).

[20] M. Gregg Bloche and Elizabeth R. Jungman, *Id.*; Patrick L. Wojahn, *Id.*

[21] James Thuo Gathii, *supra* note 19, at 6; *see* Patrick L. Wojahn, *Id.*, at 13.

declaration as an interpretive tool for substantive provisions of GATT/WTO.[22]

The second one deals with the Article 31§ 3 (b) of the Vienna Convention. It states subsequent practice constitutes an agreement among parties about interpreting provisions of a treaty.[23] The Doha Declaration can be assumed as a subsequent practice on the ground that the declaration was produced by an agreement or understanding among all members of the WTO. It provides better definitions for the interpretation of the TRIPS provisions which had been unclear and a source of disputes among the members of the WTO.[24]

Another interpretation considers how strongly members supported the declaration through their apparent acceptances. Their level of acceptance would have influence as a binding or non-binding statement among the WTO members.[25] This perspective appears to endorse the Doha Declaration as a binding statement based upon intent and commitment. When the Doha Declaration was announced, no member directly expressed their rejection of its legitimacy.[26]

In addition to these perspectives about the legal status of the Doha Declaration, the declaration fulfilled the requirements for an interpretive tool for the TRIPS Agreement. The TRIPS safeguards, such as compulsory license and parallel imports are regulated under the minimum standards and it is evident that the TRIPS Agreement has caused the disparities level of adoption among the members of the WTO. Since the provisions dealing with those safeguards are

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[22] *Id.*

[23] *Id.*, at 10; Sandra Bartelt, *Compulsory Licenses Pursuant to TRIPS Article 31 in the light of the Doha Decalaration on the TRIPS Agreement and Public Health*, 6 (2) J. WORLD INTELL. PROP. 283, 286 (2003); *see* also 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*, 7 J. INT'L ECON L. 73, 6 (2004).

[24] James Thuo Gathii, *supra* note 23, at 10; Duncan Matthews, *Id.*

[25] James Thuo Gathii, *Id.*, at 11.

[26] *Id.*

very flexible and text and context of the treaty cannot solve it, the intent of the parties to make the safeguards is also useful to interpret the provisions.

The intent of members to strengthen TRIPS safeguards through the Doha Declaration balance the interests of pharmaceutical companies and societies in general. These objectives are expressed in Articles 7 and 8 of the TRIPS Agreement and elaborated by Articles 6, 30 and 31 of the TRIPS Agreement. The Doha Declaration clarifies the interpretation of those articles accord legally in with Article 31 par.3 (a) and (b) of the Vienna Convention on the Law of Treaties, and follows the lawful legislative process of negotiation under the WTO decision-making framework.

c). The problems of the Doha Declaration implementation

The Doha Declaration is intended to address public health issues of developing and least developed countries. Paragraph 4 of the Doha Declaration, for example, provides a valid reason of applying the TRIPS safeguards for the purpose of protecting public health and access to medicines.[27] In addition, it helps those countries interpret the TRIPS safeguards, such as compulsory license and parallel imports.[28]

A key question for paragraph 6 of the Doha Declaration is how to implement it in developing and least developed countries which have no or insufficient domestic capacity to produce pharmaceutical products.[29] This becomes a serious problem because according to

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[27] Nabila Ansari, *International Patent Rights in a Post – Doha World*, 11 INT'L TRADE L. J. 57, 9 (2002).

[28] *Id.*

[29] There are 61 countries which have no pharmaceutical industry and most of them are from Africa: Andorra, Antigua and Barbuda, Aruba, Bahrain, Bermuda, Bhutan, Bostwana, British Virgin Islands, Burkina Vaso, Burundi, Central African Republic, Chad, Comoros, Congo, Cook Islands, Djibouti, Dominica, Equatorial Guinea, Faeroe Islands, French Guyana, French Polynesia, Gabon,

Article 31 (f) of the TRIPS Agreement, the adoption of compulsory licenses in the WTO members is for the domestic market only. As a consequence, countries with little or no domestic capacity to produce pharmaceuticals cannot import pharmaceuticals products produced under compulsory licenses from other countries. This conflicts with the purpose of article 31, to provide a safeguard against pharmaceutical patent protection being harmful to public health. According to paragraph 6, the solution to this problem was decided by the TRIPS Council by the end of 2002. But no final solutions were achieved despite several meetings by 2002.[30] In 2003, the Council reached a consensus about paragraph 6 of the Doha Declaration. It broadened the scope of compulsory licenses from only a member's domestic market according to article 31 (f) of the TRIPS Agreement, allowing a waiver for the production of pharmaceuticals intended for exporting the products to eligible importing members.[31]

The waiver is designed to allow imports by those countries designated as eligible as importing members. Application to become eligible importing members under this system is done by notifying the TRIPS Council that they want to import pharmaceuticals produced under compulsory licenses in another country. This waiver is temporary and will end when the Council amends the TRIPS Agreement, a process started during 2003.[32] This

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Greenland, Grenada, Guadeloupe, Guam, Guinea, Guinea-Bissau, Iceland, Laos, Libyan Arab Jamah., Liechtenstein, Luxembourg, Maldives, Martinique, Mauritania, Mayotte, Micronesia, Nauru, Netherlands Antilles, New Caledonia, Niue, Oman, Qatar, Reunion, Rwanda, St. Kitts and Nevis, St. Lucia, St. Vincent-Grenadines, Samoa, San Marino, Sao Tome and Principe, Senegal, Suriname, Swaziland, Togo, Tuvalu, US Virgin Island, Vanuatu, Western Samoa(Annex 2 Levels of development of pharmaceutical industry, by country (Carlos Correa (2), *supra* note 15, at 55-56).

[30] Jennifer May Rogers, *The TRIPS Council's Solution To the Paragraph 6 Problem: Toward Compulsory Licensing Viability for Developing Countries*, 13 MINN. J. LOBAL TRADE 443, 4 (2004).

[31] *Id.*, at 6.

[32] *Id.*

Council decision to permit waivers caused many countries to use of compulsory license under article 31 (f) of the TRIPS Agreement. The Brazilian government, for example, started to produce pharmaceuticals for HIV/AIDS under compulsory license for export. Other countries, including Canada, Norway and Switzerland are working to amend their patent laws and get compulsory license to export the pharmaceutical products to other countries. In 2003, the Canadian government decided to amend its patent law to give the legal basis for the country to export pharmaceuticals produced under compulsory license to developing countries which have no capacity to manufacture them.[33] The TRIPS Council's decision to allow temporary waiver of paragraph 6 of the TRIPS Agreement appears to be a helpful initial step. The ultimate solution will be found when the Council amends the TRIPS Agreement dealing with the Article 31 (f) and the amendment takes force.

C. Conclusion

The different level of economy, technology and interests among the members of the WTO will color the ongoing debate about the benefits of pharmaceutical patent protection under the WTO and effect upon access to essential medicines. The debate will reflect those favoring pro status quo for the TRIPS Agreement (hereinafter developed countries) and the large number of countries which rely on the existence of the Doha Declaration (hereinafter developing and least-developed countries). The outcome of this battle ends depends upon the willingness to seek the optimal solution for all. The initial step is undertaking discussions to negotiate and compromise in order to reach mutual goal. If this fails, all international laws, international standards and other conventions developed to protect both pharmaceutical patents and public health needs will be futile.

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[33] *Id.* at 11.

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